FINAL REPORT

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Data Requirement(s)

Series 875 - Occupational and Residential Exposure Test Guidelines
U.S. Environmental Protection Agency Good Laboratory Practice Standards
FIFRA Program (40 CFR Part 160)
FIFRA Program (40 CFR Part 26, subparts K and L and §12(a)(2)(P)
OECD Principles of Good Laboratory Practice
California Code of Regulations, Title 3 §6710

Study Director/Authors

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Completion Date

January 31, 2018

Testing Facility

Golden Pacific Laboratories, LLC (GPL)
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Study Identifications

GPL Report Number: 120463
AEATF II Project ID: AEA09

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II
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Washington, DC 20002

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C).

Company: American Chemistry Council
Antimicrobial Exposure Assessment Task Force II

Company Agent: Hamida Shah 02/05/18
Title: Sponsor Representative Date

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

I hereby certify that all data generated and collected during this portion of the analytical and field phase of this study was in compliance with the U.S. Environmental Protection Agency Good Laboratory Practice Standards; FIFRA Program 40 CFR Part 160 and 40 CFR Part 26 with the following exceptions:

1. The BIT internal standard was purchased from a reputable chemical manufacturer. Although a certificate of analysis was received with this standard, the analysis was not conducted according to the GLPs. The internal standard was also used after its retest date as its suitability at time of use was confirmed.
2. The study Registered Nurse collected sweat wipe samples from subjects requesting sweat be wiped from their face during their monitoring event. Although documentation was properly recorded, the nurse did not have written evidence of GLP.

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QUALITY ASSURANCE STATEMENT

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

GPL Report Number: 120463
AEATF II Project ID: AEA09

The study described in this report was subject to inspection by the Quality Assurance Unit of Golden Pacific Laboratories, LLC. Inspections were performed and reported to the Study Director and GPL Management on the dates listed below:

Phase of Study	Date of Inspection	Date Reported to	
		Study Director	Testing Facility Management
Extraction BIT in Paint – 463SET02	06/08/16	06/08/16	06/13/16
Field Phase Day 1	06/10/16 and 06/13/16	06/14/16	06/16/16
Field Fortification Samples Day 2	06/15/16	06/16/16	06/16/16
Field Phase Day 7	06/27/16	06/27/16	06/28/16
Extraction Air Sampling Tubes - 463SET70	01/16/17	01/16/17	01/16/17
Extraction Outer Dosimeters - 463SET68	01/16/17	01/16/17	01/16/17
Raw Data	06/30/17, 07/06-07/17, 07/10-12/17	07/12/17	07/12/17
Field Notebook Data	08/22/17	08/22/17	08/22/17
Report Tables	10/16-20/17	10/20/17	10/20/17
Support Data and Draft Report	7/12/17, 11/10/17, 11/13-17/17, 11/20/17, 11/28/17, 12/4-8/17, 12/11-12/17, 1/9-12/18, 1/15/18	1/15/18	1/15/18
Final Report	1/31/18	1/31/18	1/31/18

This report and the raw data were found to accurately reflect the study as it was conducted at Golden Pacific Laboratories, LLC.

Margaret A Hamelin 01/31/18

Margaret A. Hamelin, B.S., RQAP-GLP Date
Quality Assurance Officer
Golden Pacific Laboratories, LLC

SIGNATURE AND APPROVALS

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Submitted to Sponsor by:

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Robert J. Testman, M.B.A.
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Date

GENERAL INFORMATION

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The following contributed to this study in the capacities indicated:

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Study Dates

Study Initiation:	March 15, 2016
Experimental Start:	June 13, 2016
Experimental Termination:	April 27, 2017
Study Completion:	January 31, 2018

GENERAL INFORMATION (Continued)

Retention of Samples

Aliquots of sample extracts, extracted sample matrices and analytical standards will be retained until the Study Director and Sponsor's Representative determined they were no longer useful.

Retention of Data

All original raw data generated during this study will be organized and indexed by GPL. GPL will temporarily archive the original raw data then subsequently transfer it to a permanent location selected by the Sponsor. Study subject personal information will be kept in a separate location of the GPL archive room and will be marked confidential. GPL will retain all original facility specific raw data as well as verified copies of the report, protocol and raw data.

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1.0 SUMMARY

The American Chemistry Council Antimicrobial Exposure Assessment Task Force II (AEATF II) contracted with Golden Pacific Laboratories, LLC to conduct the field phase and analytical phase of a human exposure monitoring study. This study was conducted to determine potential dermal and inhalation exposures to residential consumer painters who apply paint containing 1,2-Benzisothiazolin-3-one (BIT), a paint preservative, using brush and roller painting equipment.

Recruitment

Following approval of the protocol by the United States Environmental Protection Agency, California Department of Pesticide Regulation and an independent Investigational Review Board (IRB), newspaper advertisements were used to recruit subject participants. Advertisements were placed in the major local newspaper, the Fresno Bee, as well as a newspaper circulating in the Spanish speaking community. The advertisements included a description of the study and provided phone numbers to call for more information. Interested callers were interviewed by phone to determine whether they met the inclusion criteria.

Informed Consent

Meetings with potential subjects were scheduled at Golden Pacific Laboratories (GPL) to go over the Informed Consent Forms. During the meeting, potential subjects were given an English or Spanish version of the Informed Consent Form (ICF), the "Experimental Subject's Bill of Rights," which is part of the ICF, and a Qualification Worksheet. Subjects were also offered a copy of the Safety Data Sheet of BIT, the Material Safety Data Sheet of the latex paint, and the paint product label in both English and Spanish. Subjects were asked to complete the top portion of the Qualification Worksheet, which inquired about the health of the subject. If none of the answers disqualified the subject from participating, the ICF and subject's Bill of Rights were described to each volunteer in detail in their preferred language. Subjects who met the inclusion criteria and were interested in enrolling into the study were then asked to complete the bottom portion of the Qualification Worksheet and sign and date the Informed Consent Form.

A total of 37 subjects were enrolled into the study during the two-week enrollment period in response to the newspaper advertisements. After the enrollment period ended, subjects were assigned numbers in a consecutive order. Five of the enrolled subjects were assessed by the Study Director as having unanticipated risks, and removed from scheduling. The subject numbers were randomized, with the first 18 subjects in the generated randomized list placed into the study as primary subjects to conduct the painting tasks. The remaining subjects were held as alternates for potential entry into the study in the sequence determined by the randomization process. The monitoring events (ME01-ME18) were randomly assigned to paint with one of three test substance concentrations, a low ppm level, a mid ppm level and a high ppm level.

The primary subjects were contacted and scheduled to come to the site on a specific day and time, along with an alternate. An alternate was on hand for each monitoring event in case the primary subject did not show, was unable or chose not to participate, or stopped painting before painting the minimum volume required.

Study Design

Upon arrival at the study location, the subjects were offered food and beverages, and were reminded that they could withdraw from the study at any time. Subjects were asked if they had any questions. The nurse examined the subject's hands for disqualifying skin conditions. Female subjects were taken to a private area by a female researcher and asked to self-administer an over-the-counter urine pregnancy test. Qualified subjects were taken to a private area to wash their hands and face with Ivory soap and water. The subjects were then taken to the dosimeter assembly room by a same gender study personnel and asked to don inner and outer dosimeters for the exposure monitoring. Two air sampling pumps, each connected to Tygon tubing, were attached to the belt of the subject. One pump was attached to an air sampling tube containing XAD sorbent which was placed in the subject's breathing zone. The other pump was attached to a RespiCon™ Particle Sampler (to collect airborne particles) attached to a harness over their chest. The subjects were given safety glasses and photographed; care was taken not to photograph their faces.

All monitoring events were conducted using paint containing one of three concentrations of BIT (~144 ppm, ~375 ppm, or ~619 ppm). Prior to the monitoring events, the concentration of BIT in each subject's paint was determined. The total amount of paint used by each subject during the monitoring events was calculated by weighing the paint containers before, during, and after use.

Once the subjects entered the area to be painted, the air pumps were turned on and the subjects were given the first closed 1-gallon can of pre-weighed paint. They were asked to open the can then paint the walls, ceiling, and trim around the door and window as they would normally do at home. The subjects were offered breaks periodically and subjects were informed a break could be taken as needed during the monitoring event. The total amount of time spent painting, the total surface area painted and the total amount of paint used were calculated. Detailed observations of subjects were recorded during the monitoring events.

The air sampling pumps were checked periodically throughout the monitoring period to ensure that they were functioning properly. Dry gauze pads were used when requested to wipe excess sweat from the face/neck area of the subject, collected, and later analyzed.

After the monitoring event was completed, the subject returned to the clean changing room with a same gender researcher for the removal of dosimeters and collection of samples. The samples, which consisted of air sampling tubes, fiberglass filters, hand washes, face/neck wipes, painter's hats, painter's hat inner dosimeters, outer dosimeters, and inner dosimeters, were collected by study personnel and were placed immediately in the appropriate collection vessels. All samples were transported to GPL within 4 hours of collection, where samples were placed into frozen storage. After all samples were

collected, the subject got dressed and was given the chance to ask any remaining questions. A nurse examined the subject's hands for irritation, after which the subject was paid in cash for their participation and was free to leave.

Sample matrix fortifications were performed in a designated area at the test site each day of the study to assess the stability of the active ingredient under field, storage, and transport conditions in or on the sampling material. Three samples of each matrix type were fortified with two known concentrations of BIT (low and high). The fortification concentrations varied for each matrix type. Two unfortified controls were reserved as field control samples. In addition, for matrices that were weathered, travel spikes were prepared to determine possible loss of BIT during transport in the event of unusually low field fortification recovery results. None of the travel spike samples were analyzed in the study.

Samples were transported from the test site location to GPL and were placed into frozen storage (<-10 °C) within 1 hour of arrival and remained in frozen storage pending analysis.

Results

Subjects performed their tasks within their assigned parameters for all 18 monitoring events (MEs): No subjects withdrew after beginning work or were unable to complete the painting tasks. One ME was conducted on June 13, 2016. Two MEs were conducted on June 15, June 17, June 20, June 22, June 24, June 27, and June 29, 2016. Three MEs were conducted on July 1, 2016. All MEs were conducted in rooms built inside a warehouse space in Fresno, CA.

Field samples were analyzed in sets. Typically, each set consisted of a solvent blank, an untreated control, two laboratory fortification samples, field study samples and field fortification samples for that particular matrix.

The active ingredient, BIT, was extracted from study samples with the appropriate solvent. An aliquot of the extract was diluted 1:1 with a deuterated internal standard (IS) solution and then analyzed by LC-MS/MS, using a previously validated method. The table below summarizes the limit of quantitation (LOQ) for each matrix:

Matrix	LOQ
Air Sampling Tubes	0.0100 µg/sample
Fiberglass Filters	0.0100 µg/sample
Hand Washes	0.500 µg/sample (1.0 ng/mL)
Face/Neck Wipes	0.100 µg/sample
Painters Hats	3.00 µg/sample
Outer Dosimeters	3.00 µg/sample
Inner Dosimeters	3.00 µg/sample

The concentration (ng/mL) of BIT detected in sample extracts was interpolated from a five or six-point standard calibration curve.

None of the laboratory control samples showed any apparent residue of BIT that was equal to or greater than the LOQ, except for one inner dosimeter control sample which contained BIT at about 100 times the LOQ.

The overall mean recoveries of fortified laboratory control samples for the various matrices are presented below:

Lab Fortification Recoveries		
Matrix	**Fortification Amounts**	**Percent Recovery (%)**
Air Sampling Tubes	0.0100 µg/sample ~10.0 µg/sample	86.2 ± 12.4
Fiberglass Filters	0.0100 µg/sample 10.0 µg/sample	86.7 ± 5.40
Hand Wash	0.250 µg/sample ~300 µg/sample ~800 µg/sample ~1500 µg/sample	88.4 ± 10.8
Face/Neck Wipes	~0.100 µg/sample ~100 µg/sample	86.1 ± 8.95
Painters Hats	3.00 µg/sample ~3000 µg/sample	95.5 ± 6.25
Outer Dosimeters	3.00 µg/sample ~3000 µg/sample	91.9 ± 8.50
Inner Dosimeters	~3.00 µg/sample ~3000 µg/sample	96.0 ± 16.3

The overall mean recoveries were well within the acceptable range of 70% to 120%. These results indicate that the analyte was extracted adequately from the different matrices, and the analytical method performed well throughout the study.

None of the field control samples for air sampling tubes, fiberglass filters, hand wash, face/neck wipes, or painter's hats showed any detectable residue of BIT equal to or greater than the LOQ. The field control samples for outer dosimeters showed measurable residues above the LOQ in 10 of 18 samples ranging from 3.78 µg to 22.5 µg per sample. The field control samples for inner dosimeters showed measurable residues above the LOQ for 13 of 18 samples ranging from 17.9 µg to 1295 µg per sample. The results from the weathered air sampling media and painter's hats indicate that the field working area (test site area) was not contaminated with BIT during exposure or sample collection.

Measurable background levels of BIT had been found in the outer dosimeter garments during method development work. This was addressed by pre-washing outer dosimeter garments prior to use in the study. Although some residues were found in the field control outer dosimeter samples these were low compared to the total BIT found in the subject outer dosimeter samples, and are not expected to impact the conclusions of the study. Any

background BIT found in subject garments would tend to overestimate the reported subject exposure.

The inner dosimeter garments had not been previously observed to contain background levels of BIT. However, unusually high levels were observed in some field controls, field fortifications, and subject inner dosimeter samples used in this study. An investigation was conducted and it was determined that the contamination was lot-specific, and the latest lots of inner dosimeters purchased for this study contained high levels of BIT which is used as an antimicrobial preservative during textile manufacturing. Subject inner dosimeter samples could be specifically identified by affected lots, however field control/fortification samples were prepared from randomly assigned pieces from various lots and could not be isolated by lot used. Since field fortification recoveries of over 100% were not used to correct subject samples, the impact of this contamination is limited. The results from subject inner dosimeter samples prepared from contaminated inner dosimeters were dropped from the study and instead a penetration factor to estimate inner dosimeter residues was established with EPA guidance. This penetration factor was calculated by comparing residues from non-contaminated subject inner dosimeters to the corresponding outer dosimeter sections. This allowed for calculation of dermal exposure based on the corresponding outer dosimeter piece multiplied by the penetration factor.

The overall mean recoveries of fortified field control samples are presented below.

Field Fortification Recoveries		
Matrix	**Fortification Amounts**	**Percent Recovery (%)**
Air Sampling Tubes	0.100 µg/sample 2.00 µg/sample	81.3 ± 7.24
Fiberglass Filters	~0.100 µg/sample 2.00 µg/sample	87.5 ± 7.75
Hand Wash	2.26 µg/sample ~200 µg/sample	92.4 ± 8.50
Face/Neck Wipes	~0.500 µg/sample 10.0 µg/sample	87.0 ± 8.13
Painters Hats	12.0 µg/sample ~1000 µg/sample	88.7 ± 9.11
Outer Dosimeters	12.0 µg/sample ~1000 µg/sample	103 ± 23.9
Inner Dosimeters	12.0 µg/sample ~1000 µg/sample	875 ± 1565

The overall mean recoveries were excellent for all matrices except dosimeters. Seven of twenty-seven outer dosimeter field fortification samples fortified at the low level had high recoveries of BIT ranging from 127-203%. These recoveries led to a mean recovery of 114% for low level fortifications, while the high fortifications were all acceptable with a mean of 92.4%. The Study Director determined these results did not impact the study as the sum of outer dosimeter sample residues for each subject were well above the low fortification level, and the high fortification level recoveries were excellent. Twelve of twenty-seven inner dosimeter field fortification samples fortified at the low level had high

recoveries of BIT ranging from 1842-6058%, while the remaining samples had acceptable recoveries ranging from 80.7-108%. These recoveries led to a mean recovery of 1645% for low level fortifications, while seven of twenty-seven high fortifications were acceptable with a mean recovery of 104%. The Study Director determined these results were the result of the high background levels of BIT in certain manufacturer lots of inner dosimeters. The pattern of some very high recoveries with the remaining recoveries support the hypothesis of random use of background contaminated lots for the field fortified samples. No unacceptably low recoveries were noted for any dosimeters. These results indicate that BIT was stable in the field, and throughout transport to the laboratory and storage.

None of the background ambient air sampling OVS tubes analyzed for this study showed any BIT residue equal to or greater than the LOQ, indicating that the air within the changing room and the test rooms used for ME monitoring were free of BIT on each study day.

Fifteen of twenty background wall wipe samples collected from the test rooms showed no BIT residue equal to or greater than the LOQ. The remaining five background wall wipe samples showed BIT residues ranging from 0.148-0.346 µg/sample. The background wall wipe residues were considerably lower than the BIT residues measured in test subject outer dosimeters indicating that potential transfer of BIT from the painted walls would not have influenced the study results.

Raw residue numbers for all matrices were initially corrected based on a matrix-specific field fortification adjustment factor (if <100%) and are represented as amount of BIT in µg per sample. The amount of BIT present in hand washes as well as face/neck wipe samples were further corrected for dermal removal efficiencies (Boatwright, 2017). The residues found in the face/neck wipe samples after correcting for the field fortification adjustment factor were also adjusted for the use of safety glasses.

The concentration of BIT in the paint used for each ME was determined and then used to calculate the total amount of active ingredient applied based on the total weight of paint used by each ME. The BIT concentration in the paint for subjects randomly assigned to the low BIT concentration group (ME01, ME02, ME04, ME11, ME13 and ME18) ranged from 141-147 ppm. The BIT concentration in the paint for subjects randomly assigned to the mid BIT concentration group (ME05, ME08, ME10, ME12, ME14 and ME15) ranged from 368-382 ppm. The BIT concentration in the paint for subjects randomly assigned to the high BIT concentration group (ME03, ME06, ME07, ME09, ME16 and ME17) ranged from 595-649 ppm. Subjects handled between 8.66 and 9.94 Kg of paint during their MEs.

The mean BIT residues per BIT concentration in paint (6 MEs per concentration) are presented below for all the matrices.

Mean BIT Residues (µg/sample) by Paint Concentration				
Matrix		**Low BIT**	**Mid BIT**	**High BIT**
		Mean Residue (µg/sample)	**Mean Residue (µg/sample)**	**Mean Residue (µg/sample)**
Air Sampling Tubes		<LOQ	<LOQ	<LOQ
RespiCon 100 µm filter		<LOQ	<LOQ	<LOQ
RespiCon 10 µm filter		<LOQ	<LOQ	<LOQ
RespiCon 2.5 µm filter		<LOQ	<LOQ	<LOQ
Hand Wash		218 ± 185	1367 ± 1411	725 ± 724
Face/Neck Wipes		1.31 ± 2.34	4.63 ± 5.60	2.67 ± 4.53
Painter's Hat		7.93 ± 5.22	30.7 ± 40.2	36.1 ± 41.2
Outer Dosimeters	**Upper Arms**	11.5 ± 6.89	37.6 ± 22.9	38.6 ± 59.3
	Lower Arms	44.1 ± 13.8	117 ± 73.0	145 ± 161
	Front Torso	33.7 ± 19.2	148 ± 79.7	88.0 ± 92.0
	Rear Torso	17.5 ± 16.0	38.7 ± 34.9	34.5 ± 26.0
	Upper Legs	35.1 ± 16.6	132 ± 110	196 ± 263
	Lower Legs	31.0 ± 26.5	111 ± 56.7	115 ± 100
Inner Dosimeters	**Painter's Hat**	11.8 ± 4.33	15.6 ± 3.16	15.8 ± 2.55
	Upper Arms	<LOQ	2.71 ± 1.88	2.14 ± 1.58
	Lower Arms	5.13 ± 2.33	14.6 ± 18.0	13.4 ± 13.1
	Front Torso	3.57 ± 2.42	14.3 ± 13.0	6.71 ± 8.42
	Rear Torso	2.59 ± 1.61	2.54 ± 1.25	4.38 ± 2.84
	Upper Legs	3.18 ± 2.13	3.92 ± 2.18	7.11 ± 6.99
	Lower Legs	1.80 ± 0.723	4.33 ± 5.52	9.29 ± 6.94

The individual residues represented as amount per sample were then normalized based on the amount of active ingredient applied by each subject (i.e. (µg/sample)/lb a.i. applied).

The total dermal exposure to each subject was calculated by adding the total corrected residue (µg) in the hand wash, the face/neck wipes, and the inner dosimeters (including the painter's hat inner dosimeter piece). The mean total dermal exposure values of all six subjects in each paint concentration group are presented below as total µg BIT. The mean dermal exposure for each BIT concentration in paint are also presented below, normalized for the amount of active ingredient handled.

Mean Normalized BIT Residues by Paint Concentration			
	Low BIT	**Mid BIT**	**High BIT**
Lb a.i. handled	0.00293 ± 0.000165	0.00767 ± 0.000329	0.0129 ± 0.000722
Total Dermal Exposure (µg)	245 ± 188	1427 ± 1401	781 ± 739
Dermal Unit Exposure (µg/lb a.i. handled)	82336 ± 59459	184382 ± 179471	58182 ± 52078

The normalized results show that there are no marked differences or clear patterns between the subject residues based on concentration of BIT in the paint. Among the dermal matrices, face/neck wipes had the least amount of detectable residues. The hand wash samples contained the highest residues as expected since the test subjects did not wear protective gloves while painting. Levels of BIT residues in the lower arms were higher than levels in the upper arms for both the inner and the outer dosimeters. Inner dosimeter residues were much lower than the corresponding outer dosimeter sections for the eight subjects wearing a non-contaminated inner dosimeter. A BIT clothing penetration factor was calculated for these subjects, and the average was applied to the remaining ten subjects to calculate their inner dosimeter values.

No measurable residues of BIT in the air were detected in any background air tubes, subject air tubes, or subject RespiCon sampler filters.

The results indicate that varied residues of BIT were transferred from paint to dermal samples as subjects painted with brush and roller based on their own painting experience.

2.0 INTRODUCTION AND BACKGROUND

The American Chemistry Council Antimicrobial Exposure Assessment Task Force II (AEATF II) contracted with Golden Pacific Laboratories, LLC (GPL) to conduct the field phase and analytical phase of a human exposure monitoring study. This study was conducted to determine potential dermal and inhalation exposures to residential consumer painters who apply paint containing antimicrobial pesticide products using brush and roller painting equipment. The results of the study are presented in this report.

3.0 TEST AND REFERENCE SUBSTANCES

3.1 Test Substance Identification

Trade name:	Sherwin-Williams SuperPaint® Interior Acrylic Latex Paint
Manufacturer:	The Sherwin-Williams Company, Cleveland, Ohio
Product code:	A86 W 151
Batch number:	WE1096GF
Active ingredients:	1,2-Benzisothiazolin-3-one (BIT)
CAS numbers:	BIT: 2634-33-5
Storage conditions:	Room Temperature (20 ± 5 °C)
Dates received:	May 3, 2016 and May 5, 2016
Expiration date:	NA

The native concentration of BIT in the base paint was found to range from 141 ppm to 147 ppm (µg BIT/g paint). Based on the measured concentration of BIT in the base paint, assigned 5-gallon buckets of paint were supplemented with BIT in diethylene glycol to prepare mid BIT level and high BIT level paints. The

concentrations of BIT in the supplemented buckets of paint were analyzed by GPL and found to range from 368 ppm to 382 ppm (µg BIT/g paint) for the mid-level and from 595 to 649 ppm (µg BIT/g paint) for the high level. Details of the preparation and analysis of the paint at each level are presented in Section 7.2 of this report. A retention sample from each concentration of paint is archived at GPL.

3.2 Reference Substance Identification

Common name:	BIT Technical (BIT)
Chemical name:	1, 2-Benzisothiazolin-3-one
CAS number:	2634-33-5
Source:	Troy Chemical
Lot number:	A121028082
Purity:	93.5%
Expiration date:	April 22, 2018
Physical characteristics:	White Powder
Storage conditions:	Ambient
Date received:	October 2, 2013

The reference substance was used to prepare a stock solution in diethylene glycol to dose the paint to higher levels and to prepare a stock solution in methanol for the preparation of calibration standards.

Information regarding the expiration date and concentration of the reference substances was provided on the Certificate of Analysis received with the reference substance. A copy of the Certificate of Analysis is kept in the archives of GPL and is attached in Appendix K. A retention sample of the reference substance is archived at Golden Pacific Laboratories, LLC.

3.3 Internal Standard Identification

Common name:	Benzoisothiazol-3-one-$^{13}C_6$
CAS number:	Not Applicable
Source:	Toronto Research Chemicals Inc.
Lot number:	3-MGG-87-2
Purity:	98.0%
Retest date:	September 21, 2015
Physical characteristics:	Brown Solid
Storage conditions:	Frozen (- 20 °C)
Date received:	September 27, 2012

A copy of the Certificate of Analysis is kept in the archives of GPL and attached in Appendix K.

4.0 RECRUITMENT PHASE PROCEDURES

4.1 Local Newspaper Advertisements

Following approval of the protocol by Schulman Investigational Review Board (IRB), the California Department of Pesticide Regulation (CDPR), and the United States Environmental Protection Agency (EPA), newspaper advertisements, in both English and Spanish, were placed in two local newspapers: The Fresno Bee and Vida en el Valle, which is widely circulated in the Spanish-speaking community. Copies of the advertisement in both English and Spanish are shown in Appendix D and Appendix E. The advertisements included a brief description of the study and directed interested volunteers to contact the Study Director, an English-speaking Coordinator, or a Spanish-speaking Coordinator for more information. The IRB approved scripts were used at the time of call-in. The approved scripts in both English and Spanish are shown in Appendix B and Appendix C.

4.2 Enrollment of Subjects

Interested callers were phone-interviewed to determine whether they met the inclusion criteria. Callers were screened for painting experience by asking if they had painted with a brush and roller in the last five years but have not been a professional painter in the last 10 years. Callers were asked if they were at least 18 years of age. During the phone call, volunteers were given a brief overview of the study and asked if they were still interested in participating. For those who met the inclusion criteria and were still interested, an Informed Consent Meeting was scheduled.

All Informed Consent Meetings were held at Golden Pacific Laboratories during the enrollment period between May 8 and May 21, 2016. Potential subjects were asked to bring a government-issued, picture ID to the meeting. The meetings were one-on-one unless family members/spouses wished to attend the meeting as a group. Volunteers could have met with either an English-speaking Field Research Associate or a Spanish-speaking Field Research Associate. All subjects in this study preferred to conduct the meeting in English. The Field Research Associate checked the government-issued picture ID to verify identity and age. Each volunteer was then given the following materials: Qualification Worksheet (Subject Self-Reporting Demographic Form), a copy of the IRB approved Informed Consent Form which included the "Experimental Subject's Bill of Rights" (Appendix F), a copy of the product label, and a copy of the paint Safety Data Sheet (SDS).

The subject was asked to first fill out Part I: Interview questions of the Qualification Worksheet. The Field Research Associate reviewed the answers to the five questions with the subject. If none of the answers disqualified the subject from participation, the Field Research Associate read the Informed Consent Form including the "Experimental Subject's Bill of Rights" to the potential subjects. The experimental study and the inclusion and exclusion criteria were described to each volunteer in detail, and potential subjects were encouraged to ask questions or

request clarification during the meeting and at any point during the rest of the study. Personnel conducting the informed consent meetings were trained to evaluate potential subject comprehension of the provided information. Potential subjects were also encouraged to take the forms and information home with them to discuss the study with family and friends. The Field Research Associate explained to potential subjects wishing to remain in consideration that they could withdraw from the study at any time without penalty.

If the eligible potential subject met the inclusion criteria, and was still interested in enrolling in the study, he or she was asked to sign and date the Informed Consent Form and fill out the second part of the Qualification Worksheet. Once these forms were fully filled out, the subject was considered officially enrolled in the study. All potential subjects received $20 for attending the Informed Consent meeting and enrolled subjects were given a copy of the signed Informed Consent Form. Enrolled subjects were informed that if they were selected to participate in the study they would receive another $100 for reporting to the study location on the scheduled day, no matter if they actually participated in the study or not.

4.3 Removal of Subjects

Five subjects who were enrolled into the study were assessed as having undue risks by the Study Director after consulting with the Field Research Associates who conducted consent meetings. Although these subjects initially were determined to meet the inclusion criteria, the Study Director determined that it was not safe or appropriate for them to participate in the study. Two of the enrolled subjects had weights greater than 300 pounds, the stated maximum safe weight of commercially available painting ladders available for the study. One of the subjects appeared to suffer from health problems severe enough to be of concern during the informed consent meeting. One of the subjects had difficulty following the conversation and directions during the informed consent meeting. One subject attended the informed consent meeting with family members who appeared to be pressuring the subject to participate. This subject also did not seem to have any experience painting when asked questions. The Study Director determined this subject did not meet the inclusion criteria.

Although these five subjects were initially enrolled, the Study Director considered their participation in the study to have undue risk and they were removed from the randomization (i.e. not scheduled into the study). This contingency (removal from study by the Study Director) was disclosed to subjects in the Informed Consent document and affected subjects were not additionally notified.

4.4 Randomization Procedure

During the two-week enrollment period, as subjects were enrolled a consecutive number, starting at 1, was assigned to the enrolled subject. After the two-week enrollment period ended, the enrolled subject's number was incorporated into the randomization process.

The subject numbers were randomized using a research randomizer program accessible at the following internet website: http://www.randomizer.org. During the enrollment period, a total of 37 subjects were enrolled to participate in the study. The first 18 numbers in the generated randomized list determined the initial group of participating subjects; the primary subjects assigned as ME01 through ME18. The subject numbers of the five subjects removed from the study were included in the randomization list, but were skipped over during assignment of subjects to participate. The remaining subjects were assigned as alternates to be entered into the alternate assignment. If needed, their order into the study would be determined by their order in the randomization process. Each monitoring event was assigned an alternate to report to the site to be used if the primary subject could not fulfill the monitoring event.

In the study, the concentration of BIT in paint used in each monitoring event would be one of three different concentrations; a low level (~144 ppm), a mid level (~375 ppm), and a high level (~619 ppm). The concentration of BIT in the paint was randomly assigned to the monitoring event using the randomization process. An input of 1 through 3 was put into the program with parameters that each input needed to be assigned six times resulting in 18 random assignments.

4.5 Scheduling of Subjects

Once assigned to a monitoring event or alternate assignment, subjects were contacted and informed of the day and time to report to the site. In order to accommodate the subjects' schedules, the primary subjects assigned to ME02 and ME04 switched days with each other, completing each other's assignments. The primary subject for ME05, was disqualified upon reporting to the test site due to a wrist injury, therefore the alternate completed the ME. The primary subject for ME08 could not be reached and there was difficulty in contacting the primary subject for ME07 resulting in the alternate completing ME07 and the primary subject originally assigned ME07 completing ME08. The primary subjects assigned ME10 and ME16 did not show up to their scheduled monitoring event, therefore the alternates completed ME10 and ME16. The primary subject assigned to ME11, withdrew from the study at the last minute due to not having gas and needing to watch his son, leaving the monitoring event to be completed by the alternate. The primary subject assigned to ME12 could not accommodate the schedule and was re-assigned as an alternate for ME18. The alternate completed ME12 and the primary subject for ME12 completed ME18 when the primary subject for ME18 did not show up.

A complete account of subjects is given in Tables 4 through 6. A list of subject numbers and ME conducted is given in Table 7.

5.0 FIELD PHASE PROCEDURES

5.1 Test Site Set up

The study was setup in a warehouse space located in Fresno, CA with a suitable floor plan that included restrooms, rooms for conducting field fortifications, dressing subjects, and storing the paint, as well as a large open space in which six identical rooms for painting were constructed. Six identical rooms measuring 10 feet by 12 feet with 8 foot ceilings were constructed with an exhaust fan and light in the ceiling and base board and trim around the floor, door, and simulated window.

The supplies were transported to the test site and set up appropriately for exposure monitoring a few days before the study was to be conducted.

Field Fortification

A clean room, away from the rooms intended for use for the monitoring events, was designated solely for the field fortification process. In the field fortification room, three tables lined with paper sheeting, which was changed daily to avoid any cross contamination, were setup for the fortification procedure. Previously sectioned pieces of inner and outer dosimeters enclosed in properly labeled resealable plastic bags, painter hats, water/IPA (50:50, v/v) solution, gauze pads, OVS tubes, fiberglass filters, air sampling pumps, aluminum foil, appropriate glassware, latex and/or nitrile gloves, and pre-labeled jars for sample collection were transported to the fortification room and staged during setup. Field fortification solutions needed to conduct fortifications at the site were stored at GPL and brought from the laboratory each day in a small ice chest on blue ice.

Changing Room

A clean room, away from the rooms intended for use for the monitoring events, was designated as the changing room in order to prepare the subjects for monitoring events and to collect the samples at the end of each monitoring event. The changing room was lined with plastic sheeting to avoid any cross contamination. In between the monitoring events, the room was cleaned, the plastic sheeting was changed, and the supplies were prepared for the next ME. The table in the room was also lined with absorbent pads, which were also changed in between subjects.

ME Test Areas

Appendix G contains a diagram of the test area. Six identical rooms, constructed specifically for this study, were used for subject exposure monitoring. A mobile cart containing painting supplies (brush, edger, roller, key to open the cans, paint tray, and cup, etc.), a data logger, extra air pumps, a garbage can, latex and/or nitrile gloves, pre-labeled jars for sample collection, gauze pads, fresh water or sport drink, and clean drinking straws accompanied the subjects from room to room.

A greeting and reception area was designated for subject arrival at the site. This area was equipped with tables and chairs, snacks, beverages, and a heat stress poster in English and Spanish.

5.2 Environmental Monitoring

Air temperature and relative humidity of the test site location for the duration of exposure monitoring were monitored by automated instrumentation logging and recording (data loggers). A data logger was placed in the test substance room where the 5 gallon buckets of paint were being stored on site. Data logger were also located in the field fortification room and changing room to monitor temperature and relative humidity during activities.

During the first week of monitoring, portable air conditioners, located in the doorways, were used in each room to cool the rooms. Due to the units being inconveniently in the way of monitoring, each of the six rooms were equipped with a window HVAC system. During each monitoring event the temperature and relative humidity were recorded by a data logger located on the clipboard of the observer following the subject throughout their task.. The maximum, minimum, and average temperature and the maximum, minimum, and average relative humidity for each monitoring event are summarized in Table 8. The maximum, minimum, and average temperature and the maximum, minimum, and average relative humidity for the changing room and the field fortification room for each day of monitoring, along with the test substance room over the course of the study, are summarized in Table 9.

The air changes per hour (ACH) of two of the test rooms was measured before the start of the study using a tracer gas decay method. The ventilation fan was turned on during the measurement as it was during study use. The room air exchange was measured as 11-12 ACH with the door open, and 7 ACH with the door closed. The portable and window air conditioner units used to cool the rooms were designed to recirculate room air and not expected to change the ACH.

5.2.1 Heat Stress Avoidance

A data logger was placed on a mobile cart that accompanied subjects as they performed the painting task. Temperature and humidity on the mobile cart were monitored to determine heat stress of the subjects. Subjects were made aware of the symptoms of heat stress and were instructed to inform study personnel immediately if they felt ill. Heat stress posters were displayed in several locations within the facility and subjects were made aware of their content and locations. To minimize the possibility of heat stress, study personnel and an on-site nurse observed the subjects for heat stress effects and were instructed to stop subjects' work if any signs of heat stress were observed. During the monitoring events, the temperature ranged from 19.9 to 29.3 °C (67.9 to 84.8 °F) and the heat index did not exceed 95 at any time. The subjects were asked repeatedly if they would like to take a brief break. If they answered affirmatively, the subjects stopped working and were given their choice of water or a sports drink. If the subject answered negatively, they were permitted to continue working, and were asked frequently thereafter whether they would like a break.

5.3 Application Equipment and Parameters

Subjects were tasked to paint the surfaces (walls, ceiling, base boards, and trim) of typical rooms as they would if painting their home, using painting equipment provided by study personnel. The available equipment for subject use during the paint application is listed below:

-**Roller**, Better, 9 in. Smooth to Semi-Smooth Surfaces 3/8 in nap Roller, Home Depot.
-**Brush**, Better, 3 in. Semi-Smooth to Rough Brush, Home Depot.
-**Roller Frame**, Economy, 9 in. Heavy Duty Roller Frame, Home Depot.
-**Paint Cup**, HANDy, 1500-CC HANDy Paint Cup, Amazon.
-**Can Opener**, Always Tools, Paint Can and Bottle Opener, Home Depot.
-**Extension Pole**, Economy, 4 ft. Wood Extension Pole with Metal Tip, Home Depot.
-**Trim Guard**, Dynamic, Deluxe Metal Edge Painter's Trim Guard, 12-inch, Amazon.
-**Roller Tray**, Wooster Brush, R402-11 Deluxe Metal Tray, 11-inch, Amazon.
-**Paint Rags**, Dynamic, KA220005 General Purpose Painter's Rags, Amazon.
-**Stir Stick**, Complimentary, Paint Mixing Stir Stick, Home Depot.
-**Foldable Ladder**, Werner, 6 ft. Aluminum Step Ladder, Home Depot.
-**Cushion**, Fiskars, 11 in. x 18 in. Kneeling Cushion, Home Depot.
-**Step Ladder**, Gorilla Ladders, 2Step Compact Stool, Home Depot.
-**Rag Bucket**, Economy, 2 gal. White Plastic Bucket, Home Depot.
-**Safety Glasses**, JORESTECH Eyewear, Safety Protective Glasses UV 400, Amazon.

Subjects were given minimal instruction beyond the need to paint both walls and trim as they would when painting their own residence. Subjects were also asked not to re-paint any surface during a given monitoring event. Once the subject was done painting one room, the subject continued in the next room or rooms until the subject had applied 1.75 to 2.25 gallons of paint, determined by weight. The total weight of paint handled by the subjects ranged from 8.66 to 9.94 Kg. A summary of the paint handled by each applicant, mass of paint and active ingredient handled, surface area and rooms painted, and duration of painting are listed in Table 10.

Rooms were not painted more often than every other day to allow for the paint to dry.

5.4 Preparation of Paints for Study Use

A total of eighteen 5-gallon containers of paint were purchased from a local Sherwin-Williams store. Nine containers were left untinted and nine containers were tinted a cream color. Each container was assigned a unique identification code and was assigned for use by one subject for each monitoring event. Six containers were not fortified with additional BIT, six containers were dosed to

approximately 360 ppm BIT, and six were dosed to approximately 600 ppm BIT. Of the six paint containers at each BIT level, three paint containers were left untinted and three were tinted.

The BIT concentration of all containers was empirically determined prior to use. For each monitoring event, paint was transferred from the assigned 5-gallon container to 1-gallon paint cans for use by the subjects.

Section 7.2 details the dosing of each paint container and Table 10 summarizes unique information of each paint container.

5.5 Sampling for Background Air and Surface Residues of BIT

Air samples were collected from the changing room and painting rooms prior to exposure to determine background levels of BIT in the air each study day. Air monitoring was performed by collecting samples for at least 15 minutes in changing rooms and painting rooms at sampling heights of 3 feet and 5 feet. Background samples were collected within 2 hours prior to subject activity. Air sampling tubes were connected with tygon tubing to personal air pumps with a flowrate of approximately 2 L/min.

Dry gauze wipe samples were collected from the changing room and painting rooms prior to exposure to determine background levels of BIT on wall surfaces each study day. These background wall wipes were collected in changing rooms and painting rooms at sampling heights of 3 feet and 5 feet. One wall wipe sample was collected at each height within each room that was sampled. Wall wipes were prepared by rubbing an approximately 1-foot square area of wall for 15 seconds with a package of dry gauze wipes.

Background air sampling and wall wipe results are documented in the raw data, summarized in the results section of this report, and individually presented in Tables 12 and 13, respectively.

On the first study day, only one subject applied paint, whereas two subjects painted on study days 2 through 8, and three subjects painted on study day 9. Background air sampling tube and wall wipe samples were collected in the changing room and painting rooms 1-3 on the first study day since the subject would not realistically be able to paint more than three rooms. On all other study days, background air and wall surface samples were taken in the changing room and all painting rooms.

5.6 Exposure Monitoring Procedures

During each monitoring event, subjects applied the test substance (paint containing BIT) at the assigned concentration using a brush and roller. The amount of active ingredient applied was varied by having three different concentrations of BIT. Each participating subject was monitored one time for a total of 18 MEs.

Upon arrival to the study location, the subjects were greeted and offered food and drink. The subjects were reminded of their role in the study and the study procedures, their right to withdraw at any time without negative consequences, and then asked if they had any questions. Once questions were answered, the nurse inspected the subject's hands to ensure that there were no existing abrasions, cuts, or skin conditions that could have increased the risk of exposure or skin problems or influence the removal of the paint during the monitoring period.

Heat stress posters in English and Spanish were displayed in the changing room as well as the reception area. Subjects were made aware of the locations of the posters and were encouraged to read the content.

Per protocol, a urine pregnancy test (using an over-the-counter pregnancy test kit) was administered to female subjects. After the subject took the pregnancy test, she was asked if she still wished to participate in the study. All female subjects responded that they wanted to continue, and a female member of the research team was present to confirm the negative results of the pregnancy test. All results of the pregnancy tests were kept in confidence and were not recorded.

5.7 Sampling Media

The following table lists the sampling media used to prepare background, subject, field fortification, and concurrent lab recovery samples.

Matrix	Product Information
Air Sampling Tubes	OVS Tubes – XAD-2, SKC West, Inc. (Catalog # 226-30-16)
Fiberglass Filters	RespiCon™ Glass Fiber, 1.0 µm, 37 mm, with and without Hole for RespiCon™, No Support Pad, SKC-West Part #: 225-716 and 225-715.
Hand Wash Solution	Isopropyl alcohol/Water (50:50, v/v); Isopropyl alcohol (2-propanol) Optima grade, Fisher Scientific Company, LLC, Catalog # A464-4. Distilled Water, Great Value Brand, purchased at WalMart.
Face/Neck Wipes	Johnson and Johnson Mirasorb® Gauze Sponges, 4 ply 4 in. x 4 in (10.1 cm x 10.1 cm), Reference # 723832, Amazon.com.
Inner Dosimeters	Indera Coldmaster Rib Knit Long Sleeve Union Suit – White, Item No. IND-860, Gray and Holt Dry Goods Inc.
Outer Dosimeters	Shirt – DP 100% Cotton Shirt, L/S, White or Tan, Pants – DP 100% Cotton Work Pants, White, Universal Overall Company, Catalog # Style # 945-S-1 (White) and Style # 946-1.
Painter's Hats	Dalix Mens Cotton Twill Painters Cap - Adjustable Hat Unstructured Low Crown, Amazon.com.

Air sampling tubes were connected via tygon tubing to personal air pumps inhaling at a rate of ~2 L/min for background air sampling, subject exposure, and field fortified sample weathering. Travel spike and concurrent lab QC air tubes were not weathered. Fiberglass filters were placed in the RespiCon holder and connected to personal air pumps inhaling at a rate of ~3.1 L/min for subject exposure sampling. Field fortified and concurrent lab QC fiberglass filters were not weathered. Background wall wipe samples and sweat wipe samples were taken using dry gauze sponges. Field fortified, concurrent lab QC, and final face/neck wipe samples were

wetted with 4 mL of Isopropyl alcohol/Water (50:50, v/v) per sponge (8 mL total per sample). Inner dosimeter garments were sectioned according to the SOP AEATF II-8A.2 after exposure for subject samples. Inner dosimeter pieces were used for field fortified and concurrent lab QC samples. Inner dosimeter pieces were also cut into 3 in x 3 in squares and lined under the painter's hats as painter's hat inner dosimeter samples. Outer dosimeter garments were sectioned according to the SOP AEATF II-8A.2 after exposure for subject samples. Outer dosimeter pieces were used for field fortified and concurrent lab QC samples. Painter's hats were analyzed as is after exposure for subject samples and as field fortified and concurrent lab QC samples.

5.8 Subject Preparation

SOPs AEATF II-8A.2, AEATF II-8B.3, AEATF II-8C.2 and AEATF II-8D.1 were followed when preparing subjects for exposure monitoring.

5.8.1 Hand/Face Wash

Once done with preliminary procedures, subjects were given a locker to store their personal belongings and were led to a bathroom. Subjects were instructed to wash their hands and face with Ivory soap and water. The subject used paper towels to dry after washing.

5.8.2 Inner and Outer Dosimeters

After the hand/face washing, subjects were taken to a clean, private room (dosimeter assembly room) by a same gender study personnel and given the proper size inner and outer dosimeters. The subjects were asked to remove their street clothes down to their underwear and wear the outer dosimeter on top of the inner dosimeter. The inner dosimeter consisted of a one-piece, white, long underwear union suit made of 100% cotton. The outer dosimeter consisted of 100% cotton long pants and a long-sleeve shirt. The inner dosimeter was used to capture test substance that would normally contact the subject's skin and was kept slightly shorter than the outer dosimeter on the arms and legs, either by fit or by trimming to fit to avoid contamination. The outer dosimeter pant cuffs were also cut so that cuffs did not drag on the floor, but would not be so short that they would expose worker's socks or inner dosimeter leg. Subjects were offered shoe covers to protect their footwear. Both dosimeters were worn through the entire monitoring period.

5.8.3 Air Sampling

Once the subjects were dressed in dosimeters, a low-volume, personal air-sampling pump and OVS air sampling tube with glass filter and XAD2 sorbent was placed in the subjects' breathing zones to determine subjects' inhalation exposure to BIT. The OVS air sampling tube was used to determine the total concentration of BIT in the air. The air flow of the

pump was calibrated to a targeted rate of 2.0 liters per minute prior to use. A second low-volume, personal air-sampling pump attached to a three stage RespiCon™ Particle Sampler was placed in the subjects' breathing zones using a chest harness to determine the size distribution of any particles containing BIT in the air. The air flow of the pump was calibrated to a targeted rate of 3.1 liters per minute prior to use. The actual airflow of each pump was documented. The pumps were then attached to the belt around the waist of the subject. Tygon® tubing attached to the inlet valve of the pumps was placed over the shoulders of the subject. The OVS air sampling tube was held in a plastic tube sleeve clipped to the subject's outer collar with the intake facing downward to simulate the nasal passage of the subject. The RespiCon™ Particle Sampler incorporates the air intake into its assembly, which was centered on the subject's chest.

5.8.4 Painter's Hats

Each subject was fitted with a painter's hat and a 3" by 3" single layer square of inner dosimeter material under the hat laid upon their head. The inner dosimeter square was used to capture test substance that would normally contact the subject's hair and/or skin under a hat. The hat measured the amount of residue that an unprotected (uncovered) head would encounter.

5.8.5 Eyewear

Subjects were given safety glasses that provided front, and supplemental brow and temple protection. If the subject wore eyeglasses, the subject was given safety glasses made to wear over the glasses.

5.8.6 Photographs/Videos

Photographs were taken of each outfitted subject. To avoid identification, the face of each subject was not shown, or was covered with a paper sheet during frontal photographs. Representative video was taken of each subject conducting the ME. Video files were edited to remove any scenes where subjects might be identifiable. Photographs and videos will be archived with the study raw data.

5.9 Conduct of the Monitoring Event

Once prepared the subjects were taken to the first room to be painted. The air pumps were turned on at the start of the monitoring period. The subjects were given the first closed 1-gallon can of paint, opened the can and began painting. Subjects painted the walls, ceiling, baseboards, and door and window trims. Subjects were tasked to paint both trim and walls as they would when painting their own residence. Subjects were free to use accessory equipment such as paint cups and rags at their discretion. A transcription of the observer's notes taken during

each subjects monitoring event is attached as Appendix H. Once the paintable surfaces were painted, subjects moved from room to room until the requested amount of paint was used. At the end of the monitoring event, the pumps were turned off and the subject was taken back to the subject changing room. The surface area painted by each subject during the entire monitoring period was estimated from pre-study measurements of surfaces, and these estimates along with the total amount of paint applied are presented in the Table 10 of this report.

Subjects were assigned paint containing one of three concentrations of BIT and were asked to apply 2 gallons (8,636 to 11,104 grams) of paint to the surfaces using as many rooms as needed. Subjects were given a new 1-gallon can of paint by study investigators when the prior can was exhausted. The weight of the can was taken prior to handing it to the subject. Additional weighings of the can were taken prior to starting a new room and after the can was completed. The final weight of the exhausted can was taken and documented. The series of weighings were documented in the raw data. The total amount of paint applied from each can used in the ME was determined and tallied for total amount of paint applied. The amount of paint applied during the entire monitoring period was calculated for every subject and is presented in Table 10 of this report.

The subjects were frequently offered a break during the monitoring event. Often, the subjects wished to continue painting and rejected the offer. Subjects were reminded they could break at any time upon request. While on break, subjects sat in a chair covered with plastic sheeting outside of the rooms being painted. They were not permitted to smoke or eat, but were encouraged to drink either water or a sports drink. The air sampling pumps remained on during the entire monitoring event including any break periods. If they expressed a desire to drink, they were not permitted to touch the bottle, and had to sip from a straw while a researcher held the straw up to their mouth. One subject (ME-02) asked for a cigarette and then stated they were feeling dizzy during their monitoring event. The nurse asked the subject to sit down and put their head down, then gave the subject sips of Gatorade. After 2-3 minutes the subject indicated they were “fine now” and resumed painting. The nurse followed up and the subject indicated they had no more dizziness and did not want another break. The total amount of time spent painting by each subject, not including rest periods, is presented in Table 10 of this report.

The environmental data (temperature and relative humidity) during each monitoring event is presented in Table 8 of this report.

5.9.1 Field Study Personnel

There were always three to four study personnel following the subject during a given monitoring event. One researcher was assigned as the “observer” and remained with the subject throughout the duration of the monitoring period. The observer recorded observational notes of the subject’s activities and guided the subject from room to room.

A second researcher was assigned to supply and weigh the cans of paint. This researcher provided the subject with the can, weighed and recorded the can weights, kept a record of the amount of paint applied.

A study assistant operated the digital camera and video camera during the monitoring period.

A registered nurse was always on site to monitor the well-being of the subject during the monitoring period, she held the drink for subject during breaks and she collected the face wipe samples generated from wiping the sweat off the subject's face.

In addition, the Study Director and/or the Field Coordinator were also on site. On at least three days, a quality assurance representative was present. On one day representatives from the California Department of Pesticide Regulation were present.

Other study personnel were responsible for activities supportive to the monitoring event. One researcher was assigned to performing field fortifications on site and another was responsible for the calibration of air-sampling pumps and recording air pump flow rates before and after monitoring. This researcher along with one or two additional researchers collected the background samples each morning.

5.9.2 Observations

The activities of each subject were recorded by study personnel. These observations comprise all activities that occurred during the monitoring event, including start and stop times and break times. Any incidental occurrences that may have affected individual exposure were clearly documented in the observational notes. The raw data contain the original notes, as well as digital photography and videography of each subject. General observations recorded during monitoring events are presented in Appendix H of this report.

5.9.3 Inhalation Exposure Sampling

The air sampling pumps operated for the entire monitoring period, including breaks. The pumps were checked periodically through the monitoring period to ensure that they were functioning correctly and that the tubing was still intact. Occasionally, the OVS tube would shift positions and point upwards, in which case study personnel would adjust it back to its original downward position. Occasionally, the harness would shift and require readjustment.

Air pump flow rates were measured before and after each exposure monitoring period and detailed records of flow rates and sampling duration were recorded. The air pump on and off times and average flow rates are included in Tables 44 and 45, respectively.

5.9.4 Face/Neck Wipe Sampling during Monitoring Event

A packet containing two dry gauze pads (not moistened with the water/isopropyl alcohol (IPA) solution) were used to wipe excess sweat from the face/neck area of the subject during the monitoring event. Typically, the subject would request that his/her face be wiped and the registered nurse or a researcher would collect the sample. These face/neck wipe samples were collected into pre-labeled glass jars. The number of jars collected varied from subject to subject according to the number of times wipe samples were taken. The samples remained at ambient temperature until the completion of the monitoring event, at which time they transported with the other samples to GPL. Each of these interim samples and the final face/neck wipe sample were analyzed separately. The analytical results from each sample were added together with the final face/neck wipe sample to generate one face/neck wipe value.

5.10 Sample Collection

SOPs AEATF II-8A.2, AEATF II-8C.2 and AEATF II-8D.1 were followed when collecting exposure monitoring samples.

After the monitoring event was completed, the subject returned to the changing room with a same gender researcher for removal of dosimeters and collection of samples.

Samples were generally collected in the following order to minimize cross contamination: painter's hat, painter's hat inner dosimeter piece, air sampling tube, fiberglass filters, hand wash, face/neck wipe, outer dosimeter pieces, and inner dosimeter pieces. The samples were collected by study personnel and placed immediately in the appropriate collection vessels. All samples were transported to GPL and placed in frozen storage.

5.10.1 Painter's Hat and Inner Dosimeter Square

Once in the changing room, the safety glasses and the painter's hat were removed from the subject. The painter's hat was placed in a pre-labeled glass jar and the painter's hat inner dosimeter square was removed from the head and placed in a pre-labeled glass jar. The time the samples were collected were recorded.

5.10.2 Air Sampling Tubes

The air sampling pump, and air tube train were removed from the subject and handed off to another researcher who determined and recorded the ending flow rate. The OVS air sampling tube was removed from the pump tubing, capped at both ends, and placed in a pre-labeled re-sealable bag. The pump on- and off-times were recorded in the raw data.

5.10.3 Fiberglass Filters

The air sampling pump, tubing and RespiCon™ Particle Sampler train along with the harness were removed from the subject. The air sampling pump, tubing and RespiCon™ Particle Sampler train was handed off to another researcher who determined and recorded the ending flow rate. The RespiCon™ Particle Sampler was removed from the pump tubing and the three filters were removed from the RespiCon™ Particle Sampler, each transferred to pre-labeled 25-mL culture tubes, and placed in a pre-labeled re-sealable bag. The pump on- and off-times were recorded in the raw data.

5.10.4 Hand Wash

Dermal hand exposure was assessed by washing and scrubbing the subjects' hands with 500 mL of water/IPA (50:50, v/v) solution and one package of gauze wipes (two per package). Over a sample collection bowl, a small amount (~50 mL) of the premeasured 500 mL of isopropyl alcohol/water (50:50, v/v) sample was poured over one of the gauze wipes (BAND-AID® Johnson & Johnson Large Mirasorb® Gauze Sponges, 4 in. x 4 in.) and the subject's hands to moisten the paint. With the wet gauze wipe, study personnel scrubbed one hand, loosening and removing the paint. The second gauze wipe was wet with some fresh isopropyl alcohol/water (50:50, v/v) and used to scrub the second hand, loosening and removing the paint. The two gauze wipes were added to the collection bowl. Study personnel then poured more of the isopropyl alcohol/water (50:50, v/v) over the subject's hands while they rubbed and washed their hands together like one would when washing under a faucet. Subjects were instructed to rub and scrub their hands together. The remainder of the premeasured 500 mL of isopropyl alcohol/water (50:50, v/v) was slowly poured over the subject's hands while they were directed to rub and rinse their hands for a final clean rinse. The solution and wipes were collected as a sample. A hand wash sample was collected at the end of the monitoring event from each subject.

5.10.5 Face/Neck Wipes

At the end of the monitoring event, two gauze pads, moistened with 4 mL of water/IPA (50:50, v/v) each, were used to take a final face/neck wipe sample. All face/neck wipe samples, including those used to wipe sweat

during the monitoring event as well as the final sample, were analyzed separately. The analytically determined residue values were added together to generate one face/neck wipe value.

5.10.6 Outer Dosimeters and Inner Dosimeters

Both dosimeters were worn throughout the monitoring event and removed at the end of the work period with the assistance of a same gender member of the monitoring team. Care was taken to ensure that the outer shirts and pants did not contaminate each other or the inner dosimeters. Study personnel changed gloves frequently to avoid cross contamination during the removal of dosimeters. The shirt and paint outer dosimeters were removed first and placed on hangers followed by the removal of the inner dosimeter which was also put on a hanger. The inner dosimeter was cut into sections before the outer dosimeter. Study personnel changed gloves and cleaned the scissors with isopropyl alcohol when switching between sectioning operations on the inner and outer dosimeters. After the removal of the buttons, both the inner and outer dosimeters were cut into the following six sections in this order:

1. Lower Legs: Knees to Cuff, Left and Right Combined
2. Upper Legs: Knees to Waist, Left and Right Combined
3. Lower Arms: Elbow to Cuff, Left and Right Combined
4. Upper Arms: Elbow to Shoulder, Left and Right Combined
5. Front Torso: Above the Waist Front
6. Rear Torso: Above the Waist Back

Sections were placed immediately into pre-labeled glass jars.

When all samples were collected, the subjects got dressed in their street clothes and were asked to wash their hands with soap and water. All subjects were given the chance to ask any remaining questions and had their hands checked for redness and/or irritation, after which they were paid for their participation in cash and were free to leave. No adverse effects were reported by the subjects or noted by the nurse during or after the study.

5.11 BIT Removal Efficiency

A hand surface removal efficiency study was conducted in 2015 at the analytical laboratory in GPL Study # 130503 (Sponsor Study # AEA08). Subjects had pre-weighed, 100-µL aliquots of paint added to hand surfaces at two levels of BIT, 154 ppm BIT base paint and 547 ppm BIT supplemented paint (n=5 subjects for each BIT level in paint). The paint was allowed to dry for 45 minutes, then removed using a wash and wipe procedure. The procedure consisted of moistening two separate dressing sponges with hand wash solution (isopropyl alcohol/water (50:50, v/v) and scrubbing each hand, then rinsing with more hand wash solution. The

dressing sponges and wash solution were collected and combined, representing a hand wash sample. For hands dosed with the base paint, the average BIT recovery after the hand wash procedure was 73.3%. For hands dosed with the 547 ppm BIT paint, the average BIT recovery after the hand wash procedure was 60.3%. These removal factors were applied to hand wash residue results and neck/face wipe residue results to accurately determine total human exposure of BIT in paint for subjects handling low and high BIT level paints, respectively. For subjects handling mid-level paint, the average of these two factors was used (66.8%).

5.12 Field Fortification Procedures

SOPs AEATF II-8E.1 was followed when preparing field fortification samples.

Field fortification was conducted to assess the stability of the active ingredient under field, storage and transport conditions in or on the sampling material. Sample matrix fortifications were performed in a designated area (away from any potential contamination), at the test site each day of the study for inner and outer dosimeters, and painter's hats. For air sampling tubes, fiberglass filters, face wipes, and hand washes, field fortification samples were fortified at GPL then transported to the test site prior to returning to the laboratory. For field fortification samples fortified at the test site, fortification solutions were transported to the test site for fortification.

BIT-fortified paint, water diluted paint solutions, or BIT diluted in methanol were used to fortify the various matrices. Fortification solutions were analyzed to verify accurate concentrations, prior to use in the study.

Field fortifications were conducted at the following levels during the study:

Matrix	Fortification Solution Type	Target Fortification Level (low and high)
Air Sampling Tubes	BIT diluted in methanol BIT diluted in methanol	100 ng/tube 2.0 µg/tube
Hand Wipes/Washes	Water diluted paint BIT-fortified paint	4.0 ng/mL 400 ng/mL
Face/Neck Wipes	Water diluted paint Water diluted paint	400 ng/sample 10 µg/sample
Painter's Hats	Water diluted paint BIT-fortified paint	12 µg/sample 1.0 mg/sample
Inner Dosimeter Section	Water diluted paint BIT-fortified paint	12 µg/sample 1.0 mg/sample
Outer Dosimeter Section	Water diluted paint BIT-fortified paint	12 µg/sample 1.0 mg/sample
RespiCon Fiberglass Filters	Water diluted paint Water diluted paint	100 ng/filter 2.0 µg/filter

On each study day, three samples were fortified at the lower fortification levels indicated and three samples were fortified at the higher fortification levels for each

matrix. Two unfortified controls were reserved as field control samples. In addition, for air sampling tubes, inner and outer dosimeters, and painter's hats, two travel spikes at the higher fortification level were prepared. These would be analyzed at the discretion of the Study Director if unusually low field fortification recovery results were observed. In this study, the travel spikes were never deemed necessary to analyze as recoveries of the field spikes were not low.

5.12.1 Air Sampling Tubes

Using a syringe, each OVS air sampling tube was fortified at the appropriate level with 25 µL of fortification solution at GPL before being transported to the study site. OVS tubes were then connected to calibrated air pumps in the field fortification room at the test site. Air pumps were turned on and OVS tubes (control and fortified) were exposed to ambient conditions for more time than the longest exposure monitoring event for that day. After the weathering period, pumps were turned off and OVS tubes were disconnected, capped on both ends and placed into pre-labeled re-sealable bags. In addition, two OVS tubes (fortified at the highest fortification level) were not weathered and were transported to the test site and back to the lab as travel spikes.

5.12.2 Fiberglass Filters

For each fortification sample, a RespiCon™ fiberglass filter was placed into a pre-labeled culture tube. Using a manual pipette, fiberglass filter samples were fortified at the appropriate level with 25 µL of fortification solution. Samples were taken to the test site at ambient temperature prior to transporting back to the lab for frozen storage. Fiberglass filters were not weathered.

5.12.3 Hand Washes

To prepare each fortification sample, a volume of 500 mL of the hand wash solvent (water/isopropyl alcohol (50:50, v/v)) was measured in a graduated cylinder and poured into a pre-labeled glass jar along two gauze wipes. Using a manual pipette, hand wash solvent was fortified with 500 µL of fortification solution (diluted paint) for the samples fortified at the low level. For samples fortified at the high level, ca. 0.4 g of 595 ppm BIT paint was added by weight to the sample. Samples were taken to the test site at ambient temperature prior to returning to the lab for frozen storage. Hand washes were not weathered.

5.12.4 Face/Neck Wipes

For each fortification sample, two gauze pads were placed into a pre-labeled glass jar and moistened with 4 mL of water/isopropyl alcohol (50:50, v/v) per gauze wipe for a total of 8 mL. Using a manual pipette, face/neck wipe samples were fortified at the appropriate level with 100 or

125 µL of fortification solution. Samples were taken to the test site at ambient temperature prior to returning to the lab for frozen storage. Face/neck wipes were not weathered.

5.12.5 Outer Dosimeters and Inner Dosimeters

Previously sectioned inner and outer dosimeters were placed on sheets of aluminum foil. Using a manual pipette, dosimeter sections were fortified with 400 µL of fortification solution (diluted paint) for the samples fortified at the low level. For samples fortified at the high level, ca. 1.8 g of 595 ppm BIT paint was added by weight to a swatch of fiber cut away from the sample, then returned to the garment piece. The outer and inner dosimeter sections were then exposed, uncovered, to ambient conditions for more time than the longest exposure monitoring event for that day . The two control samples of outer and inner dosimeter section were also exposed to the same weathering process as the fortified samples. After weathering, fortified samples were placed in pre-labeled glass jars. In addition, two sectioned samples for both inner and outer dosimeters were fortified at the test site at the highest fortification level, but were not weathered and returned to the lab for frozen storage as travel spikes.

5.12.6 Painter's Hats

Painter's hats were placed on sheets of aluminum foil. Using a manual pipette, dosimeter sections were fortified with 400 µL of fortification solution (diluted paint) for the samples fortified at the low level. For samples fortified at the high level, ca. 1.8 g of 595 ppm BIT paint was added by weight to a swatch of fiber cut away from the hat, then returned to the remaining sample. The painter's hats were then exposed, uncovered, to ambient conditions for more time than the longest exposure monitoring event for that day. The two control painter's hats were also exposed to the same weathering process as the fortified samples. After weathering, fortified samples were placed in pre-labeled glass jars. In addition, two painter's hats were fortified at the test site at the highest fortification level, but were not weathered and returned to the lab for frozen storage as travel spikes.

6.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

Samples were transported from the trial location to GPL at ambient temperature as the test site was approximately ¼ mile from GPL. The samples were placed into frozen storage (<-10 °C) within 1 hour of arrival and remained in frozen storage pending analysis. Appendix I presents the sample tracking table including the date each sample was sampled, delivered to the laboratory, extracted and total number of days in storage.

Samples were identified and tracked by unique sample numbers during the field phase of the study. For example, for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject 1 in chronological order of participation
ID = Inner Dosimeter
LA = Lower Arm

Additional designations were as follows:
AR = Air Sampling Tube
RES-01 = RespiCon™ Fiberglass Filter 100 µm
RES-02 = RespiCon™ Fiberglass Filter 10 µm
RES-03 = RespiCon™ Fiberglass Filter 2.5 µm
HW = Hand Wash
FW = Face and Neck Wipe
SW = Sweat Wipe
OD = Outer Dosimeter
PH = Painter's Hat
FF = Field Fortification
BS = Background Sample
CR = Changing Room
WW = Wall Wipes
H1/H2 = Height 1/Height 2
T = Travel Spike

In the analytical laboratory, samples were referenced by subject's chronological order, (AEA09-BRS-01), not by subject number/ID or by ME assignment. Table 7 lists the subject number (Field ID), corresponding monitoring event ID with the subject's chronological order for each study subject.

7.0 ANALYTICAL PHASE PROCEDURES

Study sample analysis was initiated on June 7, 2016 and was completed on April 27, 2017.

A total of 890 samples were extracted and analyzed. Field samples were grouped by matrix type and were analyzed in 74 sets with an additional two sets analyzed during investigation into the inner dosimeter test system. Typically, each set consisted of a solvent blank, an untreated control, two laboratory fortification samples, field study samples and at least one control field fortification sample, and two fortified field fortification samples generated the same day as the field samples for that particular matrix. Prior to extraction, a unique laboratory code designation was assigned to each field sample. The laboratory code consisted of the last three digits of the GPL study number, the sample set and a sample number (e.g. 463SET01-1). The original sample identity and laboratory code were documented on the master laboratory worksheet. When analytical sets required reanalysis due to the need for dilutions or failure of QC samples, the sets were identified by adding "A", "B", "C" etc. to the end of the sample set ID (e.g. 463SET01A).

7.1 Preparation of Standard Solutions

Refer to Section 3.1 for test substance details. Refer to Section 3.2 for reference substance details and 3.3 for internal standard details.

7.1.1 BIT Calibration Standards

The reference substance was used to prepare a stock solution in diethylene glycol to dose the paint to higher levels (discussed in section 7.2) and to prepare a stock solution in methanol for the preparation of fortification solutions and calibration standards.

A stock solution of BIT (402 µg/mL after correcting for purity) was prepared by weighing 0.0215 g of BIT reference substance into a 50 mL volumetric flask and diluting to volume with methanol. The stock solution was stored refrigerated and assigned an expiration date of 1 year.

In addition, the reference substance, BIT (402 µg/mL), served as a laboratory fortification solution and was further diluted to prepare fortification solutions in methanol at the following concentrations: 80.0 µg/mL, 4.00 µg/mL, and 400 ng/mL. Fortification solutions prepared in methanol were used to fortify the air sampling tubes either in the field during the preparation of field fortification samples or in the laboratory during sample analysis.

The fortification solution prepared at 400 ng/mL was also used as an intermediate to prepare calibration standards. Aliquots of the intermediate solution were diluted in methanol/water/formic acid (70:30:0.016, v/v/v) as outlined in the following table to prepare calibration standards for determination of BIT in study samples.

Intermediate Solution	Volume Added (mL)	Final Volume (mL)	Standard Concentration (ng/mL)
400 ng/mL	0.1	80	0.500
	0.1	40	1.00
	0.5	100	2.00
	1	80	5.00
	2	40	20.0
	5	40	50.0

The intermediate solution and calibration standards were prepared as needed using the same outline, assigned an expiration of three months and were stored in a refrigerator set at 4 °C when not in use.

7.1.2 BIT Internal Standard

The internal standard, Benzoisothiazol-3-one-$^{13}C_6$ (BIT-IS), was used to prepare solutions of internal standard (IS) that were used alongside the calibration standards to determine the amount of BIT in study samples

A stock solution of BIT-IS (102 µg/mL after correcting for purity) was prepared by weighing 0.0026 g of BIT-IS reference substance into a 25 mL volumetric flask and bringing it to volume with acetonitrile.

A BIT-IS solution at a concentration of 50.0 ng/mL was prepared by adding a sufficient volume of the stock solution to an appropriate amount of methanol/water/formic acid (70:30:0.016, v/v/v). The 50 ng/mL solution of BIT-IS was used to dilute the sample extracts 1:1 and calibration standards just prior to LC-MS/MS analysis.

BIT-IS solutions were not assigned an expiration date and were prepared when needed. All BIT-IS solutions were stored in a refrigerator set at 4 °C when not in use.

7.2 Preparation of Paint and Paint Based Fortification Solutions

GPL purchased eighteen 5-gallon buckets of Sherwin-Williams SuperPaint® Interior Acrylic Latex Paint, with the same batch number. Nine of the buckets were left untinted (white), while nine of the buckets were tinted (a cream color). Six buckets, three untinted and three tinted, were prepared for each BIT level to be used during the monitoring events.

Field fortified samples and QC samples of all matrices, with the exception of air sampling tubes, were fortified using paint based fortification solutions.

7.2.1 Dosing of Paint for Use in Monitoring Events

Six buckets of the base paint were assayed to determine the native BIT concentration. Three aliquots from each bucket, each weighing ~1 g, were diluted with 19 mL of methanol/water (10:90, v/v) and shaken on a platform shaker set at >30 rpm for 30 minutes. The exact weight of each aliquot was recorded in the raw data. The samples were quantitatively transferred into labeled 250-mL mixing cylinders. The qualitative transfer was completed using at least three 20 mL volumes of methanol/water (10:90, v/v). Once transferred, each sample was brought to a final volume of 250 mL with methanol/water (10:90, v/v). An aliquot of each sample was filtered through a 0.45-µm PVDF filter attached to a plastic syringe into a glass sample vial. Samples were further diluted using methanol/water/formic acid (70:30:0.016, v/v/v) so that the response fell within the calibration range of the standard curve. An aliquot of the

diluted sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the samples were analyzed by LC-MS/MS.

Based on the average measured concentration of base paint, six solutions of BIT were prepared by dissolving approximately 12 grams of neat BIT reference substance into 300 mL of diethylene glycol by sonicating each solution. The homogenous solutions of BIT in diethylene glycol were then each added to each of the 5-gallon bucket assigned as a high BIT level to increase the concentration of BIT in the paint to the targeted level of 600 ppm. Once the paint was dosed with BIT, the buckets were taken to Sherwin-Williams and placed on their tumbler for 8 minutes each. The concentration of the high-level supplemented paint was determined by GPL for each bucket in the same manner as the base paint. The concentration of the high-level supplemented paint was found to range from 531 ppm to 571 ppm (µg BIT/g paint), which the Study Director determined to be too low. Six additional solutions of BIT in diethylene glycol were prepared by dissolving approximately 1.6 grams of neat BIT reference substance into 50 mL of diethylene glycol by sonicating each solution. The homogenous solutions of BIT in diethylene glycol were then each added to one of the 5-gallon bucket to further increase the concentration of BIT in the paint to the targeted of 600 ppm. Once again, the buckets were taken to Sherwin-Williams and placed on their tumbler for 8 minutes. The concentration of the high-level supplemented paint was determined by GPL for each bucket in the same manner as the base paint ranging from 595 ppm to 649 ppm.

The six buckets of base paint assigned at the targeted mid ppm level of 360 ppm were dosed in a similar manner as the high ppm level buckets by adding solutions of BIT in diethylene glycol that were prepared by dissolving approximately 6.8 grams of neat BIT reference substance into 150 mL of diethylene glycol. The buckets were mixed by Sherwin-Williams and analyzed in triplicate to determine the final concentration as in the same manner as the base paint.

The final determined amount of BIT in ppm (active ingredient) in each 5-gallon bucket of paint (test substance) is present in Table 10.

7.2.2 Paint Based Fortification Solutions

A sub-sample of a high level supplemented paint (TC-246 Container #4) was transferred into a 1-gallon metal paint pail and adopted as a fortification solution. This solution had a determined concentration of 595 ppm. This fortification solution was used to fortify or prepare fortifications solutions that would be used when fortifying field fortified samples and QC samples of fiberglass filters, hand washes, face/neck wipes, inner and outer dosimeters, and painter's hats.

An aliquot (~16 g) of the 595 ppm fortification solution was diluted in 100 mL of water to prepare a fortification solution with a concentration of 100 µg/mL.

The 100 µg/mL fortification solution was further diluted to prepare fortification solutions in water at the following concentrations: 80.0 µg/mL, 30.0 µg/mL, 4.00 µg/mL, 3.00 µg/mL, and 500 ng/mL.

Paint based fortification solutions prepared in water were stored refrigerated and assigned an expiration date of 3 months.

7.3 Analytical Method GPL-MTH-081

7.3.1 Principles of the Method

The method used for analysis in this study allows for the quantitative determination of residues of BIT in different matrices. The Golden Pacific Laboratory method GPL-MTH-081 (Revision 2), "Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (Appendix L) was used to analyze the samples.

BIT residues were extracted from paint with methanol/water (10:90, v/v), from air sampling tubes with acetonitrile/water/formic acid (70:30:0.016, v/v/v) [AWF] and from fiberglass filters, face wipes (dressing sponges), inner and outer dosimeters, and painter's hats with methanol/water/formic acid (70:30:0.016, v/v/v) [MWF]. Hand wash samples did not require adding extraction solvent as they are inherently comprised of solvent.

After adding an appropriate amount of extraction solvent, samples were placed on a platform shaker for 15 minutes (30 minutes for paint samples) at ~200 rpm. After shaking, painter's hats, inner dosimeter, and outer dosimeter samples were allowed to settle overnight and then shaken a second time for 15 minutes. Air sampling tube samples were allowed to settle for at least 5 minutes before going to the next step. Sample extract requiring further dilutions were appropriately diluted using methanol/water/formic acid (70:30:0.016, v/v/v) so that the concentration fell within the range of the calibration curve. An aliquot of the final extract was diluted 1:1 with the working internal standard (IS) solution and analyzed by LC-MS/MS. No cleanup of the samples was needed.

7.3.2 Limits of Quantitation (LOQ)

The table below summarizes the limit of quantitation (LOQ) for each matrix:

Matrix	LOQ
Air Sampling Tubes	0.0100 µg/sample
Fiberglass Filters	0.0100 µg/sample
Hand Washes	1.0 ng/mL
Face/Neck Wipes	0.100 µg/sample
Outer Dosimeters	3.00 µg/sample
Inner Dosimeters	3.00 µg/sample
Painter's Hats	3.00 µg/sample

7.3.3 Untreated Control and Quality Control Samples

For the determination of method performance, untreated control samples and laboratory fortified quality control (QC) samples were analyzed with each analytical set.

Laboratory fortifications were prepared by directly fortifying untreated control samples at the following (nominal) levels:

Matrix	BIT Fortification Levels
Air Sampling Tubes	0.0100 µg/sample, 10.0 µg/sample
Fiberglass Filters	0.0100 µg/sample, 10.0 µg/sample
Hand Washes	1.00 ng/mL, 1.00 µg/mL, and 3.00 µg/mL
Face/Neck Wipes	0.100 µg/sample and 100 µg/sample
Outer Dosimeters	3.00 µg/sample and 3.00 mg/sample
Inner Dosimeters	3.00 µg/sample and 3.00 mg/sample
Painter's Hats	3.00 µg/sample and 3.00 mg/sample

7.4 Sample Analysis

For each matrix, a solvent blank, laboratory fortified QC samples, field fortified samples and treated study samples were extracted alongside one another and were analyzed within the same analytical set. The solvent blank was generally MWF vialed with internal standard, however for 463SET52, 463SET53, and 463SET54, the solvent blank was MWF only. Fortified field fortification samples of each matrix were collected in triplicate each day of the field phase and all field fortified samples were extracted.

For all matrices, samples having residue levels higher than the range of the standard curve were diluted to an appropriate final volume prior to addition of IS using MWF and re-injected so that the response fell within the calibration range of the standards. Analytical sets consisting of the diluted samples included the laboratory control and one lab QC sample.

7.4.1 Air Sampling Tubes

Laboratory fortified QC samples of air sampling tubes were prepared by fortifying the absorbent bed with the appropriate fortification solutions.

After the laboratory QC samples were fortified, the contents of each air tube sample were emptied into individual 25-mL glass culture tubes and extracted with 10 mL of acetonitrile/water/formic acid (70:30:0.016, v/v/v). The samples were placed on a platform shaker set at ~200 rpm for 15 minutes then allowed to settle for at least 5 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.4.2 Fiberglass Filters

Each laboratory fortified QC sample was prepared by placing a RespiCon™ fiberglass filter into 25-mL glass culture tubes. The laboratory QC samples were fortified with the appropriate fortification solutions and the fortification solution was allowed to absorb for 15 minutes prior to addition of extraction solvent. After the laboratory QC samples were fortified, samples were extracted with 10 mL of methanol/water/formic acid (70:30:0.016, v/v/v) [MWF]. The samples were placed on a platform shaker set at ~200 rpm 15 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.4.3 Hand Washes

Laboratory fortified QC samples were prepared by transferring 250 mL of isopropyl alcohol/water (50:50, v/v) and one dressing sponge into a 500-mL glass jar. The laboratory QC samples were fortified with the appropriate fortification solutions. All samples were shaken on a platform shaker set at ~200 rpm for 15 minutes. An equal volume of sample and IS were added to a chromatography vial and samples were analyzed by LC-MS/MS.

7.4.4 Face/Neck Wipes, Sweat Wipes, and Background Wall Wipes

Laboratory fortified QC samples were prepared by placing two dressing sponges into a 120-mL glass jar and moistening each pad with 4 mL of isopropyl alcohol: water (50:50, v/v) resulting in an initial volume of 8 mL. The laboratory QC samples were fortified with the appropriate fortification solutions and the fortification solution was allowed to absorb for 15 minutes prior to addition of extraction solvent. All samples were extracted with 100 mL of MWF and were placed on a platform shaker set at ~200 rpm for 15 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.4.5 Outer Dosimeters

To prepare laboratory fortified QC samples, pre-cut sections of each outer dosimeter were placed individually into 4-L glass jars and then fortified

with the appropriate fortification solutions. The fortification solution was allowed to absorb for 15 minutes prior to addition of extraction solvent. Samples were extracted with 2000 mL of MWF then placed on a platform shaker set at ~200 rpm for 15 minutes. After letting samples sit for at least 4 hours at ambient temperature, all samples were shaken again on a platform shaker set at ~200 rpm for 15 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.4.6 Inner Dosimeters and Painter's Hat Inner Dosimeters

To prepare laboratory fortified QC samples, pre-cut sections of each inner dosimeter were individually placed into 1-L glass jars and then fortified with the appropriate fortification solutions. The fortification solution was allowed to absorb for 15 minutes prior to addition of extraction solvent. Samples were extracted with 750 mL of MWF then placed on a platform shaker set at ~200 rpm for 15 minutes. After letting samples sit for at least 4 hours at ambient temperature, all samples were shaken again on a platform shaker set at ~200 rpm for 15 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.4.7 Painter's Hats

To prepare laboratory fortified QC samples painter's hats were individually placed into 4-L glass jars and then fortified with the appropriate fortification solutions. The fortification solution was allowed to absorb for 15 minutes prior to addition of extraction solvent. Samples were extracted with 2000 mL of MWF then placed on a platform shaker set at ~200 rpm for 15 minutes. After letting samples sit for at least 4 hours at ambient temperature, all samples were shaken again on a platform shaker set at ~200 rpm for 15 minutes. An aliquot of each sample was transferred to a chromatography vial, an equal amount of IS solution was added, and the sample was analyzed by LC-MS/MS.

7.5 Instrumentation

7.5.1 HPLC/MS/MS Conditions

Instruments: Sciex API4000 LC/MS/MS with Shimadzu LC-20AD HPLC Pumps, Shimadzu SCL-10A VP Controller, Shimadzu SIL-20AC HT Autosampler, Valco Divert Valve

HPLC Column: Phenomenex Luna 3µ C18(2) 100Å (50 mm x 3.00 mm), Part Number: 00B-4251-Y0

Mobile Phase (Gradient Program):

Time	A%	B%
0.0	10	90
4.0	60	40
4.1	10	90
5.1	10	90
Where A = 0.2% Formic Acid in Acetonitrile and B = 0.2% Formic Acid in Water		

Flow Rate: 0.300 mL/minute
Injection Volume: 20 µL
Retention Time: BIT and BIT-IS ~3.6 minutes

7.5.2 Mass Spectrometer Parameters

Interface: TurboIonSpray® (ESI)
Polarity: Positive
Scan Type: MRM Monitoring with Unit/Unit resolution

Ions Monitored:

(BIT)	m/z 152.2 (Q1)
	m/z 105.0 (Q3)
(IS)	m/z 158.2 (Q1)
	m/z 111.0 (Q3)

LC-MS/MS conditions varied slightly from run to run when instrument and column maintenance were performed. The internal standard was included in each run to account for any changes caused by maintenance. The instrument parameters were verified for analyte sensitivity and resolution prior to each chromatographic run and the exact parameters were documented with each data set.

7.6 Quantitation

Analyst Chromatography Data System (Analyst 1.6) was used to acquire, integrate, and calculate the concentration of BIT as ng/mL using the linear regression function.

7.6.1 Detector Response Calibration

The peak area response ratios for BIT versus IS were determined for a series of calibration standards. The concentration ratio of BIT versus IS of the standards and their corresponding responses were compiled. The BIT/IS concentration ratio was designated as the independent variable and plotted on the x-axis. The BIT/IS peak area ratio was designated as the dependent variable and plotted on the y-axis. From this, Analyst 1.6 calculated a standard calibration curve. The slope, y-intercept, and correlation coefficient of the standard curve run with each analytical set

were calculated. The correlation coefficients were all equal to or greater than 0.9970.

Calibration standards were injected to bracket a maximum of six sample injections as well as at the beginning and ending of the injection sequence. At least five different standard concentrations were injected within each analytical set. The concentration (ng/mL) of BIT detected in sample extracts was interpolated from the standard calibration curve. In instances where the calculated concentration was above the calibration curve, the samples were diluted and re-injected, along with a laboratory control and a laboratory fortification sample to ensure extract stability.

The linear regression function with 1/x weighting was used to calculate a best-fit line and to determine concentration of the analyte found during sample analysis. The equation used for the linear fit is as follows:

$$y = ax + b \qquad \textbf{[Equation 1]}$$

where:

y = peak area response ratio (analyte peak area/IS peak area)
a = slope of the regression line
x = analyte concentration ratio (analyte concentration [in ng/mL]/IS concentration [in ng/mL])
b = intercept of the regression line

peak area ratio = a(analyte/IS concentration ratio [in ng/mL]) + b

Using these parameters, Analyst calculated the BIT concentration in sample extracts using the following equation:

$$\text{BIT ng/mL} = \frac{[(\text{BIT peak area/IS peak area}) - b] \times (\text{IS conc. in ng/mL})}{a} \qquad \textbf{[Equation 2]}$$

7.7 Example Calculations of Residues and Recoveries

The concentrations found in the samples, as µg/sample, were calculated by Microsoft® Excel using the following equation:

$$\text{BIT in µg/sample} = \frac{(\text{ng/mL from curve}) \times (\text{final vol. in mL}) \times 1\ \mu g}{(1\ \text{sample})(1000\ \text{ng})} \qquad \textbf{[Equation 3]}$$

BIT in µg/sample = total µg of BIT present per sample analyzed. One sample is equivalent to one section (dosimeter), one painter's hat, one whole air sampling tube, 1 fiberglass filter, two wipes, or 500 mL of

		hand wash (250 mL of hand wash for laboratory QC samples)
ng/mL from curve	=	concentration of analyte calculated from standard curve regression.
Final Volume in mL	=	final volume of sample extract submitted to LC-MS/MS including any dilution factor and addition of IS.

Both samples and standards were analyzed under the same LC-MS/MS conditions and within the same analytical sequence.

Recovery of BIT from fortified samples was calculated as follows:

$$\% \text{ Recovery} = \frac{\text{(Measured Concentration, µg/sample)}}{\text{(Theoretical Concentration, µg/sample)}} \times 100$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of extraction solvent and/or dilution factor.

Minor variations in values between example calculations, tables and the raw data sheets were due to differences in the number of significant digits for values used in the calculations.

7.7.1 Air Sampling Tubes

An example calculation for a BIT laboratory fortification in set 463SET34, sample 463SET34-2, Laboratory QC spiked at 0.0100 µg/sample is as follows:

standard curve equation: y = 9.63 (x) + (-0.0034)
BIT peak area = 1329.9
IS peak area = 8716.2
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL=

$$\frac{[(1329.9/8716.2) - (-0.0034)]}{9.63} \times (25.0 \text{ ng/mL}) = 0.405 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.405 \text{ ng/mL})\ (20 \text{ mL}) \times 1\ \mu\text{g}}{(1 \text{ sample})\ (1000 \text{ ng})} = 0.00810\ \mu\text{g/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{0.00810 \text{ µg/sample}}{0.0100 \text{ µg/sample}} \times 100 = 81.0\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of dilution factor.

7.7.2 Fiberglass Filters

An example calculation for a BIT laboratory fortification in set 463SET24, sample 463SET24-2, Laboratory QC spiked at 0.0100 µg/sample is as follows:

standard curve equation: y = 11.7 (x) + (-0.00563)
BIT peak area = 1427.0
IS peak area = 6606.1
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL=

$$\frac{[(1427.0/6606.1) - (-0.00563)]}{11.7} \times (25.0 \text{ ng/mL}) = 0.475 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.475 \text{ ng/mL})\ (20 \text{ mL}) \times 1 \text{ µg}}{(1 \text{ sample})\ (1000 \text{ ng})} = 0.00950 \text{ µg/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{0.00950 \text{ µg/sample}}{0.0100 \text{ µg/sample}} \times 100 = 95.0\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of dilution factor.

7.7.3 Hand Washes

An example calculation for a BIT laboratory fortification in set 463SET06, sample 463SET06-2, Laboratory QC spiked at 0.250 µg/sample is as follows:

standard curve equation: y = 4.22 (x) + 0.00228
BIT peak area = 2090.8
IS peak area = 27394.6
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL =

$$\frac{[(2090.8/27394.6) - 0.00228]}{4.22} \times (25.0 \text{ ng/mL}) = 0.439 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.439 \text{ ng/mL})\ (500 \text{ mL}) \times 1\ \mu\text{g}}{(1 \text{ sample})\ (1000 \text{ ng})} = 0.220\ \mu\text{g/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{0.220\ \mu\text{g/sample}}{0.250\ \mu\text{g/sample}} \times 100 = 88.0\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of extraction solvent and/or dilution factor.

7.7.4 Face/Neck Wipes, Sweat Wipes, and Background Wall Wipes

An example calculation for a BIT laboratory fortification in set 463SET19, sample 463SET19-2, Laboratory QC spiked at 0.100 µg/sample is as follows:

standard curve equation: $y = 11.9 (x) + 0.0121$
BIT peak area = 1655.6
IS peak area = 7712.1
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL =

$$\frac{[(1655.6/7712.1) - 0.0121]}{11.9} \times (25.0 \text{ ng/mL}) = 0.425 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.425 \text{ ng/mL})\ (216 \text{ mL}) \times 1\ \mu\text{g}}{(1 \text{ sample})\ (1000 \text{ ng})} = 0.0918\ \mu\text{g/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{0.0918\ \mu\text{g/sample}}{0.100\ \mu\text{g/sample}} \times 100 = 91.8\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of extraction solvent and/or dilution factor.

7.7.5 Outer Dosimeters

An example calculation for a BIT laboratory fortification in set 463SET47, sample 463SET47-2, Laboratory QC spiked at 3.00 µg/sample is as follows:

standard curve equation: y = 9.18 (x) + (-0.00439)
BIT peak area = 2586.6
IS peak area = 9995.5
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL =

$$\frac{[(2586.6/9995.5) - (-0.00439)]}{9.18} \times (25.0 \text{ ng/mL}) = 0.716 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.716 \text{ ng/mL})(4000 \text{ mL}) \times 1 \text{ µg}}{(1 \text{ sample})(1000 \text{ ng})} = 2.86 \text{ µg/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{2.86 \text{ µg/sample}}{3.00 \text{ µg/sample}} \times 100 = 95.3\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of dilution factor.

7.7.6 Inner Dosimeters and Painter's Hat Inner Dosimeters

An example calculation for a BIT laboratory fortification in set 463SET52, sample 463SET52-2, Laboratory QC spiked at 3.00 µg/sample is as follows:

standard curve equation: y = 9.02 (x) + 0.0198
BIT peak area = 6943.0
IS peak area = 9799.5
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL =

$$\frac{[(6943.0/9799.5) - 0.0198]}{9.02} \times (25.0 \text{ ng/mL}) = 1.91 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(1.91 \text{ ng/mL})(1500 \text{ mL}) \times 1 \text{ µg}}{(1 \text{ sample})(1000 \text{ ng})} = 2.87 \text{ µg/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{2.87 \text{ µg/sample}}{3.00 \text{ µg/sample}} \times 100 = 95.7\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of dilution factor.

7.7.7 Painter's Hats

An example calculation for a BIT laboratory fortification in set 463SET45, sample 463SET45-2, Laboratory QC spiked at 3.00 µg/sample is as follows:

standard curve equation: $y = 9.53 (x) + 0.00417$
BIT peak area = 2284.0
IS peak area = 9649.6
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL =

$$\frac{[(2284.0/9649.6) - 0.00417]}{9.53} \times (25.0 \text{ ng/mL}) = 0.610 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.610 \text{ ng/mL}) (4000 \text{ mL}) \times 1 \text{ µg}}{(1 \text{ sample}) (1000 \text{ ng})} = 2.44 \text{ µg/sample}$$

Using the recovery equation,

$$\% \text{ Recovery} = \frac{2.44 \text{ µg/sample}}{3.00 \text{ µg/sample}} \times 100 = 81.3\%$$

BIT concentration in field fortified samples was calculated using the same procedures. However, final volume varied according to quantity of dilution factor.

7.8 Statistics

Statistical evaluations performed on the residue data include mean and standard deviation calculations of fortified samples analyzed. Linear regression analysis was used to determine the slope and intercept values of the calibration curves.

8.0 DATA CALCULATIONS

8.1 BIT Concentration in Paint

The concentration of BIT in paint (Sherwin Williams SuperPaint® Interior Acrylic Latex Paint, tinted and un-tinted) was determined by analyzing triplicate aliquots of each 5-gallon bucket of paint and calculating the total amount of active ingredient present in ppm BIT in paint (µg of BIT/g of paint).

The amount of BIT present in the base paint was expected to be approximately 120 ppm although it was not documented by the manufacturer. The amount of BIT measured in batch #WE1096GF of base paint ranged from 141 ppm to 147 ppm; this was used for low level BIT paint. After supplementing the base paint with more BIT, the six buckets prepared at the mid-level ranged from 368 ppm to 382 ppm and the six buckets prepared at the high level ranged from 595 ppm to 649 ppm.

The final determined amount of BIT in ppm (active ingredient) in each 5-gallon bucket of paint (test substance) is present in Table 10.

8.2 Amount of Active Ingredient Applied by Subjects

Prior to each monitoring event, research staff transferred sufficient paint from the 5-gallon paint bucket assigned to that ME to fill two 1-gallon paint cans. The lids were placed on the 1-gallon paint cans and pounded securely closed. The paint can weights used during the monitoring event were recorded immediately before use and after depletion of the can. The data was recorded on a form retained in the field raw data (Paint Can Weights) from which the net weight of paint used was totaled.

The amount of active ingredient applied during each monitoring event was calculated using the measured concentration of BIT (ppm BIT or µg BIT/g paint) for each paint and the total weight of paint used. This yielded Equation A as follows:

Equation A

Total Amount Active Ingredient Applied (mg) =
(net weight of paint in grams x BIT concentration of paint (µg BIT/g paint) x (1 mg/1000 µg)

8.3 Residue Adjustments of All Matrices

Raw residue numbers were corrected based on a field fortification adjustment factor using AEATF II SOP 9B.3. All sets were run with field fortification samples fortified on the same date as the field sample(s) in the set were collected. The average percent recovery of field fortification samples was calculated for each set. If the average recovery of field fortified samples was above 100%, no corrections were made to the residues found in the field samples in that set. If the average recovery of field fortified samples was less than 100%, the residues found in the

field samples in that set were corrected using Equation B. In sets that were reanalyzed to dilute samples appropriately into the calibration curve range, the average field fortification recovery in the original set was used to correct the residues found in the field samples in that reanalysis set.

Equation B

$$\text{Corrected Residue (µg/sample)} = \frac{\text{Original Residue (µg/sample) x 100\%}}{\text{Average Field Fortification Recovery (\%)}}$$

For example, in hand wash set 463SET06, the average field fortification recovery was 96.1%. Sample number 463SET06-4 (AEA09-BRS-01-HW-01) was found to have residue levels of 417 µg/sample. The residue was corrected to 434 µg/sample using Equation B:

$$\frac{\text{417 µg/sample x 100\%}}{\text{96.1\%}} = \text{434 µg/sample}$$

8.4 Removal Efficiency in Hand Wash and Face and Neck Wipes

The efficiency of dermal removal of the BIT test material used in this study, via the isopropyl alcohol/water wash and wipe procedure, has been shown to be 73.3% from those treated with paint containing 154 ppm of BIT and 60.3% for from those treated with paint containing 547 ppm of BIT (Boatwright 2017; GPL Study No. 130503). In that study the investigators applied 100 µL aliquots of paint between both subject's palms. Half of the subjects had base paint applied to their palms containing 154 ppm BIT and the other half of subjects had paint applied containing 547 ppm BIT (n=20 hands/dose level; low and high dose levels conducted on separate days). Removal efficiency was determined by washing and wiping each hand surface (after 45 minutes of drying time) using a packet of wetted 4" x 4" 6-ply dressing sponge (wetted using isopropyl alcohol/water (50:50, v/v)) to scrub the hands and fingers coupled with the subjects rubbing their hands together while isopropyl alcohol/water (50:50, v/v) was poured over their hands. The wipes and isopropyl alcohol/water (50:50, v/v) were collected and analyzed for BIT. For subjects in this study that painted with base paint (ca. 130 ppm BIT), a 73.3% removal efficiency factor was applied. For subjects painting with high BIT level paint (ca. 600 ppm BIT), a 60.3% removal efficiency factor was applied. For subjects painting with mid-level BIT paint, a removal efficiency reflecting the average of these values (66.8%) was applied.

After correcting for the hand wash field fortification recovery, BIT concentrations in hand wash samples were adjusted according to the removal efficiency correction factor using Equation C:

Equation C

$$\text{Residue Corrected for Removal Efficiency (µg/sample)} = \frac{\text{Corrected Residue (µg/sample) x 100}}{\text{Removal Efficiency Value (\%)}}$$

For hand wash samples, concentrations were first corrected as necessary according to field fortification recoveries and then corrected a second time using the removal efficiency correction factor. For example, the hand wash sample AEA09-BRS-01-HW-01 was determined to have a concentration of 417 µg/sample BIT, which was corrected to 434 µg/sample based on a 96.1% average field fortification recovery. The subject performing ME-01 handled 141 ppm BIT paint, so the 73.3% removal efficiency factor was applied. Using the removal efficiency correction factor equation, the final, corrected concentration of BIT in AEA09-BRS-01-HW-01 is 592 µg/sample. This value is calculated using Equation C:

Equation C

$$\frac{434\ \mu g/sample \times 100\%}{73.3\%} = 592\ \mu g/sample$$

For face/neck wipe samples, concentrations were first corrected as necessary according to field fortification recoveries and then corrected a second time using a safety glasses correction factor of 1.11 per AEATF II SOP 9K.0 to account for the area of the face that was covered by the use of personal protection equipment (PPE). A final correction factor was applied to the face/neck wipe samples using the appropriate removal efficiency correction factor.

After being corrected according to field fortification recoveries, BIT concentrations in face/neck wipe samples were adjusted according to the PPE correction factor using Equation D:

Equation D

PPE Corrected Conc. (µg/sample) = Corrected Residue (µg/sample) x 1.11

After being corrected according to field fortification recoveries and the PPE correction factor, BIT concentrations in face/neck wipe samples were adjusted according to the removal efficiency correction factor using Equation C:

Equation E

$$\text{Residue Corrected for Removal Efficiency } (\mu g/sample) = \frac{\text{Corrected Residue } (\mu g/sample) \times 100}{\text{Removal Efficiency Value } (\%)}$$

Only final face/neck wipe samples collected at the end of the monitoring event in the changing room with moistened wipes were corrected for the removal efficiency. Interim face/neck wipes collected during the ME were not corrected for the removal efficiency since the wipes were dry. After all factors were applied appropriately, the residue values of each sample for the individual subjects were added together to generate one face/neck wipe value per subject.

For example, face/neck wipe sample AEA09-BRS-12-FW-01 was determined to have a concentration of 1.66 µg/sample BIT, which was corrected to 1.81 µg/sample based on a 91.7% average field fortification recovery. Using the PPE

correction factor equation, corrected concentration of BIT in AEA09-BRS-12-FW-01 is 2.01 µg/sample. This value is calculated using Equation D:

Equation D

$$1.81 \text{ µg/sample} \times 1.11 = 2.01 \text{ µg/sample}$$

The subject performing ME-12 handled 370 ppm BIT paint, so the 66.8% removal efficiency factor was applied. Using the removal efficiency correction factor equation, the final, corrected concentration of BIT in AEA09-BRS-12-FW-01 is 3.01 µg/sample. This value is calculated using Equation E:

Equation E

$$\frac{2.01 \text{ µg/sample} \times 100\%}{66.8\%} = 3.01 \text{ µg/sample}$$

8.5 Total Dermal Exposure Calculations

Dermal exposure was calculated by combining residue values from matrices that represented the subject's skin (hand washes, face wipes, and inner dosimeters, including the inner dosimeter square from the head). The calculation is shown below:

Total Dermal Exposure (µg) =
Total µg in Hand Wash + Total µg in Face/Neck Wipes + Total µg in Inner Dosimeters

9.0 INNER DOSIMETER CONTAMINATION

9.1 Investigation

Upon completion of sample analysis for inner and outer dosimeters it was noted that certain subject inner dosimeter segments showed residues much higher than the corresponding outer dosimeter segment (Table 34). It was also noted that BIT residues in some of the inner dosimeter field fortification samples were much higher than the fortified level, while others demonstrated acceptable recoveries. These high residues had not been observed during method development, method validation, or freezer storage stability work with the inner dosimeter matrices.

An investigation was conducted to determine possible sources for the high BIT residues. The subject inner dosimeter rear torso pieces were examined to look for patterns on the manufacturers label. A pattern was noted as shown in Table 36 which indicated that inner dosimeters with lot numbers beginning with "GPU 14" or "GPU 15" were associated with the high subject residues. A set of unused dosimeters still in manufacturer's wrapping were carefully opened and screened for background residues. That data is presented in Table 38, and demonstrates that lots beginning with "GPU 14" and "GPU 15" contained high residues of BIT while other lots had minimal residues. Our conclusion is that the lots with high BIT

residues were those purchased most recently for this study, and must have resulted from a manufacturer process change since BIT is labeled for use in textile production. Inner dosimeters were assigned to subjects randomly based on size and kept sealed in the manufacturer's packaging until dressing the subject. Field fortification pieces were cut from randomly selected inner dosimeters, and although no record of dosimeter lot is available, it is likely that high field fortification recoveries are associated with use of one or more lots containing high background residues.

9.2 Study Impact

After completing the investigation into the high BIT residues in inner dosimeter segments, the AEATF II contacted the EPA with a proposed correction for the impacted subject samples. A copy of the letter sent to EPA detailing the issue, and the reply from EPA with their suggested correction are attached in Appendix M. Consistent with this guidance the actual residues found are presented in Table 34, but the exposure summary tables (Table 40 through Table 44) use an agreed upon penetration factor of 12.3% for the contaminated inner dosimeter samples. The inner dosimeter numbers for monitoring events ME01, ME02, ME04, ME06, ME07, ME10, ME12, ME13, ME16 and ME17 are calculated by multiplying the corresponding outer dosimeter residue value by the penetration factor of 12.3%.

It is expected that some of the painter's hat inner dosimeter pieces may have been contaminated. However, there is no label on these cut pieces and the measured residue values were used as a conservative approach. Similarly, many inner dosimeter field fortification sample residues were far higher than the fortification level. Since test subject samples are not corrected for field fortification recoveries above 100%, and the other field fortification samples and concurrent fortification samples showed good recoveries it is not expected this will negatively impact the study conclusions.

10.0 RESULTS

10.1 Overview

A total of 37 subjects were enrolled into the study. Eighteen subjects successfully completed monitoring events in the study; 6 painting with paint containing low ppm levels of BIT, 6 painting with paint containing mid ppm levels of BIT, and 6 painting with paint containing high ppm levels of BIT. No subjects withdrew after beginning work or were unable to complete the painting tasks.

10.2 Chronological Listing of Events

The chronological listing of events for this study is summarized in Table 1.

10.3 Recruitment

A total of 37 subjects were enrolled in the study. After enrollment, a total of 5 subjects were removed from the study, four for safety concerns and one for not meeting the inclusion criteria. These subjects were disqualified by the Study Director after consulting the research associates that conducted the interviews. The remaining 32 subjects were assigned into randomized spots in the study.

10.3.1 Recruitment

a. Response to Local Newspaper Advertisements

Many subjects responded to the ads placed in the two local newspapers, the Fresno Bee and Vida en el Valle. Interested callers were interviewed by phone to determine if they met the inclusion criteria. The study was described to the subjects. Subjects that were interested in participating were invited to come to GPL.

b. Enrollment of Subjects

A total of 38 subjects came to GPL for the interview, and were compensated $20. Of those 38, thirty-seven (37) signed Informed Consent Forms and filled out the Qualification worksheet, enrolling them into the study. Five (5) subjects of those enrolled were removed from the study; four for safety concerns and one for not meeting the inclusion criteria. The completed and signed Informed Consent Forms as well as the Qualification Worksheet (Subjects' Demographic Form) are kept locked in a confidential area. Subject demographic information of the 37 enrolled subjects is presented in Tables 4 through 6. The table below summarizes the demographic information of the 37 subjects enrolled into the study.

	Randomized Subjects	Monitored Subjects	Alternate/Extra Subjects	Dropped/ Withdrawn Subjects
Male	19	13	4	2
Female	18	5	10	5
English	37	18	14	7
Spanish	0	0	0	0
Age Range	20-64	20-64	21-60	24-72

A mixture of male and female subjects was well represented in the enrollment and during the randomization of monitored subjects and alternates. The language preference of all subjects was English. Monitored subjects' age ranged from 20 years old to 64 years old.

c. Randomization

Each subject was given a number (AE1-AE37) based on the order of enrollment. The subjects were assigned a randomized order and placed

into the study using the randomized order. The randomized list is kept in GPL's archives and is summarized in Table 2.

The first 18 randomized subjects were assigned to monitoring events. The remaining 14 subjects were assigned as alternates to be contacted in their randomized order as necessary. These assignments are presented in Table 2.

The three concentrations of paint to be used were randomly assigned to six MEs each. The paint assignment is summarized in Table 3.

d. Scheduling of Subjects

Following randomization, the subjects were contacted to schedule them into their assigned monitoring event or alternate position. Table 4 summarizes which subject completed which monitoring event and presents the original assignment of each subject after randomization, as well as each subject's demographics. Table 5 presents the demographics of the alternate/extra subjects, while Table 6 presents the demographics of the subjects that were dropped from the study. These tables also include notes and explanations of reasons for replacement and reassignment of subjects. All subjects who were scheduled and reported to the test site for monitoring, or as an alternate, were compensated $100.

10.3.2 Conduct of Monitoring Events

Table 7 connects the subjects' number (subjects ID in field phase), the monitoring event conducted by the subject, and the code assigned to the subjects' collected samples (analytical sample ID).

10.4 Environmental Conditions

The environmental conditions during the monitoring events (mobile data loggers) are shown in Table 8. The average temperature during monitoring events ranged from 70.5°F to 82.1°F. Table 9 summarizes the environmental conditions of the changing room, field fortification room, and test substance storage room during use.

10.5 Observation of Subjects

Transcribed observation notes of subjects as they worked are presented in Appendix H. All subjects painted with both brush and roller and painted both wall surfaces and trim. Painting techniques and order of surfaces painted varied considerably based on each subject's experience and preference.

10.6 Background Sampling, Laboratory and Field Fortification

10.6.1 Air Sampling for Pre-existing BIT

The results of the analysis of background air sampling tubes collected in the dosimeter assembly room and the test rooms prior to each monitoring event are shown in Table 12. None of the background air sampling tubes analyzed showed any residue of BIT that was equal to or greater than the LOQ. This result demonstrates that the air within the dosimeter assembly room and the painting rooms were free of measurable BIT.

10.6.2 Wall Wipe Sampling for Pre-existing BIT

The results of the analysis of background wall wipe samples collected in the changing room and selected test rooms at the test site are shown in Table 13. None of the six analyzed wall wipe samples from the changing room showed any residue of BIT that was equal to or greater than the LOQ (<0.100 µg/sample), indicating that the changing room walls were clean. The fourteen analyzed wall wipe samples from the painting rooms showed no residue of BIT that was equal to or greater than the LOQ (<0.100 µg/sample) for nine samples. Five wall wipes from rooms sampled on days 4, 6, 7, and 8 showed BIT residues that ranged from 0.148 to 0.346 µg/sample. The background wall wipe residues were much less than the total BIT residues observed in subject outer dosimeters, and show that BIT transfer from subjects rubbing against dried painted walls did not influence the study results.

At PMRA's request, the AEATF II is having the remaining wall wipe samples analyzed by Golden Pacific Laboratory. The results of these additional analyses will be reported separately in a non-GLP report.

10.6.3 Pre-existing BIT in Field Dosimeter Matrices

a. Outer Dosimeters

The outer dosimeter garments had been previously observed to contain background levels of BIT which were addressed by pre-washing outer dosimeter garments prior to use in the study. This washing was not completely effective in eliminating BIT from outer dosimeters used in the field. The field control samples for outer dosimeters showed measurable residues above the LOQ in 10 of 18 samples ranging from 3.78 µg to 22.5 µg per sample. Although some residues were found in the field control outer dosimeter samples these were low compared to the total BIT found in the subject samples, and are not expected to impact the conclusions of the study. Any background BIT found in subject garments would tend to overestimate the reported subject exposure.

b. Inner Dosimeters

Background residues found in inner dosimeter garments and the effect on various subject and field fortification samples are detailed in Section 9.0. Garment pieces used to prepare lab QC samples in 463SET71, 463SET72, and 463SET73 contained background residues resulting in failing analyte recoveries of greater than 10000% recovery for low lab QC samples. For these sets, new garment pieces which were verified as not containing background BIT residues >LOQ were extracted and analyzed as lab QC samples to demonstrate method performance. The affected sample sets were re-run in their entirety with the replacement lab QC samples.

10.6.4 Laboratory Control and Fortification Samples

a. Air Sampling Tubes

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 14. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at 0.0100 µg per sample and ~10 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified air sampling tubes are shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std Dev)
LOQ	10	0.0100	75.7 ± 7.23
1000x LOQ	10	~10.0	96.7 ± 5.00
Overall Mean % Recovery ± Standard Deviation			**86.2 ± 12.4**

The recoveries of BIT for laboratory fortified samples were within the acceptable range of 70% to 120%, except for the low lab QC sample in set 463SET33, which recovered at 63.2%. This recovery was accepted by the Study Director and is included in the above summary.

b. Fiberglass Filters

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 15. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at 0.0100 µg per sample and 10.0 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified fiberglass filter samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample*)	% Recovery (Mean ± Std)
LOQ	10	0.0100	86.1 ± 5.81
1000x LOQ	10	10.0	87.3 ± 5.24
Overall Mean % Recovery ± Standard Deviation			**86.7 ± 5.40**

The recoveries of BIT for all laboratory fortified samples were within the acceptable range of 70% to 120%.

c. Hand Wash Samples

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 16. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at 0.250 µg per sample, ~300 µg per sample, ~800 µg per sample, and ~1500 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified hand wash solution is shown below:

Fortification Level	N	Fortification Amount (µg/sample*)	% Recovery (Mean ± Std)
LOQ	9	0.250	94.8 ± 12.2
1000x LOQ	3	~300	82.9 ± 2.29
3000x LOQ	5	~800	81.8 ± 2.51
6000x LOQ	1	~1500	80.7
Overall Mean % Recovery ± Standard Deviation			**88.4 ± 10.8**

* 1 sample = 250 mL isopropyl alcohol/water (50:50, v/v) and one dressing sponge.

The recoveries of BIT for all laboratory fortified samples were within the acceptable range of 70% to 120%.

d. Face/Neck Wipes

The results of the analysis of non-fortified laboratory control samples and laboratory fortified control samples are shown in Table 17. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at ~0.100 µg per sample and ~100 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified face/neck wipe samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
LOQ	10	~0.100	88.9 ± 12.0
1000x LOQ	10	~100	83.4 ± 3.02
Overall Mean % Recovery ± Standard Deviation			**86.1 ± 8.95**

The recoveries of BIT for laboratory fortified samples were within the acceptable range of 70% to 120%.

e. Outer Dosimeters

The results of the analysis of non-fortified laboratory control samples and laboratory fortified control samples are shown in Table 20. None of the laboratory control samples in accepted sets showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at 3.00 µg per sample and ~3000 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified outer dosimeter samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
LOQ	10	3.00	92.3 ± 9.77
1000x LOQ	10	~3000	91.4 ± 7.53
Overall Mean % Recovery ± Standard Deviation			**91.9 ± 8.50**

The recoveries of BIT for all laboratory fortified samples were within the acceptable range of 70% to 120.

f. Inner Dosimeters

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 18. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ, except for the control in 463SET64, which had residues that measured 395 µg/sample. The recoveries of individual laboratory fortified control samples, fortified at ~3.00 µg per sample and ~3000 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified inner dosimeter samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
LOQ	12	~3.00	104 ± 19.8
1000x LOQ	12	~3000	88.0 ± 4.81
Overall Mean % Recovery ± Standard Deviation			**96.0 ± 16.3**

The recoveries of BIT for all laboratory fortified samples were within the acceptable range of 70% to 120%, except for the low lab QC samples in sets 463SET49, 463SET60, and 463SET71, which were 128%, 124%, and 147%, respectively. These recoveries were accepted by the Study Director and are included in the above summary.

g. Painter's Hats

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 19. None of the laboratory control samples showed any residue of BIT that was equal to or greater than the LOQ. The recoveries of individual laboratory fortified control samples, fortified at 3.00 µg per sample and ~3000 µg per sample, were acceptable. A summary of the mean recoveries of the laboratory fortified painter's hat samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
LOQ	9	3.00	97.2 ± 7.65
1000x LOQ	9	~3000	93.8 ± 4.25
Overall Mean % Recovery ± Standard Deviation			**95.5 ± 6.25**

The recoveries of BIT for all laboratory fortified samples were within the acceptable range of 70% to 120%.

10.6.5 Field Control and Fortification Samples

a. Air Sampling Tubes

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 21. None of the field control samples showed any residue of BIT that was equal to or greater than the LOQ. The mean recoveries of field fortified control samples, fortified at 0.100 µg per sample and 2.00 µg per sample were acceptable. A summary of the mean recoveries of the field fortified air sampling tubes is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
10x LOQ	27	0.100	76.6 ± 6.93
200x LOQ	27	2.00	86.0 ± 3.60
Overall Mean % Recovery ± Standard Deviation			**81.3 ± 7.24**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%.

b. Fiberglass Filters

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 22. None of the field control samples showed any residue of BIT that was equal to or greater than the LOQ. The mean recoveries of field fortified control samples, fortified at ~0.100 µg per sample and 2.00 µg per sample, were acceptable. A summary of the mean recoveries of the field fortified fiberglass filter sample is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
10x LOQ	27	~0.100	81.7 ± 5.69
200x LOQ	27	2.00	93.2 ± 4.68
Overall Mean % Recovery ± Standard Deviation			**87.5 ± 7.75**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%.

c. Hand Washes

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 23. None of the field control samples showed any residue of BIT that was equal to or greater than the LOQ. The mean recoveries of field fortified control samples, fortified at ~2.00 µg per sample and ~200 µg per sample, were acceptable. A summary of the mean recoveries of the field fortified hand wash samples is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
4x LOQ	27	~2.00	85.8 ± 3.84
400x LOQ	27	~200	98.9 ± 6.61
Overall Mean % Recovery ± Standard Deviation			**92.4 ± 8.50**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%.

d. Face/Neck Wipes

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 24. None of the field control samples showed any residue of BIT that was equal to or greater than the LOQ. The mean recoveries of field fortified control samples, fortified at ~0.500 µg per sample and 10.0 µg per sample, were acceptable. A summary of the mean recoveries of the field fortified face/neck wipes is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
4x LOQ	27	~0.500	83.0 ± 4.05
100x LOQ	27	10.0	91.0 ± 9.22
Overall Mean % Recovery ± Standard Deviation			**87.0 ± 8.13**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%.

e. Outer Dosimeters

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 27. The field control samples for outer dosimeters showed measurable residues above the LOQ in 10 of 18 samples ranging from 3.78 µg to 22.5 µg per sample.

The outer dosimeter garments had been previously observed to contain background levels of BIT which were addressed by pre-washing outer dosimeter garments prior to use in the study. This washing was not completely effective in eliminating BIT from outer dosimeters used in the field. The field control samples for outer dosimeters showed measurable residues above the LOQ in 10 of 18 samples ranging from 3.78 µg to 22.5 µg per sample. Although residues were found in the field control outer dosimeter samples these were low compared to the total BIT found in the subject samples, and are not expected to impact the conclusions of the study. Any background BIT found in subject garments would tend to overestimate the reported subject exposure.

The mean recoveries of field fortified control samples, fortified at 12.0 µg per sample and ~1000 µg per sample, were acceptable. A summary of the mean recoveries of the field fortified outer dosimeters is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
4 X LOQ	27	12.0	114 ± 29.6
~333 X LOQ	27	~1000	92.4 ± 6.48
Overall Mean % Recovery ± Standard Deviation			**103 ± 23.9**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%, except for two field fortified low samples in 463SET47, and one field fortified low sample in each of 463SET50, 463SET58. 463SET61, 463SET65, and 463SET68.

f. Inner Dosimeters

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 25. At least one field control sample from each day's samples that were prepared showed residue of BIT that were greater than the LOQ. Background BIT contamination in the various test system pieces used to prepare field fort samples affected recoveries in low and high field fortified samples. A summary of the mean recoveries of the field fortified inner dosimeters is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
4 X LOQ	27	12.0	1645 ± 1940
~333 X LOQ	27	~1000	104 ± 20.3
Overall Mean % Recovery ± Standard Deviation			**875 ± 1565**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120% for fifteen low and twenty high field fort samples, and above 120% for twelve low and seven high field fort samples.

g. Painter's Hats

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 26. None of the field control samples showed any residue of BIT that was equal to or greater than the LOQ. The mean recoveries of field fortified control samples, fortified at 12.0 µg per sample and ~1000 µg per sample, were acceptable. A summary of the mean recoveries of the field fortified painter's hats is shown below:

Fortification Level	N	Fortification Amount (µg/sample)	% Recovery (Mean ± Std)
4 X LOQ	27	12.0	84.6 ± 9.12
~333 X LOQ	27	~1000	92.9 ± 7.04
Overall Mean % Recovery ± Standard Deviation			**88.7 ± 9.11**

The recoveries of BIT for all field fortified samples were within the range of 50% to 120%.

10.7 Brush/Roller Results

10.7.1 Monitoring Event Application Parameter Results

Table 10 summarizes the application parameters of the individual monitoring events. Included in the table are the date the monitoring event took place, the weight of paint handled, the total amount of BIT handled, rooms painted, the approximate surface area painted and the total painting time. All 18 subjects successfully completed the assigned painting task

while applying between 8.52 kg and 9.94 kg of latex paint with a brush and roller.

10.7.2 Analysis of Matrix Residues

The magnitude of the residues found in the different matrix samples for different subjects depended upon a number of factors, including the time spent painting, the total amount of paint applied, the concentration of BIT in the test substance, the area covered, as well as the personal painting technique.

For monitoring events completed in this study, the results are presented first as amount of residue detected in the different matrices in individual tables (Table 28 to Table 37). Data presented in Table 40 to Table 42 summarizes the overall amount of residues detected in each matrix, for all subjects using low, medium, and high BIT concentration paint. These residues were then normalized by the total amount of BIT handled by each subject (i.e. (µg/sample)/lb a.i. applied) in the Dermal Unit Exposure tables (Table 43 and Table 44). The amounts of BIT present in hand wash samples were corrected for removal efficiency and are presented in Table 30. The amounts of BIT present in face and neck wipe samples were corrected for wearing safety glasses and for removal efficiency and are presented in Table 31. Air concentration was calculated based on volume of air pumped using average pump flowrates and run times (Table 45 and Table 46) and normalized by the total amount of BIT handled by each subject (i.e. (µg/sample)/lb a.i. applied) in the Inhalation Unit Exposure table (Table 47).

a. Air Sampling Tubes

The results of the analysis of individual air sampling tubes for residues of BIT for each ME are shown in Table 28. No BIT residues above the LOQ were observed in any sample. These results, summarized in Table 40 to Table 42 and Table 47, show that BIT was not present in the air at measurable concentrations during brush/roller painting.

b. Fiberglass Filters

The results of the analysis of individual fiberglass filters for residues of BIT for each ME are shown in Table 29. No BIT residues above the LOQ were observed in any sample. These results, summarized in Table 40 to Table 42, confirm that BIT in airborne particles was not present in the air at measurable concentrations during brush/roller painting. Size distribution particles of BIT are summarized in Table 48.

c. Hand Wash

The results of the analysis of hand wash samples for residues of BIT are shown in Table 30. Detectable residues were present in all hand wash

samples. Residues were corrected for field fortification recovery and removal efficiency. Corrected residues ranged from 64 µg/sample to 4045 µg/sample, or approximately 128 to 8090 times the LOQ. Hand wash samples were the largest source of BIT residues for all subjects. These results, summarized in Table 40 to Table 42, show that the mean residue of BIT detected in hand wash samples for subjects was 218 ± 185 µg/sample, 1367 ± 1411 µg/sample, and 725 ± 724 µg/sample for low, mid, and high BIT paint concentrations, respectively.

d. Face/Neck Wipes

For subjects, the results of the analysis of face and neck wipe samples for residues of BIT from subjects painting with low, mid, and high level BIT in paint are shown in Table 31, Table 32, and Table 33, respectively. Residues were corrected to account for three factors: field fortification recovery, surface area covered by the safety glasses, and removal efficiency. The final residue value for each subject was the sum of any and all face/neck wipe and sweat wipe samples, corrected appropriately. Corrected residues ranged from 0.1 µg/sample to 15.7 µg/sample, or up to approximately 157 times the LOQ. These results, summarized in Table 40 to Table 42, show that the mean residue of BIT detected in face/neck wipe samples for subjects was 1.31 ± 2.34 µg/sample, 4.63 ± 5.60 µg/sample, and 2.67 ± 4.53 µg/sample for low, mid, and high BIT paint concentrations, respectively.

e. Painters Hat

The results of the analysis of painters hats for residues of BIT for subjects are shown in Table 36. Painters hat samples had residues with corrected values ranging from <LOQ µg/sample to 101 µg/sample. The summarized results are shown in Table 40 to Table 42 and show the painters hats varied from subject to subject as a result of their individual painting techniques.

f. Painters Hat Inner Dosimeter

The results of the analysis of painter's hat inner dosimeters for residues of BIT for subjects are shown in Table 35. Painters hat inner dosimeter samples had residues with corrected values ranging from 5.54 µg/sample to 19.1 µg/sample. The summarized results are shown in Table 40 to Table 42 and show the painters hats inner dosimeter varied from subject to subject as a result of their individual painting techniques. Some painters hat inner dosimeter pieces may have been prepared from contaminated inner dosimeters, and thus have artificially high residues. These pieces were reported as analyzed to represent the most conservative potential exposure values.

g. Outer Dosimeter

The results of the analysis of outer dosimeters for residues of BIT for subjects are shown in Table 37. Only two rear torso sections had residues <LOQ, all other sections for each subject had detectable residues with corrected values ranging from 3.57 µg/sample to 721 µg/sample. The summarized results are shown in Table 40 to Table 42 and show the dosimeter section with highest residues varied from subject to subject as a result of their individual painting techniques.

h. Inner Dosimeter

Inner dosimeter sections were analyzed if the corresponding outer dosimeter section had residues above the LOQ for BIT. The rear torso inner dosimeter sections from ME02 and ME18 were not analyzed.

The results of the analyzed samples are shown in Table 34. Corrected residues above the LOQ ranged from 3.00 to 1197 µg/sample. The summarized results are shown in Table 40 to Table 42 and show the dosimeter section with highest residues varied from subject to subject as a result of their individual painting techniques.
Residue results for BIT in ten of eighteen subject inner dosimeter were rejected from the study due to confirmed background contamination as detailed in Section 9.0, and in Appendix M. The inner dosimeter results from these subjects were replaced by a calculated value derived from the corresponding outer dosimeter BIT residue multiplied by a penetration factor of 12.3%.

10.7.3 Summary Residues

Table 40 to Table 42 summarizes the overall residues found in each matrix for all subjects painting with low BIT concentration paint, mid BIT concentration paint, and high BIT concentration paint, respectively. Table 43 and Table 44 presents the overall residues found in each matrix normalized for the amount of active ingredient applied by each subject painting with low BIT concentration paint, mid BIT concentration paint, and high BIT concentration paint, respectively.

11.0 CONCLUSIONS

A total of 37 subjects were enrolled into the study in response to newspaper advertisements and were randomly assigned to monitoring events. Eighteen monitoring events were completed, six each with low concentration BIT, mid concentration BIT and high concentration BIT. Subjects performed their tasks within their assigned parameters for all 18 monitoring events: No subjects withdrew after beginning work or were unable to complete the painting tasks. No subjects experienced any adverse effects during or after participation in the study.

The residue results show that there are no marked differences or clear patterns between the subject residues. Among the dermal matrices, face/neck wipes had the least amount of detectable residues. The hand wash samples contained the highest residues as expected since the painting equipment was in direct contact with the subjects' bare hands. Levels of BIT residues in the lower arms samples were higher than levels in the upper arm samples for both the inner and the outer dosimeters. Inner dosimeter residues were much lower than the corresponding outer dosimeter sections for the eight subjects wearing a non-contaminated inner dosimeter. The penetration of BIT residues was calculated for these subjects and the factor applied to the remaining ten subjects to calculate their inner dosimeter values.

The total dermal exposure to each subject was calculated by adding the total corrected residue (µg) in the hand wash, the face/neck wipes, and all inner dosimeter pieces.

The mean total dermal exposure values of all six subjects in each paint concentration group are presented below as total µg BIT.

Mean Normalized BIT Residues by Paint Concentration			
	Low BIT	**Mid BIT**	**High BIT**
Lb a.i. handled	0.00293 ± 0.000165	0.00767 ± 0.000329	0.0129 ± 0.000722
Total Dermal Exposure (µg)	245 ± 188	1427 ± 1401	781 ± 739
Dermal Unit Exposure (µg/lb a.i. handled)	82336 ± 59459	184382 ± 179471	58182 ± 52078

No residues of BIT were detected in the air above the LOQ in any background air tubes, subject air tubes, or subject RespiCon sampler filters.

12.0 RECORDS TO BE MAINTAINED

The original, signed copy of the final study report and study-specific raw data will be archived at GPL until the Sponsor requests that the report be transferred to another facility. Original facility-specific raw data such as equipment maintenance logs, personnel training records, GPL SOP's, and quality assurance records will be archived at GPL. An electronic copy of the final report and raw data will also be maintained at GPL.

13.0 SUMMARY OF AMENDMENTS AND DEVIATIONS

13.1 Protocol Amendments

A total of two protocol amendments were generated for this study.

1. Amendment No. 1 corrected a typo to the reference method, gave additional detail to the method summary, and added information on pre-washing of outer dosimeter garments.

2. Amendment No. 2 clarified the sample transport guidelines from test site to analytical laboratory.

13.2 Protocol Deviations

Two protocol deviation documents were issued during the conduct of this study. The first deviation documented (1) the use of a penetration factor to estimate inner dosimeter residues, (2) the inability to advertise in a local newspaper, (3) the use of a different solvent to dissolve BIT for addition into paint, (4) the use of BIT internal standard after its retest date, (5) a device malfunction for monitoring room temperature storage conditions of paints, (6) the analysis of select samples after being stored for 6 months, and (7) the generation of samples not listed in study sample list. The second deviation documented the incorrect method reference in two sections of the protocol.

The deviations from the protocol except item (1) were not expected to impact the outcome of the study. The impact of item (1) is discussed in Section 9.0 and Appendix M.

13.3 Method Deviation

One method deviation occurred during the conduct of this study. This method deviation was due to not analyzing a sample after being diluted into the linear calibration range.

The deviation from the method had no impact on the outcome of the study.

13.4 SOP Deviations

Seven SOP deviations occurred during the conduct of this study. The first deviation documented field personnel assigning inconsistent expiration dates for hand wash solvent. The second SOP deviation documented (1) various temperature excursions in different laboratory temperature controlled storage units and (2) instances of inadvertently not recording weekly temperatures. The third deviation documented the QA consultant reviewing the study protocol but not generating an audit report. The fourth deviation documented an instance of alterations to field fortification forms not being made promptly. The fifth deviation documents the lack of communication documentation. The sixth deviation documents minor modification to certain GPL forms. The seventh deviation documents an instance of phase audits not being returned within the 2-week period.

The deviations from the SOP had no impact on the outcome of the study.

14.0 REFERENCES

Boatwright, M.T., 2017. *Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure*. Golden Pacific Laboratories, Fresno, CA. (GPL Study # 130503)

15.0 TABLES

Table 1 Chronological Listing of Events

28 Oct 2013	Submission of Protocol 120463 and Rational for Study Design to CDPR
8 Nov 2013	GPL submission of Protocol 120463, Single Site Submission Form, Rational for Study Design, CVs and NIH Certificates for the PI and Sub-Investigators, Inform Consent Form, and EPA Inspections to IRB
12 Nov 2013	IRB requested justification of why protocol is draft vs. final and submission of material supporting on-site health professional
13 Nov 2013	GPL responded to IRB request with justification and license and NIH Certificate for nurse
14 Nov 2013	IRB conditionally approved the protocol and supporting materials pending submission of final protocol along with documentation from CDPR and HSRB indicating their review and approval.
20 Nov 2013	GPL response to IRB question to the recording of pregnancy test
4 Dec 2013	IRB notification that one of the conditions for approval had been met
19 Dec 2013	CDPR reviewed protocol submitted on 8 Nov 2013 and provided summary of requested revisions to GPL
24 Jan 2014	GPL re-submission of revised Protocol 120463 dated 22 Jan 2014 and letter responding to CDRP's request on 19 Dec 2013
5 Feb 2014	Submission of 120463 protocol and supporting material to EPA
14 Mar 2014	EPA Science and Ethics Review of Protocol
8 Apr 2014	HSRB Discussion of Proposal
25 June 2014	HSRB Final Report of April public meeting
6 Nov 2014	GPL submission of Single Site Periodic and Continuing Review Report Form and explanation letter rationalizing why final condition has not yet been met
17 Nov 2014	IRB issued re-approval letter for the continuation of 120463
9 Dec 2014	IRB issued a memorandum and revised conditional re-approval letter for 120463
15 Oct 2015	GPL submission of Single Site Periodic and Continuing Review Report Form
23 Oct 2015	GPL submission of explanation letter rationalizing why final condition has not yet been met
10 Nov 2015	IRB issued conditional re-approval letter for the continuation of 120463
19 Feb 2016	GPL submitted final version of Protocol 120463 to IRB also requesting translations of required material be completed
22 Feb 2016	GPL submitted HSRB Meeting Report and initial CDPR Review with GPL Responses to findings to SAIIR to fulfill remaining conditions of approval
26 Feb 2016	IRB responded to review leaving status conditional approval pending review of GPL response/action to HSRB/EPA findings
29 Feb 2016	GPL submitted letter summarizing HSRB/EPA findings and GPL response/action to IRB
3 Mar 2016	IRB notified GPL responses satisfied the conditions of approval
4 Mar 2016	IRB approved study issuing Approval Letter and Informed Consent Form (English)
10 Mar 2016	IRB issued approved Spanish translated Informed Consent Form
14 Mar 2016	IRB issued approved Spanish translated documents
15 Mar 2106	"Study Initiation" (p. 6) [Date on which SD signed protocol]
15 Mar 2016	GPL sent CDPR the Final Protocol 120463, the letter to IRB addressing HSRB/EPA findings, and the IRB approval letter

17 Mar 2016	CDPR grants final approval of the protocol 120463
3 May 2016	GPL submission of Amendment 1 correcting the analytical method number, changing the summary of the method in the protocol, and adding a pre-wash step to remove potential BIT background residues in the matrix prior to use from the outer dosimeter clothes to IRB and CDPR.
5 May 2016	CDPR acknowledgement of receipt of Amendment 1 and requested IRB approval letter
6 May 2016	IRB approval of Amendment 1
8 May 2016	Start of newspaper advertisement initializing the two-week enrollment process
9 May 2016	GPL submission of IRB approval letter to CDPR
11 May 2016	First subject enrolled into the study
21 May 2016	End of the two-week enrollment
13 June 2016	GPL submission of Amendment 2 removing the need to add dry ice to samples when transported from the test site to the laboratory freezers to IRB
13 June 2016	First day of subject monitoring; "Experimental Start"
15 June 2016	Representative of CDPR observed subject monitoring
15 June 2016	IRB approval of Amendment 2
20 June 2016	GPL submission of Amendment 2 and IRB approval letter to CDPR
23 June 2016	CDPR acknowledgement of receipt of Amendment 2 and IRB approval letter
23 June 2016	CDPR sent GPL a Review Report
1 July 2016	Last day of subject monitoring
27 Oct 2016	GPL submission of annual progress report "Single Site Study Periodic and Continuing Review Report" to IRB along with CDPR Review Report
7 Nov 2016	IRB issued re-approval letter for the continuation of 120463
27 Apr 2017	"Experimental Termination" (p. 6) "Last day of data collection"
27 Oct 2017	GPL submission of Deviation 1 to IRB
27 Oct 2017	IRB acknowledgement of receipt of Protocol Deviation 1 and submission form
30 Oct 2017	GPL submission of "Single Site Study Final Report" to IRB
30Oct 2017	IRB acceptance of closeout report (letter dated 10/30/2017)
31 Oct 2017	GPL submission to CDPR of IRB Closeout Letter and Protocol Deviation 1 though not required by protocol
31 Jan 2018	"Study Completion" [Final report Signed by Study Director]

Table 2 Randomized Order of the 37 Enrolled Subjects

Randomized Order	Subject Number	Assignment
1	AE-30	ME01
2	AE-29	ME02
3	AE-13	ME03
4	AE-19	ME04
5	AE-12	ME05
6	AE-26	ME06
7	AE-28	ME07
8	AE-15	①
9	AE-1	ME08
10	AE-35	ME09
11	AE-31	ME10
12	AE-3	ME11
13	AE-36	ME12
14	AE-20	ME13
15	AE-16	ME14
16	AE-7	ME15
17	AE-10	①
18	AE-33	ME16
19	AE-4	ME17
20	AE-6	①
21	AE-37	ME18
22	AE-22	Alternate 1
23	AE-24	Alternate 2
24	AE-25	Alternate 3
25	AE-27	Alternate 4
26	AE-32	①
27	AE-9	Alternate 5
28	AE-2	Alternate 6
29	AE-11	Alternate 7
30	AE-18	Alternate 8
31	AE-14	①
32	AE-34	Alternate 9
33	AE-5	Alternate 10
34	AE-21	Alternate 11
35	AE-17	Alternate 12
36	AE-23	Alternate 13
37	AE-8	Alternate 14

① Subjects were removed from study for various reasons. See Table 6 for details.

Table 3 Randomized Paint Concentration Assignment

ME Number	Paint Assignment
ME01	1
ME02	1
ME03	3
ME04	1
ME05	2
ME06	3
ME07	3
ME08	2
ME09	3
ME10	2
ME11	1
ME12	2
ME13	1
ME14	2
ME15	2
ME16	3
ME17	3
ME18	1

1 = Low ppm Concentration
2 = Mid ppm Concentration
3 = High ppm Concentration

Table 4 Subject Demographics

Monitoring Event Assigned After Randomization	Monitoring Event Conducted	Subject Number	Age[1]	Sex[1]	Weight (lb.)[1]	Height (feet-inches)[1]	Language	Notes
ME01	ME01	AE-30	36	M	185	5-10	English	
ME04	ME02	AE-19	64	F	145	5-7	English	AE-19 and AE-29 switched to fit subjects' schedule
ME03	ME03	AE-13	20	M	165	6-1	English	
ME02	ME04	AE-29	34	M	182	5-11	English	AE-29 and AE-19 switched to fit subjects' schedule
Alternate 5	ME05	AE-9	DNF	F	195	5-8	English	Replaced AE-12 who was disqualified
ME06	ME06	AE-26	48	M	250	5-10	English	
Alternate 2	ME07	AE-24	59	M	160	5-9	English	Replaced AE-28 who was reassigned as ME08
ME07	ME08	AE-28	53	M	180	5-11	English	Replaced AE-1
ME09	ME09	AE-35	42	M	185	5-8	English	
Alternate 8	ME10	AE-18	52	F	165	5-8	English	Replaced AE-31
Alternate 12	ME11	AE-17	50	M	200	5-7	English	
Alternate 11	ME12	AE-21	57	M	180	6-2	English	Replaced AE-36 who was reassigned as ME18
ME13	ME13	AE-20	55	F	130	5-2	English	
ME14	ME14	AE-16	57	F	157	DNF	English	
ME15	ME15	AE-7	53	M	182	6-1	English	
Alternate 3	ME16	AE-25	38	M	270	5-10	English	Replaced AE-33
ME17	ME17	AE-4	27	M	150	5-10	English	
ME12	ME18	AE-36	55	M	165	5-7	English	Replaced AE-37

[1] Transcribed from self- reporting questionnaire as subject had written it.
DNF = Did not fill in on form

Table 5 Subject Demographics - Alternates

Monitoring Event Assigned After Randomization	Subject Number	Age[1]	Sex[1]	Weight (lb.)[1]	Height (feet-inches) [1]	Language	Notes
ME05	AE-12	58	F	147	5-3	English	Subject was disqualified after reporting to paint with a wrist injury
ME08	AE-1	50	F	145	5-0	English	Could not reach
ME10	AE-31	53	F	180	5-2	English	Did not show up
ME11	AE-3	33	M	235	5-8	English	Withdrew because had no gas and needed to watch son
ME16	AE-33	56	F	160	5-6	English	Did not show up
ME18	AE-37	34	M	175	5-9	English	Did not show up
Alternate 1	AE-22	55	F	135	5-3	English	
Alternate 4	AE-27	44	M	230	6-0	English	
Alternate 6	AE-2	25	F	150	5-1	English	Withdrew to take care of son
Alternate 7	AE-11	57	F	180	5-7	English	
Alternate 9	AE-34	21	F	180	5-3	English	Could not reach
Alternate 10	AE-5	39	F	176	5-6	English	Could not reach
Alternate 13	AE-23	60	M	220	DNF	English	
Alternate 14	AE-8	42	F	248	5-8	English	

[1] Transcribed from self- reporting questionnaire as subject had written it.
DNF = Did not fill in on form

Table 6 Subject Demographics – Removed by Study Director After Enrollment

Subject Number	Age[1]	Sex[1]	Weight (lb.)[1]	Height (feet-inches)[1]	Language	Notes
AE-15	24	M	450	6-2	English	Subject weight exceeds ladder safety limit
AE-10	24	F	256	DNF	English	Interviewer felt that subject had never painted and may not have been there willingly but brought with other family members who were interviewing
AE-6	53	F	DNF	5-7	English	Interviewer felt subject was in poor physical health and would not be able to complete the tasks being asked safely
AE-32	72	F	145	5-6	English	Interviewer felt subject may have difficulty following directions which could put self and others in danger
AE-14	51	M	390	6-0	English	Subject weight exceeds ladder safety limit

[1] Transcribed from self- reporting questionnaire as subject had written it.
DNF = Did not fill in on form

Table 7 Field Codes and Analytical Codes

Subject Order (Analytical ID)	Subject Number (Field ID)	ME Conducted
AEA09-BRS-01	AE-30	ME01
AEA09-BRS-02	AE-19	ME02
AEA09-BRS-03	AE-13	ME03
AEA09-BRS-04	AE-29	ME04
AEA09-BRS-05	AE-9	ME05
AEA09-BRS-06	AE-26	ME06
AEA09-BRS-07	AE-24	ME07
AEA09-BRS-08	AE-28	ME08
AEA09-BRS-09	AE-35	ME09
AEA09-BRS-10	AE-18	ME10
AEA09-BRS-11	AE-17	ME11
AEA09-BRS-12	AE-21	ME12
AEA09-BRS-13	AE-20	ME13
AEA09-BRS-14	AE-16	ME14
AEA09-BRS-15	AE-7	ME15
AEA09-BRS-16	AE-25	ME16
AEA09-BRS-17	AE-4	ME17
AEA09-BRS-18	AE-36	ME18

Table 8 Environmental Conditions of Test Rooms during Monitoring Events

Monitoring Event	Monitoring Date	Time Monitored	Temperature (°F)			Humidity (%)		
			Minimum	Maximum	Average	Minimum	Maximum	Average
ME01	06/13/16	9:50 am – 11:54 am	72.3	80.3	75.6	41.8	53.4	48.6
ME02	06/15/16	9:00 am – 10:39 am	67.9	73.5	70.8	37.1	45.1	40.7
ME03	06/15/16	10:17 am – 12:33 pm	68.1	72.5	70.5	38.6	57.3	45.5
ME04	06/17/16	8:41 am – 10:31 am	69.2	72.8	71.0	47.2	63.3	53.7
ME05	06/17/16	11:28 am – 1:34 pm	71.5	79.5	76.2	41.0	51.2	46.3
ME06	06/20/16	9:25 am – 11:00 am	70.8	79.0	73.6	36.6	55.4	47.0
ME07	06/20/16	10:11 am – 12:55 pm	73.5	80.4	75.2	34.0	50.2	41.9
ME08	06/22/16	8:43 am – 11:35 am	69.8	78.7	72.9	34.1	50.1	42.9
ME09	06/22/16	9:36 am – 12:16 pm	71.5	80.4	76.0	32.4	45.0	39.8
ME10	06/24/16	9:04 am – 11:17 am	73.2	77.5	75.4	35.7	44.7	39.2
ME11	06/24/16	10:55 am – 12:43 pm	71.1	80.1	73.7	32.2	46.4	41.3
ME12	06/27/16	9:40 am – 10:45 am	69.5	82.3	76.7	35.6	54.1	46.6
ME13	06/27/16	10:23 am – 11:57 am	76.3	83.6	78.2	34.8	48.4	44.2
ME14	06/29/16	8:57 am – 9:45 am	74.6	79.2	76.4	36.4	53.2	45.6
ME15	06/29/16	10:39 am – 11:36 am	76.4	84.8	79.9	33.2	46.0	40.2
ME16	07/01/16	7:58 am – 8:57 am	79.7	81.4	80.3	40.4	41.3	40.7
ME17	07/01/16	9:05 am – 10:09 am	81.4	82.6	82.1	41.1	45.3	42.7
ME18	07/01/16	10:19 am – 12:12 pm	75.8	83.6	80.0	37.7	50.4	44.3

Table 9 Environmental Conditions of Changing Room, Field Fortification Room, and Test Substance Room

Monitoring Area	Monitoring Date	Temperature (°F)			Humidity (%)		
		Minimum	Maximum	Average	Minimum	Maximum	Average
Changing Room	06/13/16	73.8	80.8	77.1	33.3	39.5	36.7
	06/15/16	67.0	71.1	69.2	30.2	36.7	33.1
	06/17/16	64.9	80.1	71.7	30.3	58.3	42.2
	06/20/16	70.4	82.2	75.9	30.2	39.1	34.5
	06/22/16	68.3	80.1	73.2	26.0	39.5	33.5
	06/24/16	65.6	79.4	70.6	26.3	41.5	34.6
	06/27/16	69.7	75.9	72.7	25.7	33.8	29.7
	06/29/16	74.5	80.8	76.9	32.4	34.7	33.6
	07/01/16	68.3	77.3	72.1	28.4	35.3	32.5
Field Fortification Room	06/13/16	81.5	87.3	84.4	23.9	29.6	25.9
	06/15/16	73.8	78.7	76.4	23.5	27.8	25.2
	06/17/16	74.5	84.4	79.2	25.7	33.6	28.6
	06/20/16	80.8	88.0	84.9	24.4	28.9	26.4
	06/22/16	78.0	85.1	81.5	23.6	29.6	25.3
	06/24/16	77.3	85.8	83.0	23.6	25.8	24.1
	06/27/16	77.3	83.0	80.2	23.5	25.8	24.4
	06/29/16	83.0	88.0	85.5	25.7	27.9	26.8
	07/01/16	80.1	87.3	83.7	26.2	28.3	27.2
Test Substance Room	06/12/16-07/01/16	68.3	95.5	81.0	23.5	43.5	28.7

Table 10 Monitoring Event Application Parameter Results for Subjects

Monitoring Event	Subject Number	Date of ME	Test Substance ID and Tinting Info	Test Substance Active Ingredient Concentration (ppm)[a]	Total Paint Handled (kg)	Total Amount of Active Ingredient Handled (mg BIT)[b]	Total Amount of Active Ingredient Handled (lb BIT)[c]	Surface Area Painted (approx. sq. ft.)	Rooms Painted	Total Time Painting (hours:minutes)
ME01	AE-30	06/13/16	TC-246 Container #1 (untinted)	141	9.94	1402	0.00308	677	1, 2	2:04
ME02	AE-19	06/15/16	TC-247 Container #1 (tinted)	145	8.52	1235	0.00272	267	1	1:39
ME03	AE-13	06/15/16	TC-247 Container #4 (tinted)	649	9.88	6412	0.0141	448	4	2:16
ME04	AE-29	06/17/16	TC-246 Container #2 (untinted)	142	9.77	1387	0.00305	773	1, 2	1:50
ME05	AE-9	06/17/16	TC-246 Container #7 (untinted)	376	9.77	3674	0.00808	798	4, 5	2:06
ME06	AE-26	06/20/16	TC-247 Container #5 (tinted)	603	9.63	5807	0.0128	813	1, 2	1:35
ME07	AE-24	06/20/16	TC-247 Container #6 (tinted)	617	9.59	5917	0.0130	680	4, 5	2:44
ME08	AE-28	06/22/16	TC-248 Container #1 (untinted)	382	9.11	3480	0.00766	641	1, 2	2:52
ME09	AE-35	06/22/16	TC-246 Container #6 (untinted)	622	8.80	5474	0.0120	448	4	2:40

[a] Experimentally determined BIT concentration in paint.
[b] Total Amount Active Ingredient Handled = (Total Paint Handled in kg x (1000 g/kg) x Test Substance Active Ingredient Concentration in ppm) x (1 mg/1000 µg).
[c] Total Amount Active Ingredient Handled (lb) = Total Amount Active Ingredient Handled (mg) x (1 g/1000 mg) x (1 kg/1000 g) x (2.2 lb/1 kg).

Table 10 Monitoring Event Application Parameter Results for Subjects (continued)

Monitoring Event	Subject Number	Date of ME	Test Substance ID	Test Substance Active Ingredient Concentration (ppm)[a]	Total Paint Handled (kg)	Total Amount of Active Ingredient Handled (mg BIT)[b]	Total Amount of Active Ingredient Handled (lb BIT)[c]	Surface Area Painted (approx. sq. ft.)	Rooms Painted	Total Time Painting (hours:minutes)
ME10	AE-18	06/24/16	TC-247 Container #7 (tinted)	376	9.51	3576	0.00787	643	1, 2	2:13
ME11	AE-17	06/24/16	TC-247 Container #2 (tinted)	147	9.53	1401	0.00308	888	4, 5	1:48
ME12	AE-21	06/27/16	TC-248 Container #2 (untinted)	370	9.25	3423	0.00753	448	1	1:05
ME13	AE-20	06/27/16	TC-246 Container #3 (untinted)	144	9.05	1303	0.00287	672	4, 5	1:34
ME14	AE-16	06/29/16	TC-247 Container #8 (tinted)	368	8.80	3238	0.00712	448	1	0:48
ME15	AE-7	06/29/16	TC-247 Container #9 (tinted)	379	9.32	3532	0.00777	444	4	0:57
ME16	AE-25	07/01/16	TC-246 Container #4 (untinted)	595	9.49	5647	0.0124	436	1	0:59
ME17	AE-4	07/01/16	TC-246 Container #5 (untinted)	628	9.55	5997	0.0132	634	4, 5	1:04
ME18	AE-36	07/01/16	TC-247 Container #3 (tinted)	145	8.66	1256	0.00276	624	3, 6	1:53

[a] Experimentally determined BIT concentration in paint.
[b] Total Amount Active Ingredient Handled = (Total Paint Handled in kg x (1000 g/kg) x Test Substance Active Ingredient Concentration in ppm) x (1 mg/1000 µg).
[c] Total Amount Active Ingredient Handled (lb) = Total Amount Active Ingredient Handled (mg) x (1 g/1000 mg) x (1 kg/1000 g) x (2.2 lb/1 kg).

Table 11 Paint Rag Weights Used by Subjects

Monitoring Event	Mass of Rags in Bucket Prior to Painting (kg)	Mass of Rags in Bucket After Painting (kg)	Mass of Paint on Rags (kg)
ME01	1.05	1.10	0.05
ME02	1.13	1.14	0.01
ME03	1.02	1.12	0.10
ME04	0.90	0.90	0.00
ME05	0.99	0.99	0.00
ME06	1.34	1.38	0.04
ME07	0.84	0.85	0.01
ME08	1.23	1.23	0.00
ME09	1.05	1.06	0.01
ME10	1.05	1.05	0.00
ME11	1.14	1.14	0.00
ME12	1.40	1.40	0.00
ME13	1.10	1.10	0.00
ME14	1.50	1.76	0.26
ME15	1.54	1.56	0.02
ME16	1.75	1.75	0.00
ME17	1.55	1.81	0.26
ME18	1.14	1.15	0.01

Table 12 Background Air Sampling for Pre-existing BIT

Sample ID	Laboratory ID	Date Sampled	Measured Residue
AEA09-BS-1-R1-AR-H1	463SET36-4	6/13/2016	<LOQ
AEA09-BS-1-R1-AR-H2	463SET36-5	6/13/2016	<LOQ
AEA09-BS-1-CR-AR-H1	463SET36-6	6/13/2016	<LOQ
AEA09-BS-1-CR-AR-H2	463SET36-7	6/13/2016	<LOQ
AEA09-BS-2-CR-AR-H1	463SET36-8	6/15/2016	<LOQ
AEA09-BS-3-R1-AR-H1	463SET36-9	6/17/2016	<LOQ
AEA09-BS-4-CR-AR-H2	463SET36-10	6/20/2016	<LOQ
AEA09-BS-5-R1-AR-H2	463SET36-11	6/22/2016	<LOQ
AEA09-BS-6-CR-AR-H1	463SET36-12	6/24/2016	<LOQ
AEA09-BS-7-R1-AR-H1	463SET36-13	6/27/2016	<LOQ
AEA09-BS-8-CR-AR-H2	463SET36-14	6/29/2016	<LOQ
AEA09-BS-9-R1-AR-H2	463SET36-15	7/1/2016	<LOQ

LOQ = 0.01 µg/sample

Table 13 Background Wall Wipe Sampling for Pre-existing BIT

Sample ID	Laboratory ID	Room Sampled	BIT Concentration of Paint Last Painted in Room[a]	Date Sampled	Time Sampled	Measured Residue (µg/sample)	Residues/ Area Sampled[b] (µg/sq. foot)
463SET75-4	AEA09-BS-1-CR-WW-H1	Changing Room	NA	6/13/2016	9:21 am	<LOQ	<LOQ
463SET75-5	AEA09-BS-1-CR-WW-H2	Changing Room	NA	6/13/2016	9:22 am	<LOQ	<LOQ
463SET75-6	AEA09-BS-1-R1-WW-H1	R1	NA	6/13/2016	9:02 am	<LOQ	<LOQ
463SET75-7	AEA09-BS-1-R2-WW-H2	R2	NA	6/13/2016	9:10 am	<LOQ	<LOQ
463SET75-8	AEA09-BS-2-R1-WW-H1	R1	141 ppm (ME-01)	6/15/2016	7:20 am	<LOQ	<LOQ
463SET75-9	AEA09-BS-2-R4-WW-H2	R4	NA	6/15/2016	7:28 am	<LOQ	<LOQ
463SET75-10	AEA09-BS-3-CR-WW-H1	Changing Room	NA	6/17/2016	7:16 am	<LOQ	<LOQ
463SET75-11	AEA09-BS-3-R2-WW-H2	R2	NA	6/17/2016	7:21 am	<LOQ	<LOQ
463SET75-12	AEA09-BS-4-R3-WW-H1	R3	NA	6/20/2016	7:18 am	<LOQ	<LOQ
463SET75-13	AEA09-BS-4-R5-WW-H2	R5	376 ppm (ME-05)	6/20/2016	7:24 am	0.284	0.284
463SET75-14	AEA09-BS-5-CR-WW-H1	Changing Room	NA	6/22/2016	7:10 am	<LOQ	<LOQ
463SET75-15	AEA09-BS-5-R6-WW-H2	R6	NA	6/22/2016	7:21 am	<LOQ	<LOQ
463SET75-16	AEA09-BS-6-R1-WW-H1	R1	382 ppm (ME-08)	6/24/2016	7:46 am	0.148	0.148
463SET75-17	AEA09-BS-6-R4-WW-H2	R4	622 ppm (ME-09)	6/24/2016	7:56 am	0.346	0.346
463SET75-18	AEA09-BS-7-CR-WW-H1	Changing Room	NA	6/27/2016	7:49 am	<LOQ	<LOQ
463SET75-19	AEA09-BS-7-R2-WW-H2	R2	376 ppm (ME-10)	6/27/2016	7:56 am	0.332	0.332
463SET75-20	AEA09-BS-8-R3-WW-H1	R3	NA	6/29/2016	8:17 am	<LOQ	<LOQ
463SET75-21	AEA09-BS-8-R5-WW-H2	R5	144 ppm (ME-13)	6/29/2016	8:20 am	0.252	0.252
463SET75-22	AEA09-BS-9-CR-WW-H1	Changing Room	NA	7/1/2016	6:31 am	<LOQ	<LOQ
463SET75-23	AEA09-BS-9-R6-WW-H2	R6	NA	7/1/2016	6:52 am	<LOQ	<LOQ

LOQ = 0.100 µg/sample.

[a] BIT concentration in the paint which was used to paint the rooms prior to collection of background wall wipe sample .

[b] Residues/Area Sampled (µg/sq. foot) = Measured Residues (µg/sample) ÷ Wall Wipe Sampling Area (1 sq. foot).

Table 14 Summary of Concurrent Laboratory Fortification Recoveries for Air Sampling Tubes

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET33-1	NA	<LOQ	NA
463SET34-1	NA	<LOQ	NA
463SET35-1	NA	<LOQ	NA
463SET36-1	NA	<LOQ	NA
463SET37-1	NA	<LOQ	NA
463SET38-1	NA	<LOQ	NA
463SET39-1	NA	<LOQ	NA
463SET40-1	NA	<LOQ	NA
463SET41-1	NA	<LOQ	NA
463SET70-1	NA	<LOQ	NA
Low Fortification (0.0100 µg/sample)			
463SET33-2	0.0100	0.00632	63.2[a]
463SET34-2	0.0100	0.00810	81.0
463SET35-2	0.0100	0.00798	79.8
463SET36-2	0.0100	0.00838	83.8
463SET37-2	0.0100	0.00702	70.2
463SET38-2	0.0100	0.00704	70.4
463SET39-2	0.0100	0.00868	86.8
463SET40-2	0.0100	0.00766	76.6
463SET41-2	0.0100	0.00720	72.0
463SET70-2	0.0100	0.00730	73.0
	Mean =	**0.00757**	**75.7**
	Standard Deviation =	**0.000723**	**7.23**
	CV =	**9.55**	**9.55**

LOQ = 0.0100 µg/sample

[a] Percent Recovery < 70%

Table 14 Summary of Concurrent Laboratory Fortification Recoveries for Air Sampling Tubes (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~10.0 µg/sample)			
463SET33-3	10.1	10.2	101
463SET34-3	10.1	9.13	90.4
463SET35-3	10.1	9.98	98.8
463SET36-3	10.1	10.6	105
463SET37-3	10.1	9.78	96.8
463SET38-3	10.1	9.90	98.0
463SET39-3	10.1	9.41	93.2
463SET40-3	10.1	9.05	89.6
463SET41-3	10.1	9.43	93.4
463SET70-3	10.1	10.2	101
	Mean =	**9.77**	**96.7**
	Standard Deviation =	**0.505**	**5.00**
	CV =	**5.17**	**5.17**
		Overall Mean =	**86.2**
		Overall Standard Deviation =	**12.4**
		Overall CV =	**14.4**

LOQ = 0.0100 µg/sample

Table 15 Summary of Concurrent Laboratory Fortification Recoveries for Fiberglass Filter Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET24-1	NA	<LOQ	NA
463SET25-1	NA	<LOQ	NA
463SET26-1	NA	<LOQ	NA
463SET27-1	NA	<LOQ	NA
463SET28-1	NA	<LOQ	NA
463SET29-1	NA	<LOQ	NA
463SET30-1	NA	<LOQ	NA
463SET31-1	NA	<LOQ	NA
463SET32-1	NA	<LOQ	NA
Low Fortification (0.0100 µg/sample)			
463SET24-2	0.0100	0.00950	95.0
463SET25-2	0.0100	0.00944	94.4
463SET26-2	0.0100	0.00848	84.8
463SET27-2	0.0100	0.00814	81.4
463SET28-2	0.0100	0.00852	85.2
463SET29-2	0.0100	0.00780	78.0
463SET30-2	0.0100	0.00844	84.4
463SET31-2	0.0100	0.00822	82.2
463SET32-2	0.0100	0.00898	89.8
	Mean =	**0.00861**	**86.1**
	Standard Deviation =	**0.000581**	**5.81**
	CV =	**6.75**	**6.75**

LOQ = 0.0100 µg/sample

Table 15 Summary of Concurrent Laboratory Fortification Recoveries for Fiberglass Filter Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (10.0 µg/sample)			
463SET24-3	10.0	8.26	82.6
463SET25-3	10.0	8.61	86.1
463SET26-3	10.0	8.40	84.0
463SET27-3	10.0	9.53	95.3
463SET28-3	10.0	9.25	92.5
463SET29-3	10.0	8.93	89.3
463SET30-3	10.0	8.02	80.2
463SET31-3	10.0	8.32	83.2
463SET32-3	10.0	9.21	92.1
	Mean =	**8.73**	**87.3**
	Standard Deviation =	**0.524**	**5.24**
	CV =	**6.00**	**6.00**
		Overall Mean =	**86.7**
		Overall Standard Deviation =	**5.40**
		Overall CV =	**6.23**

LOQ = 0.0100 µg/sample

Table 16 Summary of Concurrent Laboratory Fortification Recoveries for Hand Wash Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET06-1	NA	<LOQ	NA
463SET07-1	NA	<LOQ	NA
463SET08-1	NA	<LOQ	NA
463SET09-1	NA	<LOQ	NA
463SET10-1	NA	<LOQ	NA
463SET11-1	NA	<LOQ	NA
463SET12-1	NA	<LOQ	NA
463SET13-1	NA	<LOQ	NA
463SET14-1	NA	<LOQ	NA
Low Fortification (0.250 µg/sample)			
463SET06-2	0.250	0.220	88.0
463SET07-2	0.250	0.227	90.8
463SET08-2	0.250	0.201	80.4
463SET09-2	0.250	0.253	101
463SET10-2	0.250	0.270	108
463SET11-2	0.250	0.288	115
463SET12-2	0.250	0.250	100
463SET13-2	0.250	0.229	91.6
463SET14-2	0.250	0.196	78.4
	Mean =	**0.237**	**94.8**
	Standard Deviation =	**0.0307**	**12.2**
	CV =	**13.0**	**12.9**
High Fortification (~300 µg/sample)			
463SET06-3	280	228	81.4
463SET07-3	303	259	85.5
463SET08-3	262	214	81.7
	Mean =	**234**	**82.9**
	Standard Deviation =	**23.0**	**2.29**
	CV =	**9.83**	**2.76**

LOQ = 1.00 ng/mL (0.250 µg/sample for Lab QC due to 250-mL sample volume)

Table 16 Summary of Concurrent Laboratory Fortification Recoveries for Hand Wash Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~800 µg/sample)			
463SET09-3	768	649	84.5
463SET10-3	768	631	82.2
463SET11-3	797	650	81.6
463SET12-3	815	675	82.8
463SET13-3	779	605	77.7
	Mean =	**642**	**81.8**
	Standard Deviation =	**25.9**	**2.51**
	CV =	**4.03**	**3.07**
High Fortification (~1500 µg/sample)			
463SET14-3	1482	1196	80.7
		Overall Mean =	**88.4**
		Overall Standard Deviation =	**10.8**
		Overall CV =	**12.2**

LOQ = 1.00 ng/mL (0.250 µg/sample for Lab QC due to 250-mL sample volume)

Table 17 Summary of Concurrent Laboratory Fortification Recoveries for Face/Neck Wipe Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET15-1	NA	<LOQ	NA
463SET16-1	NA	<LOQ	NA
463SET17-1	NA	<LOQ	NA
463SET18-1	NA	<LOQ	NA
463SET19-1	NA	<LOQ	NA
463SET20-1	NA	<LOQ	NA
463SET21-1	NA	<LOQ	NA
463SET22-1	NA	<LOQ	NA
463SET23-1	NA	<LOQ	NA
Low Fortification (~0.100 µg/sample)			
463SET15-2	0.125	0.0905 (0.0953)[a]	72.4 (76.2)[a]
463SET16-2	0.125	0.133 (0.108)[a]	106 (86.4)[a]
463SET17-2	0.125	0.117	93.6
463SET18-2	0.125	0.0957	76.6
463SET19-2	0.100	0.0918	91.8
463SET20-2	0.100	0.0784	78.4
463SET21-2	0.100	0.0998	99.8
463SET22-2	0.100	0.102	102
463SET23-2	0.100	0.0771	77.1
463SET75-2	0.102	0.0927	90.9
	Mean =	**0.0978**	**88.9**
	Standard Deviation =	**0.0168**	**12.0**
	CV =	**17.2**	**13.5**

LOQ = 0.100 µg/sample

[a] Reanalysis conducted to demonstrate extract stability in sample dilution sets (not included in mean, standard deviation or coefficient of variation calculations).

Table 17 Summary of Concurrent Laboratory Fortification Recoveries for Face/Neck Wipe Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~100 µg/sample)			
463SET15-3	113	87.0 (97.7)[a]	77.0 (86.5)[a]
463SET16-3	119	102 (106)[a]	85.7 (89.1)[a]
463SET17-3	119	102 (96.4)[a]	85.7 (81.0)[a]
463SET18-3	119	100	84.0
463SET19-3	131	111	84.7
463SET20-3	131	110	84.0
463SET21-3	113	97.3	86.1
463SET22-3	119	102	85.7
463SET23-3	125	101	80.8
463SET75-3	107	86.0	80.4
	Mean =	**99.8**	**83.4**
	Standard Deviation =	**8.21**	**3.02**
	CV =	**8.23**	**3.62**
		Overall Mean =	**86.1**
		Overall Standard Deviation =	**8.95**
		Overall CV =	**10.4**

LOQ = 0.100 µg/sample

[a] Reanalysis conducted to demonstrate extract stability in sample dilution sets (not included in mean, standard deviation or coefficient of variation calculations).

Table 18 Summary of Concurrent Laboratory Fortification Recoveries for Inner Dosimeter Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET46-1	NA	<LOQ	NA
463SET49-1	NA	<LOQ	NA
463SET52-1	NA	<LOQ	NA
463SET55-1	NA	<LOQ	NA
463SET60-1	NA	<LOQ	NA
463SET63-1	NA	<LOQ	NA
463SET64-1	NA	395	NA
463SET71-1	NA	<LOQ	NA
463SET72-1	NA	<LOQ	NA
463SET73-1	NA	<LOQ	NA
463SET74-1	NA	<LOQ	NA
463SET76-1	NA	<LOQ	NA
Low Fortification (~3.00 µg/sample)			
463SET46-2	3.00	3.32	111
463SET49-2	3.00	3.83	128[a]
463SET52-2	3.00	2.87	95.7
463SET55-2	3.00	2.67	89.0
463SET60-2	3.00	3.72	124[a]
463SET63-2	3.00	2.54	84.7
463SET64-2	3.00	3.14	105
463SET71-2	3.00	4.41	147[a]
463SET72-2	3.00	2.60	86.7
463SET73-2	3.00	2.70	90.0
463SET74-2	3.00	2.66	88.7
463SET76-2	2.92	2.88	98.6
	Mean =	**3.11**	**104**
	Standard Deviation =	**0.594**	**19.8**
	CV =	**19.1**	**19.0**

LOQ = 3.00 µg/sample

[a] Percent Recovery > 120%

Table 18 Summary of Concurrent Laboratory Fortification Recoveries for Inner Dosimeter Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~3000 µg/sample)			
463SET46-3	3157	2826 (2961)[a]	89.5 (93.8)[a]
463SET49-3	3157	2848 (2683)[a]	90.2 (85.0)[a]
463SET52-3	3131	2781 (2766)[a]	88.8 (88.3)[a]
463SET55-3	3182	2758 (2886)[a]	86.7 (90.7)[a]
463SET60-3	3116	2826 (2645)[a]	90.7 (84.9)[a]
463SET63-3	3198	2856 (2901)[a]	89.3 (90.7)[a]
463SET64-3	3233	3104 (2826)[a]	96.0 (87.4)[a]
463SET71-3	3193	2818	88.3
463SET72-3	3213	2976	92.6
463SET73-3	3182	2570	80.8
463SET74-3	3427	2886	84.2
463SET76-3	3060	2412	78.8
	Mean =	**2805**	**88.0**
	Standard Deviation =	**177**	**4.81**
	CV =	**6.31**	**5.47**
		Overall Mean =	**96.0**
		Overall Standard Deviation =	**16.3**
		Overall CV =	**17.0**

LOQ = 3.00 µg/sample

[a] Reanalysis conducted to demonstrate extract stability in sample dilution sets (not included in mean, standard deviation or coefficient of variation calculations).

Table 19 Summary of Concurrent Laboratory Fortification Recoveries for Painter's Hat Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET45-1	NA	<LOQ	NA
463SET48-1	NA	<LOQ	NA
463SET51-1	NA	<LOQ	NA
463SET54-1	NA	<LOQ	NA
463SET57-1	NA	<LOQ	NA
463SET59-1	NA	<LOQ	NA
463SET62-1	NA	<LOQ	NA
463SET66-1	NA	<LOQ	NA
463SET69-1	NA	<LOQ	NA
Low Fortification (3.00 µg/sample)			
463SET45-2	3.00	2.44	81.3
463SET48-2	3.00	2.88	96.0
463SET51-2	3.00	3.17	106
463SET54-2	3.00	2.87	95.7
463SET57-2	3.00	3.11	104
463SET59-2	3.00	2.72	90.7
463SET62-2	3.00	3.06 (2.45) [a]	102 (81.7) [a]
463SET66-2	3.00	3.06	102
463SET69-2	3.00	2.91	97.0
	Mean =	**2.91**	**97.2**
	Standard Deviation =	**0.227**	**7.65**
	CV =	**7.80**	**7.87**

LOQ = 3.00 µg/sample

[a] Reanalysis conducted to demonstrate extract stability in sample dilution sets (not included in mean, standard deviation or coefficient of variation calculations).

Table 19 Summary of Concurrent Laboratory Fortification Recoveries for Painter's Hat Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~3000 µg/sample)			
463SET45-3	3172	2983	94.0
463SET48-3	3182	2927	92.0
463SET51-3	3096	2886	93.2
463SET54-3	3101	2975	95.9
463SET57-3	3203	2814	87.9
463SET59-3	3244	3095	95.4
463SET62-3	3203	3176	99.2
463SET66-3	3264	3240	99.3
463SET69-3	3335	2919	87.5
	Mean =	**3002**	**93.8**
	Standard Deviation =	**141**	**4.25**
	CV =	**4.70**	**4.53**
		Overall Mean =	**95.5**
		Overall Standard Deviation =	**6.25**
		Overall CV =	**6.54**

LOQ = 3.00 µg/sample

Table 20 Summary of Concurrent Laboratory Fortification Recoveries for Outer Dosimeter Samples

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control			
463SET44-1	NA	<LOQ	NA
463SET47-1	NA	<LOQ	NA
463SET50-1	NA	<LOQ	NA
463SET53-1	NA	<LOQ	NA
463SET56-1	NA	<LOQ	NA
463SET58-1	NA	<LOQ	NA
463SET61-1	NA	<LOQ	NA
463SET65-1	NA	<LOQ	NA
463SET67-1	NA	<LOQ	NA
463SET68-1	NA	<LOQ	NA
Low Fortification (3.00 µg/sample)			
463SET44-2	3.00	2.76	92.0
463SET47-2	3.00	2.86 (2.44)[a]	95.3 (81.3)[a]
463SET50-2	3.00	2.45 (2.98)[a]	81.7 (99.3)[a]
463SET53-2	3.00	3.16 (3.04)[a]	105 (101)[a]
463SET56-2	3.00	2.70 (2.94)[a]	90.0 (98.0)[a]
463SET58-2	3.00	2.34 (3.08)[a]	78.0 (103)[a]
463SET61-2	3.00	3.08 (2.57)[a]	103 (85.7)[a]
463SET65-2	3.00	3.16 (2.74)[a]	105 (91.3)[a]
463SET67-2	3.00	2.49	83.0
463SET68-2	3.00	2.71 (2.58)[a]	90.3 (86.0)[a]
	Mean =	**2.77**	**92.3**
	Standard Deviation =	**0.295**	**9.77**
	CV =	**10.6**	**10.6**

LOQ = 3.00 µg/sample

[a] Reanalysis conducted to demonstrate extract stability in sample dilution sets (not included in mean, standard deviation or coefficient of variation calculations).

Table 20 Summary of Concurrent Laboratory Fortification Recoveries for Outer Dosimeter Samples (continued)

Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~3000 µg/sample)			
463SET44-3	3137	2685	85.6
463SET47-3	3091	2468	79.8
463SET50-3	3131	3176	101
463SET53-3	3162	3160	99.9
463SET56-3	3177	2910	91.6
463SET58-3	3575	3546	99.2
463SET61-3	3111	2991	96.1
463SET65-3	3269	2910	89.0
463SET67-3	3157	2822	89.4
463SET68-3	3091	2541	82.2
	Mean =	**2921**	**91.4**
	Standard Deviation =	**322**	**7.53**
	CV =	**11.0**	**8.24**
		Overall Mean =	**91.9**
		Overall Standard Deviation =	**8.50**
		Overall CV =	**9.25**

LOQ = 3.00 µg/sample

Table 21 Summary of Field Fortification Recoveries for Air Sampling Tubes

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-AR-C1	463SET33-5	NA	<LOQ	NA
AEA09-FF-01-AR-C2	463SET33-6	NA	<LOQ	NA
AEA09-FF-02-AR-C1	463SET34-6	NA	<LOQ	NA
AEA09-FF-02-AR-C2	463SET34-7	NA	<LOQ	NA
AEA09-FF-03-AR-C1	463SET35-6	NA	<LOQ	NA
AEA09-FF-03-AR-C2	463SET35-7	NA	<LOQ	NA
AEA09-FF-04-AR-C1	463SET37-6	NA	<LOQ	NA
AEA09-FF-04-AR-C2	463SET37-7	NA	<LOQ	NA
AEA09-FF-05-AR-C1	463SET38-6	NA	<LOQ	NA
AEA09-FF-05-AR-C2	463SET38-7	NA	<LOQ	NA
AEA09-FF-06-AR-C1	463SET39-6	NA	<LOQ	NA
AEA09-FF-06-AR-C2	463SET39-7	NA	<LOQ	NA
AEA09-FF-07-AR-C1	463SET40-6	NA	<LOQ	NA
AEA09-FF-07-AR-C2	463SET40-7	NA	<LOQ	NA
AEA09-FF-08-AR-C1	463SET41-6	NA	<LOQ	NA
AEA09-FF-08-AR-C2	463SET41-7	NA	<LOQ	NA
AEA09-FF-09-AR-C1	463SET70-7	NA	<LOQ	NA
AEA09-FF-09-AR-C2	463SET70-8	NA	<LOQ	NA

LOQ = 0.0100 µg/sample

Table 21 Summary of Field Fortification Recoveries for Air Sampling Tubes (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (0.100 µg/sample)				
AEA09-FF-01-AR-L1	463SET33-7	0.100	0.0790	79.0
AEA09-FF-01-AR-L2	463SET33-8	0.100	0.0816	81.6
AEA09-FF-01-AR-L3	463SET33-9	0.100	0.0828	82.8
AEA09-FF-02-AR-L1	463SET34-8	0.100	0.0818	81.8
AEA09-FF-02-AR-L2	463SET34-9	0.100	0.0930	93.0
AEA09-FF-02-AR-L3	463SET34-10	0.100	0.0838	83.8
AEA09-FF-03-AR-L1	463SET35-8	0.100	0.0744	74.4
AEA09-FF-03-AR-L2	463SET35-9	0.100	0.0844	84.4
AEA09-FF-03-AR-L3	463SET35-10	0.100	0.0774	77.4
AEA09-FF-04-AR-L1	463SET37-8	0.100	0.0760	76.0
AEA09-FF-04-AR-L2	463SET37-9	0.100	0.0744	74.4
AEA09-FF-04-AR-L3	463SET37-10	0.100	0.0780	78.0
AEA09-FF-05-AR-L1	463SET38-8	0.100	0.0768	76.8
AEA09-FF-05-AR-L2	463SET38-9	0.100	0.0822	82.2
AEA09-FF-05-AR-L3	463SET38-10	0.100	0.0778	77.8
AEA09-FF-06-AR-L1	463SET39-8	0.100	0.0792	79.2
AEA09-FF-06-AR-L2	463SET39-9	0.100	0.0780	78.0
AEA09-FF-06-AR-L3	463SET39-10	0.100	0.0792	79.2
AEA09-FF-07-AR-L1	463SET40-8	0.100	0.0610	61.0[a]
AEA09-FF-07-AR-L2	463SET40-9	0.100	0.0604	60.4[a]
AEA09-FF-07-AR-L3	463SET40-10	0.100	0.0650	65.0[a]
AEA09-FF-08-AR-L1	463SET41-8	0.100	0.0750	75.0
AEA09-FF-08-AR-L2	463SET41-9	0.100	0.0750	75.0
AEA09-FF-08-AR-L3	463SET41-10	0.100	0.0706	70.6
AEA09-FF-09-AR-L1	463SET70-9	0.100	0.0754	75.4
AEA09-FF-09-AR-L2	463SET70-10	0.100	0.0748	74.8
AEA09-FF-09-AR-L3	463SET70-11	0.100	0.0716	71.6
		Mean =	**0.0766**	**76.6**
		Standard Deviation =	**0.00693**	**6.93**
		CV =	**9.05**	**9.05**

LOQ = 0.0100 µg/sample

[a] Percent Recovery < 70%.

Table 21 Summary of Field Fortification Recoveries for Air Sampling Tubes (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (2.00 µg/sample)				
AEA09-FF-01-AR-H1	463SET33-10	2.00	1.75	87.5
AEA09-FF-01-AR-H2	463SET33-11	2.00	1.76	88.0
AEA09-FF-01-AR-H3	463SET33-12	2.00	1.73	86.5
AEA09-FF-02-AR-H1	463SET34-11	2.00	1.76	88.0
AEA09-FF-02-AR-H2	463SET34-12	2.00	1.74	87.0
AEA09-FF-02-AR-H3	463SET34-13	2.00	1.69	84.5
AEA09-FF-03-AR-H1	463SET35-11	2.00	1.80	90.0
AEA09-FF-03-AR-H2	463SET35-12	2.00	1.71	85.5
AEA09-FF-03-AR-H3	463SET35-13	2.00	1.87	93.5
AEA09-FF-04-AR-H1	463SET37-11	2.00	1.65	82.5
AEA09-FF-04-AR-H2	463SET37-12	2.00	1.68	84.0
AEA09-FF-04-AR-H3	463SET37-13	2.00	1.73	86.5
AEA09-FF-05-AR-H1	463SET38-11	2.00	1.78	89.0
AEA09-FF-05-AR-H2	463SET38-12	2.00	1.80	90.0
AEA09-FF-05-AR-H3	463SET38-13	2.00	1.64	82.0
AEA09-FF-06-AR-H1	463SET39-11	2.00	1.82	91.0
AEA09-FF-06-AR-H2	463SET39-12	2.00	1.73	86.5
AEA09-FF-06-AR-H3	463SET39-13	2.00	1.83	91.5
AEA09-FF-07-AR-H1	463SET40-11	2.00	1.76	88.0
AEA09-FF-07-AR-H2	463SET40-12	2.00	1.60	80.0
AEA09-FF-07-AR-H3	463SET40-13	2.00	1.56	78.0
AEA09-FF-08-AR-H1	463SET41-11	2.00	1.71	85.5
AEA09-FF-08-AR-H2	463SET41-12	2.00	1.67	83.5
AEA09-FF-08-AR-H3	463SET41-13	2.00	1.69	84.5
AEA09-FF-09-AR-H1	463SET70-12	2.00	1.66	83.0
AEA09-FF-09-AR-H2	463SET70-13	2.00	1.65	82.5
AEA09-FF-09-AR-H3	463SET70-14	2.00	1.68	84.0
		Mean =	**1.72**	**86.0**
		Standard Deviation =	**0.0720**	**3.60**
		CV =	**4.19**	**4.19**
			Overall Mean =	**81.3**
			Overall Standard Deviation =	**7.24**
			Overall CV =	**8.91**

LOQ = 0.0100 µg/sample

Table 22 Summary of Field Fortification Recoveries for Fiberglass Filter Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-RES-C1	463SET24-7	NA	<LOQ	NA
AEA09-FF-01-RES-C2	463SET24-8	NA	<LOQ	NA
AEA09-FF-02-RES-C1	463SET25-10	NA	<LOQ	NA
AEA09-FF-02-RES-C2	463SET25-11	NA	<LOQ	NA
AEA09-FF-03-RES-C1	463SET26-10	NA	<LOQ	NA
AEA09-FF-03-RES-C2	463SET26-11	NA	<LOQ	NA
AEA09-FF-04-RES-C1	463SET27-10	NA	<LOQ	NA
AEA09-FF-04-RES-C2	463SET27-11	NA	<LOQ	NA
AEA09-FF-05-RES-C1	463SET28-10	NA	<LOQ	NA
AEA09-FF-05-RES-C2	463SET28-11	NA	<LOQ	NA
AEA09-FF-06-RES-C1	463SET29-10	NA	<LOQ	NA
AEA09-FF-06-RES-C2	463SET29-11	NA	<LOQ	NA
AEA09-FF-07-RES-C1	463SET30-10	NA	<LOQ	NA
AEA09-FF-07-RES-C2	463SET30-11	NA	<LOQ	NA
AEA09-FF-08-RES-C1	463SET31-10	NA	<LOQ	NA
AEA09-FF-08-RES-C2	463SET31-11	NA	<LOQ	NA
AEA09-FF-09-RES-C1	463SET32-13	NA	<LOQ	NA
AEA09-FF-09-RES-C2	463SET32-14	NA	<LOQ	NA

LOQ = 0.0100 µg/sample

Table 22 Summary of Field Fortification Recoveries for Fiberglass Filter Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~0.100 µg/sample)				
AEA09-FF-01-RES-L1	463SET24-9	0.113	0.0856	75.8
AEA09-FF-01-RES-L2	463SET24-10	0.113	0.0918	81.2
AEA09-FF-01-RES-L3	463SET24-11	0.113	0.0834	73.8
AEA09-FF-02-RES-L1	463SET25-12	0.113	0.0954	84.4
AEA09-FF-02-RES-L2	463SET25-13	0.113	0.0902	79.8
AEA09-FF-02-RES-L3	463SET25-14	0.113	0.0968	85.7
AEA09-FF-03-RES-L1	463SET26-12	0.113	0.0888	78.6
AEA09-FF-03-RES-L2	463SET26-13	0.113	0.0912	80.7
AEA09-FF-03-RES-L3	463SET26-14	0.113	0.101	89.4
AEA09-FF-04-RES-L1	463SET27-12	0.113	0.0914	80.9
AEA09-FF-04-RES-L2	463SET27-13	0.113	0.0776	68.7[a]
AEA09-FF-04-RES-L3	463SET27-14	0.113	0.0870	77.0
AEA09-FF-05-RES-L1	463SET28-12	0.113	0.111	98.2
AEA09-FF-05-RES-L2	463SET28-13	0.113	0.0892	78.9
AEA09-FF-05-RES-L3	463SET28-14	0.113	0.0992	87.8
AEA09-FF-06-RES-L1	463SET29-12	0.113	0.0928	82.1
AEA09-FF-06-RES-L2	463SET29-13	0.113	0.0870	77.0
AEA09-FF-06-RES-L3	463SET29-14	0.113	0.0920	81.4
AEA09-FF-07-RES-L1	463SET30-12	0.113	0.0912	80.7
AEA09-FF-07-RES-L2	463SET30-13	0.113	0.0908	80.4
AEA09-FF-07-RES-L3	463SET30-14	0.113	0.0972	86.0
AEA09-FF-08-RES-L1	463SET31-12	0.113	0.0932	82.5
AEA09-FF-08-RES-L2	463SET31-13	0.113	0.0990	87.6
AEA09-FF-08-RES-L3	463SET31-14	0.113	0.0996	88.1
AEA09-FF-09-RES-L1	463SET32-15	0.113	0.0934	82.7
AEA09-FF-09-RES-L2	463SET32-16	0.113	0.0884	78.2
AEA09-FF-09-RES-L3	463SET32-17	0.113	0.0898	79.5
		Mean =	**0.0924**	**81.7**
		Standard Deviation =	**0.00644**	**5.69**
		CV =	**6.97**	**6.96**

LOQ = 0.0100 µg/sample

[a] Percent recovery <70%.

Table 22 Summary of Field Fortification Recoveries for Fiberglass Filter Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (2.00 µg/sample)				
AEA09-FF-01-RES-H1	463SET24-12	2.00	1.85	92.5
AEA09-FF-01-RES-H2	463SET24-13	2.00	1.84	92.0
AEA09-FF-01-RES-H3	463SET24-14	2.00	1.79	89.5
AEA09-FF-02-RES-H1	463SET25-15	2.00	1.87	93.5
AEA09-FF-02-RES-H2	463SET25-16	2.00	1.69	84.5
AEA09-FF-02-RES-H3	463SET25-17	2.00	2.03	102
AEA09-FF-03-RES-H1	463SET26-15	2.00	1.70	85.0
AEA09-FF-03-RES-H2	463SET26-16	2.00	1.91	95.5
AEA09-FF-03-RES-H3	463SET26-17	2.00	1.76	88.0
AEA09-FF-04-RES-H1	463SET27-15	2.00	1.90	95.0
AEA09-FF-04-RES-H2	463SET27-16	2.00	1.82	91.0
AEA09-FF-04-RES-H3	463SET27-17	2.00	1.97	98.5
AEA09-FF-05-RES-H1	463SET28-15	2.00	1.92	96.0
AEA09-FF-05-RES-H2	463SET28-16	2.00	1.95	97.5
AEA09-FF-05-RES-H3	463SET28-17	2.00	1.95	97.5
AEA09-FF-06-RES-H1	463SET29-15	2.00	1.79	89.5
AEA09-FF-06-RES-H2	463SET29-16	2.00	1.78	89.0
AEA09-FF-06-RES-H3	463SET29-17	2.00	1.84	92.0
AEA09-FF-07-RES-H1	463SET30-15	2.00	1.94	97.0
AEA09-FF-07-RES-H2	463SET30-16	2.00	1.70	85.0
AEA09-FF-07-RES-H3	463SET30-17	2.00	1.89	94.5
AEA09-FF-08-RES-H1	463SET31-15	2.00	1.86	93.0
AEA09-FF-08-RES-H2	463SET31-16	2.00	1.89	94.5
AEA09-FF-08-RES-H3	463SET31-17	2.00	1.88	94.0
AEA09-FF-09-RES-H1	463SET32-18	2.00	1.84	92.0
AEA09-FF-09-RES-H2	463SET32-19	2.00	2.05	103
AEA09-FF-09-RES-H3	463SET32-20	2.00	1.90	95.0
		Mean =	**1.86**	**93.2**
		Standard Deviation =	**0.0920**	**4.68**
		CV =	**4.95**	**5.02**
			Overall Mean =	**87.5**
			Overall Standard Deviation =	**7.75**
			Overall CV =	**8.86**

LOQ = 0.0100 µg/sample

Table 23 Summary of Field Fortification Recoveries for Hand Wash Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-HW-C1	463SET06-5	NA	<LOQ	NA
AEA09-FF-01-HW-C2	463SET06-6	NA	<LOQ	NA
AEA09-FF-02-HW-C1	463SET07-6	NA	<LOQ	NA
AEA09-FF-02-HW-C2	463SET07-7	NA	<LOQ	NA
AEA09-FF-03-HW-C1	463SET08-6	NA	<LOQ	NA
AEA09-FF-03-HW-C2	463SET08-7	NA	<LOQ	NA
AEA09-FF-04-HW-C1	463SET09-6	NA	<LOQ	NA
AEA09-FF-04-HW-C2	463SET09-7	NA	<LOQ	NA
AEA09-FF-05-HW-C1	463SET10-6	NA	<LOQ	NA
AEA09-FF-05-HW-C2	463SET10-7	NA	<LOQ	NA
AEA09-FF-06-HW-C1	463SET11-6	NA	<LOQ	NA
AEA09-FF-06-HW-C2	463SET11-7	NA	<LOQ	NA
AEA09-FF-07-HW-C1	463SET12-6	NA	<LOQ	NA
AEA09-FF-07-HW-C2	463SET12-7	NA	<LOQ	NA
AEA09-FF-08-HW-C1	463SET13-6	NA	<LOQ	NA
AEA09-FF-08-HW-C2	463SET13-7	NA	<LOQ	NA
AEA09-FF-09-HW-C1	463SET14-7	NA	<LOQ	NA
AEA09-FF-09-HW-C2	463SET14-8	NA	<LOQ	NA

LOQ = 1.00 ng/mL (0.500 µg/sample where one sample is 500 mL)

Table 23 Summary of Field Fortification Recoveries for Hand Wash Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~2.00 µg/sample)				
AEA09-FF-01-HW-L1	463SET06-7	2.26	2.08	92.0
AEA09-FF-01-HW-L2	463SET06-8	2.26	1.99	88.1
AEA09-FF-01-HW-L3	463SET06-9	2.26	1.98	87.6
AEA09-FF-02-HW-L1	463SET07-8	2.26	1.94	85.8
AEA09-FF-02-HW-L2	463SET07-9	2.26	1.99	88.1
AEA09-FF-02-HW-L3	463SET07-10	2.26	1.89	83.6
AEA09-FF-03-HW-L1	463SET08-8	2.26	2.01	88.9
AEA09-FF-03-HW-L2	463SET08-9	2.26	1.98	87.6
AEA09-FF-03-HW-L3	463SET08-10	2.26	2.05	90.7
AEA09-FF-04-HW-L1	463SET09-8	2.26	1.81	80.1
AEA09-FF-04-HW-L2	463SET09-9	2.26	1.84	81.4
AEA09-FF-04-HW-L3	463SET09-10	2.26	1.94	85.8
AEA09-FF-05-HW-L1	463SET10-8	2.26	1.94	85.8
AEA09-FF-05-HW-L2	463SET10-9	2.26	1.79	79.2
AEA09-FF-05-HW-L3	463SET10-10	2.26	1.83	81.0
AEA09-FF-06-HW-L1	463SET11-8	2.26	1.87	82.7
AEA09-FF-06-HW-L2	463SET11-9	2.26	1.87	82.7
AEA09-FF-06-HW-L3	463SET11-10	2.26	1.86	82.3
AEA09-FF-07-HW-L1	463SET12-8	2.26	1.92	85.0
AEA09-FF-07-HW-L2	463SET12-9	2.26	2.00	88.5
AEA09-FF-07-HW-L3	463SET12-10	2.26	1.91	84.5
AEA09-FF-08-HW-L1	463SET13-8	2.26	2.00	88.5
AEA09-FF-08-HW-L2	463SET13-9	2.26	2.03	89.8
AEA09-FF-08-HW-L3	463SET13-10	2.26	1.89	83.6
AEA09-FF-09-HW-L1	463SET14-9	2.26	1.89	83.6
AEA09-FF-09-HW-L2	463SET14-10	2.26	1.93	85.4
AEA09-FF-09-HW-L3	463SET14-11	2.26	2.16	95.6
		Mean =	**1.94**	**85.8**
		Standard Deviation =	**0.0866**	**3.84**
		CV =	**4.46**	**4.48**

LOQ = 1.00 ng/mL (0.500 µg/sample where one sample is 500 mL)

Table 23 Summary of Field Fortification Recoveries for Hand Wash Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~200 µg/sample)				
AEA09-FF-01-HW-H1	463SET06-10	202	223	110
AEA09-FF-01-HW-H2	463SET06-11	208	212	102
AEA09-FF-01-HW-H3	463SET06-12	208	201	96.6
AEA09-FF-02-HW-H1	463SET07-11	196	176	89.8
AEA09-FF-02-HW-H2	463SET07-12	250	228	91.2
AEA09-FF-02-HW-H3	463SET07-13	214	199	93.0
AEA09-FF-03-HW-H1	463SET08-11	208	199	95.7
AEA09-FF-03-HW-H2	463SET08-12	226	216	95.6
AEA09-FF-03-HW-H3	463SET08-13	202	204	101
AEA09-FF-04-HW-H1	463SET09-11	202	199	98.5
AEA09-FF-04-HW-H2	463SET09-12	208	219	105
AEA09-FF-04-HW-H3	463SET09-13	202	193	95.5
AEA09-FF-05-HW-H1	463SET10-11	208	208	100
AEA09-FF-05-HW-H2	463SET10-12	202	203	100
AEA09-FF-05-HW-H3	463SET10-13	202	212	105
AEA09-FF-06-HW-H1	463SET11-11	196	186	94.9
AEA09-FF-06-HW-H2	463SET11-12	190	171	90.0
AEA09-FF-06-HW-H3	463SET11-13	190	187	98.4
AEA09-FF-07-HW-H1	463SET12-11	196	197	101
AEA09-FF-07-HW-H2	463SET12-12	226	240	106
AEA09-FF-07-HW-H3	463SET12-13	190	200	105
AEA09-FF-08-HW-H1	463SET13-11	214	199	93.0
AEA09-FF-08-HW-H2	463SET13-12	220	207	94.1
AEA09-FF-08-HW-H3	463SET13-13	202	180	89.1
AEA09-FF-09-HW-H1	463SET14-12	202	200	99.0
AEA09-FF-09-HW-H2	463SET14-13	202	237	117
AEA09-FF-09-HW-H3	463SET14-14	214	225	105
		Mean =	**204**	**98.9**
		Standard Deviation =	**17.2**	**6.61**
		CV =	**8.43**	**6.68**
			Overall Mean =	**92.4**
			Overall Standard Deviation =	**8.50**
			Overall CV =	**9.20**

LOQ = 1.00 ng/mL (0.500 µg/sample where one sample is 500 mL)

Table 24 Summary of Field Fortification Recoveries for Face/Neck Wipe Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-FW-C1	463SET15-7	NA	<LOQ	NA
AEA09-FF-01-FW-C2	463SET15-8	NA	<LOQ	NA
AEA09-FF-02-FW-C1	463SET16-7	NA	<LOQ	NA
AEA09-FF-02-FW-C2	463SET16-8	NA	<LOQ	NA
AEA09-FF-03-FW-C1	463SET17-8	NA	<LOQ	NA
AEA09-FF-03-FW-C2	463SET17-9	NA	<LOQ	NA
AEA09-FF-04-FW-C1	463SET18-7	NA	<LOQ	NA
AEA09-FF-04-FW-C2	463SET18-8	NA	<LOQ	NA
AEA09-FF-05-FW-C1	463SET19-6	NA	<LOQ	NA
AEA09-FF-05-FW-C2	463SET19-7	NA	<LOQ	NA
AEA09-FF-06-FW-C1	463SET20-9	NA	<LOQ	NA
AEA09-FF-06-FW-C2	463SET20-10	NA	<LOQ	NA
AEA09-FF-07-FW-C1	463SET21-9	NA	<LOQ	NA
AEA09-FF-07-FW-C2	463SET21-10	NA	<LOQ	NA
AEA09-FF-08-FW-C1	463SET22-11	NA	<LOQ	NA
AEA09-FF-08-FW-C2	463SET22-12	NA	<LOQ	NA
AEA09-FF-09-FW-C1	463SET23-9	NA	<LOQ	NA
AEA09-FF-09-FW-C2	463SET23-10	NA	<LOQ	NA

LOQ = 0.100 µg/sample

Table 24 Summary of Field Fortification Recoveries for Face/Neck Wipe Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~0.500 µg/sample)				
AEA09-FF-01-FW-L1	463SET15-9	0.452	0.384	85.0
AEA09-FF-01-FW-L2	463SET15-10	0.452	0.372	82.3
AEA09-FF-01-FW-L3	463SET15-11	0.452	0.367	81.2
AEA09-FF-02-FW-L1	463SET16-9	0.452	0.380	84.1
AEA09-FF-02-FW-L2	463SET16-10	0.452	0.374	82.7
AEA09-FF-02-FW-L3	463SET16-11	0.452	0.400	88.5
AEA09-FF-03-FW-L1	463SET17-10	0.452	0.372	82.3
AEA09-FF-03-FW-L2	463SET17-11	0.452	0.415	91.8
AEA09-FF-03-FW-L3	463SET17-12	0.452	0.361	79.9
AEA09-FF-04-FW-L1	463SET18-9	0.452	0.382	84.5
AEA09-FF-04-FW-L2	463SET18-10	0.452	0.363	80.3
AEA09-FF-04-FW-L3	463SET18-11	0.452	0.365	80.8
AEA09-FF-05-FW-L1	463SET19-8	0.452	0.372	82.3
AEA09-FF-05-FW-L2	463SET19-9	0.452	0.337	74.6
AEA09-FF-05-FW-L3	463SET19-10	0.452	0.378	83.6
AEA09-FF-06-FW-L1	463SET20-11	0.452	0.372	82.3
AEA09-FF-06-FW-L2	463SET20-12	0.452	0.378	83.6
AEA09-FF-06-FW-L3	463SET20-13	0.452	0.378	83.6
AEA09-FF-07-FW-L1	463SET21-11	0.452	0.387	85.6
AEA09-FF-07-FW-L2	463SET21-12	0.452	0.387	85.6
AEA09-FF-07-FW-L3	463SET21-13	0.452	0.363	80.3
AEA09-FF-08-FW-L1	463SET22-13	0.452	0.397	87.8
AEA09-FF-08-FW-L2	463SET22-14	0.452	0.380	84.1
AEA09-FF-08-FW-L3	463SET22-15	0.452	0.367	81.2
AEA09-FF-09-FW-L1	463SET23-11	0.452	0.348	77.0
AEA09-FF-09-FW-L2	463SET23-12	0.452	0.413	91.4
AEA09-FF-09-FW-L3	463SET23-13	0.452	0.341	75.4
		Mean =	**0.375**	**83.0**
		Standard Deviation =	**0.0183**	**4.05**
		CV =	**4.88**	**4.88**

LOQ = 0.100 µg/sample

Table 24 Summary of Field Fortification Recoveries for Face/Neck Wipe Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (10.0 µg/sample)				
AEA09-FF-01-FW-H1	463SET15-12	10.0	9.07	90.7
AEA09-FF-01-FW-H2	463SET15-13	10.0	8.89	88.9
AEA09-FF-01-FW-H3	463SET15-14	10.0	9.66	96.6
AEA09-FF-02-FW-H1	463SET16-12	10.0	9.39	93.9
AEA09-FF-02-FW-H2	463SET16-13	10.0	9.93	99.3
AEA09-FF-02-FW-H3	463SET16-14	10.0	9.39	93.9
AEA09-FF-03-FW-H1	463SET17-13	10.0	7.44	74.4
AEA09-FF-03-FW-H2	463SET17-14	10.0	7.03	70.3
AEA09-FF-03-FW-H3	463SET17-15	10.0	7.71	77.1
AEA09-FF-04-FW-H1	463SET18-12	10.0	9.03	90.3
AEA09-FF-04-FW-H2	463SET18-13	10.0	8.44	84.4
AEA09-FF-04-FW-H3	463SET18-14	10.0	7.26	72.6
AEA09-FF-05-FW-H1	463SET19-11	10.0	9.34	93.4
AEA09-FF-05-FW-H2	463SET19-12	10.0	10.2	102
AEA09-FF-05-FW-H3	463SET19-13	10.0	10.2	102
AEA09-FF-06-FW-H1	463SET20-14	10.0	8.39	83.9
AEA09-FF-06-FW-H2	463SET20-15	10.0	8.53	85.3
AEA09-FF-06-FW-H3	463SET20-16	10.0	9.21	92.1
AEA09-FF-07-FW-H1	463SET21-14	10.0	10.2	102
AEA09-FF-07-FW-H2	463SET21-15	10.0	9.48	94.8
AEA09-FF-07-FW-H3	463SET21-16	10.0	10.2	102
AEA09-FF-08-FW-H1	463SET22-16	10.0	8.71	87.1
AEA09-FF-08-FW-H2	463SET22-17	10.0	9.39	93.9
AEA09-FF-08-FW-H3	463SET22-18	10.0	9.71	97.1
AEA09-FF-09-FW-H1	463SET23-14	10.0	9.07	90.7
AEA09-FF-09-FW-H2	463SET23-15	10.0	9.71	97.1
AEA09-FF-09-FW-H3	463SET23-16	10.0	10.2	102
		Mean =	**9.10**	**91.0**
		Standard Deviation =	**0.922**	**9.22**
		CV =	**10.1**	**10.1**
			Overall Mean =	**87.0**
			Overall Standard Deviation =	**8.13**
			Overall CV =	**9.34**

LOQ = 0.100 µg/sample

Table 25 Summary of Field Fortification Recoveries for Inner Dosimeters Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-ID-C1	463SET46-11	NA	<LOQ	NA
AEA09-FF-01-ID-C2	463SET46-12	NA	853	NA
AEA09-FF-02-ID-C1	463SET49-17	NA	512	NA
AEA09-FF-02-ID-C2	463SET49-18	NA	338	NA
AEA09-FF-03-ID-C1	463SET52-18	NA	654	NA
AEA09-FF-03-ID-C2	463SET52-19	NA	306	NA
AEA09-FF-04-ID-C1	463SET55-17	NA	1295 (1380[a])	NA
AEA09-FF-04-ID-C2	463SET55-18	NA	<LOQ	NA
AEA09-FF-05-ID-C1	463SET60-16	NA	287 (289[a])	NA
AEA09-FF-05-ID-C2	463SET60-17	NA	<LOQ	NA
AEA09-FF-06-ID-C1	463SET63-18	NA	<LOQ	NA
AEA09-FF-06-ID-C2	463SET63-19	NA	17.9	NA
AEA09-FF-07-ID-C1	463SET64-18	NA	406	NA
AEA09-FF-07-ID-C2	463SET64-19	NA	303	NA
AEA09-FF-08-ID-C1	463SET71-18	NA	<LOQ	NA
AEA09-FF-08-ID-C2	463SET71-19	NA	771	NA
AEA09-FF-09-ID-C1	463SET72-18	NA	558	NA
AEA09-FF-09-ID-C2	463SET73-9	NA	645	NA

LOQ = 3.00 µg/sample

[a] Reanalysis conducted to confirm residues in field control.

Table 25 Summary of Field Fortification Recoveries for Inner Dosimeters Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~12.0 µg/sample)				
AEA09-FF-01-ID-L1	463SET46-13	12.0	11.9	99.2
AEA09-FF-01-ID-L2	463SET46-14	12.0	10.9	90.8
AEA09-FF-01-ID-L3	463SET46-15	12.0	13.0	108
AEA09-FF-02-ID-L1	463SET49-19	12.0	727	6058[a]
AEA09-FF-02-ID-L2	463SET49-20	12.0	298	2483[a]
AEA09-FF-02-ID-L3	463SET49-21	12.0	476	3967[a]
AEA09-FF-03-ID-L1	463SET52-20	12.0	397	3308[a]
AEA09-FF-03-ID-L2	463SET52-21	12.0	11.2	93.3
AEA09-FF-03-ID-L3	463SET52-22	12.0	548	4567[a]
AEA09-FF-04-ID-L1	463SET55-19	12.0	11.0	91.7
AEA09-FF-04-ID-L2	463SET55-20	12.0	10.4	86.7
AEA09-FF-04-ID-L3	463SET55-21	12.0	11.0	91.7
AEA09-FF-05-ID-L1	463SET60-18	12.0	221 (217[b])	1842[a] (1808[a,b])
AEA09-FF-05-ID-L2	463SET60-19	12.0	333 (292[b])	2775[a] (2433[a,b])
AEA09-FF-05-ID-L3	463SET60-20	12.0	12.0	100
AEA09-FF-06-ID-L1	463SET63-20	12.0	10.1	84.2
AEA09-FF-06-ID-L2	463SET63-21	12.0	11.1	92.5
AEA09-FF-06-ID-L3	463SET63-22	12.0	10.3	85.8
AEA09-FF-07-ID-L1	463SET64-20	12.0	538	4483[a]
AEA09-FF-07-ID-L2	463SET64-21	12.0	9.68	80.7
AEA09-FF-07-ID-L3	463SET64-22	12.0	406	3383[a]
AEA09-FF-08-ID-L1	463SET71-20	12.0	12.4	103
AEA09-FF-08-ID-L2	463SET71-21	12.0	379	3158[a]
AEA09-FF-08-ID-L3	463SET71-22	12.0	265	2208[a]
AEA09-FF-09-ID-L1	463SET72-19	12.0	574	4783[a]
AEA09-FF-09-ID-L2	463SET72-20	12.0	12.3	103
AEA09-FF-09-ID-L3	463SET73-10	12.0	10.8	90.0
		Mean =	**197**	**1645**
		Standard Deviation =	**233**	**1940**
		CV =	**118**	**118**

LOQ = 3.00 µg/sample

[a] Percent Recovery >120%.

[b] Reanalysis conducted to confirm recoveries (not included in mean, standard deviation or coefficient of variation calculations).

Table 25 Summary of Field Fortification Recoveries for Inner Dosimeters Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~1000 µg/sample)				
AEA09-FF-01-ID-H1	463SET46-16	1053	915	86.9
AEA09-FF-01-ID-H2	463SET46-17	1017	945	92.9
AEA09-FF-01-ID-H3	463SET46-18	1232	1471	119
AEA09-FF-02-ID-H1	463SET49-22	1083	1376	127[a]
AEA09-FF-02-ID-H2	463SET49-23	1125	1018	90.5
AEA09-FF-02-ID-H3	463SET49-24	1160	1180	102
AEA09-FF-03-ID-H1	463SET52-23	1059	1474 (1421[b])	139[a] (134[a,b])
AEA09-FF-03-ID-H2	463SET52-24	1113	1054	94.7
AEA09-FF-03-ID-H3	463SET52-25	1053	864	82.1
AEA09-FF-04-ID-H1	463SET55-22	1035	914	88.3
AEA09-FF-04-ID-H2	463SET55-23	1089	900	82.6
AEA09-FF-04-ID-H3	463SET55-24	1131	973	86.0
AEA09-FF-05-ID-H1	463SET60-21	1113	1380 (1323[b])	124[a] (119[b])
AEA09-FF-05-ID-H2	463SET60-22	1065	1110	104
AEA09-FF-05-ID-H3	463SET60-23	1053	1651 (1591[b])	157[a] (151[a,b])
AEA09-FF-06-ID-H1	463SET63-23	1053	998	94.8
AEA09-FF-06-ID-H2	463SET63-24	1053	1412 (1494[b])	134[a] (142[a,b])
AEA09-FF-06-ID-H3	463SET63-25	1107	1048	94.7
AEA09-FF-07-ID-H1	463SET64-23	1208	1294	107
AEA09-FF-07-ID-H2	463SET64-24	1131	1460 (1289[b])	129[a] (114[b])
AEA09-FF-07-ID-H3	463SET64-25	1017	1142	112
AEA09-FF-08-ID-H1	463SET71-23	1095	930	84.9
AEA09-FF-08-ID-H2	463SET71-24	1077	1024	95.1
AEA09-FF-08-ID-H3	463SET71-25	1131	1006	88.9
AEA09-FF-09-ID-H1	463SET72-21	1095	1339	122[a]
AEA09-FF-09-ID-H2	463SET72-22	1142	1027	89.9
AEA09-FF-09-ID-H3	463SET73-11	1148	983	85.6
		Mean =	**1144**	**104**
		Standard Deviation =	**224**	**20.3**
		CV =	**19.6**	**19.5**
			Overall Mean =	**875**
			Overall Standard Deviation =	**1565**
			Overall CV =	**179**

LOQ = 3.00 µg/sample

[a] Percent Recovery >120%.

[b] Reanalysis conducted to confirm recoveries (not included in mean, standard deviation or coefficient of variation calculations).

Table 26 Summary of Field Fortification Recoveries for Painter's Hat Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-PH-C1	463SET45-5	NA	<LOQ	NA
AEA09-FF-01-PH-C2	463SET45-6	NA	<LOQ	NA
AEA09-FF-02-PH-C1	463SET48-6	NA	<LOQ	NA
AEA09-FF-02-PH-C2	463SET48-7	NA	<LOQ	NA
AEA09-FF-03-PH-C1	463SET51-6	NA	<LOQ	NA
AEA09-FF-03-PH-C2	463SET51-7	NA	<LOQ	NA
AEA09-FF-04-PH-C1	463SET54-6	NA	<LOQ	NA
AEA09-FF-04-PH-C2	463SET54-7	NA	<LOQ	NA
AEA09-FF-05-PH-C1	463SET57-6	NA	<LOQ	NA
AEA09-FF-05-PH-C2	463SET57-7	NA	<LOQ	NA
AEA09-FF-06-PH-C1	463SET59-6	NA	<LOQ	NA
AEA09-FF-06-PH-C2	463SET59-7	NA	<LOQ	NA
AEA09-FF-07-PH-C1	463SET62-6	NA	<LOQ	NA
AEA09-FF-07-PH-C2	463SET62-7	NA	<LOQ	NA
AEA09-FF-08-PH-C1	463SET66-6	NA	<LOQ	NA
AEA09-FF-08-PH-C2	463SET66-7	NA	<LOQ	NA
AEA09-FF-09-PH-C1	463SET69-7	NA	<LOQ	NA
AEA09-FF-09-PH-C2	463SET69-8	NA	<LOQ	NA

LOQ = 3.00 µg/sample

Table 26 Summary of Field Fortification Recoveries for Painter's Hat Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~12.0 µg/sample)				
AEA09-FF-01-PH-L1	463SET45-7	12.0	10.2	85.0
AEA09-FF-01-PH-L2	463SET45-8	12.0	10.8	90.0
AEA09-FF-01-PH-L3	463SET45-9	12.0	10.5	87.5
AEA09-FF-02-PH-L1	463SET48-8	12.0	11.1	92.5
AEA09-FF-02-PH-L2	463SET48-9	12.0	9.28	77.3
AEA09-FF-02-PH-L3	463SET48-10	12.0	12.1	101
AEA09-FF-03-PH-L1	463SET51-8	12.0	10.0	83.3
AEA09-FF-03-PH-L2	463SET51-9	12.0	10.8	90.0
AEA09-FF-03-PH-L3	463SET51-10	12.0	10.7	89.2
AEA09-FF-04-PH-L1	463SET54-8	12.0	11.4	95.0
AEA09-FF-04-PH-L2	463SET54-9	12.0	11.6	96.7
AEA09-FF-04-PH-L3	463SET54-10	12.0	11.8	98.3
AEA09-FF-05-PH-L1	463SET57-8	12.0	10.8	90.0
AEA09-FF-05-PH-L2	463SET57-9	12.0	10.2	85.0
AEA09-FF-05-PH-L3	463SET57-10	12.0	10.7	89.2
AEA09-FF-06-PH-L1	463SET59-8	12.0	10.0	83.3
AEA09-FF-06-PH-L2	463SET59-9	12.0	9.12	76.0
AEA09-FF-06-PH-L3	463SET59-10	12.0	9.00	75.0
AEA09-FF-07-PH-L1	463SET62-8	12.0	8.00 (8.36[b])	66.7[a] (69.7 [a,b])
AEA09-FF-07-PH-L2	463SET62-9	12.0	9.64	80.3
AEA09-FF-07-PH-L3	463SET62-10	12.0	7.48 (7.52[b])	62.3[a] (62.7 [a,b])
AEA09-FF-08-PH-L1	463SET66-8	12.0	9.52	79.3
AEA09-FF-08-PH-L2	463SET66-9	12.0	9.28	77.3
AEA09-FF-08-PH-L3	463SET66-10	12.0	9.00	75.0
AEA09-FF-09-PH-L1	463SET69-9	12.0	10.5	87.5
AEA09-FF-09-PH-L2	463SET69-10	12.0	10.5	87.5
AEA09-FF-09-PH-L3	463SET69-11	12.0	9.96	83.0
		Mean =	**10.1**	**84.6**
		Standard Deviation =	**1.09**	**9.12**
		CV =	**10.8**	**10.8**

LOQ = 3.00 µg/sample

[a] Percent Recovery < 70%

[b] Reanalysis conducted to confirm recoveries (not included in mean, standard deviation or coefficient of variation calculations).

Table 26 Summary of Field Fortification Recoveries for Painter's Hat Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~1000 µg/sample)				
AEA09-FF-01-PH-H1	463SET45-10	1047	1054	101
AEA09-FF-01-PH-H2	463SET45-11	1095	974	88.9
AEA09-FF-01-PH-H3	463SET45-12	1107	1071	96.7
AEA09-FF-02-PH-H1	463SET48-11	1059	1046	98.8
AEA09-FF-02-PH-H2	463SET48-12	1071	1063	99.3
AEA09-FF-02-PH-H3	463SET48-13	1065	1087	102
AEA09-FF-03-PH-H1	463SET51-11	1035	1091	105
AEA09-FF-03-PH-H2	463SET51-12	1023	953	93.2
AEA09-FF-03-PH-H3	463SET51-13	1154	1099	95.2
AEA09-FF-04-PH-H1	463SET54-11	1017	1022	100
AEA09-FF-04-PH-H2	463SET54-12	1035	1071	103
AEA09-FF-04-PH-H3	463SET54-13	1119	1071	95.7
AEA09-FF-05-PH-H1	463SET57-11	1053	1018	96.7
AEA09-FF-05-PH-H2	463SET57-12	1059	953	90.0
AEA09-FF-05-PH-H3	463SET57-13	1041	1006	96.6
AEA09-FF-06-PH-H1	463SET59-11	1047	1014	96.8
AEA09-FF-06-PH-H2	463SET59-12	1059	848	80.1
AEA09-FF-06-PH-H3	463SET59-13	1041	861	82.7
AEA09-FF-07-PH-H1	463SET62-11	1053	881	83.7
AEA09-FF-07-PH-H2	463SET62-12	1077	941	87.4
AEA09-FF-07-PH-H3	463SET62-13	1047	861	82.2
AEA09-FF-08-PH-H1	463SET66-11	1029	917	89.1
AEA09-FF-08-PH-H2	463SET66-12	1083	901	83.2
AEA09-FF-08-PH-H3	463SET66-13	1023	974	95.2
AEA09-FF-09-PH-H1	463SET69-12	1047	917	87.6
AEA09-FF-09-PH-H2	463SET69-13	1095	1002	91.5
AEA09-FF-09-PH-H3	463SET69-14	1047	917	87.6
		Mean =	**986**	**92.9**
		Standard Deviation =	**78.7**	**7.04**
		CV =	**7.98**	**7.58**
			Overall Mean =	**88.7**
			Overall Standard Deviation =	**9.11**
			Overall CV =	**10.3**

LOQ = 3.00 µg/sample

Table 27 Summary of Field Fortification Recoveries for Outer Dosimeters Samples

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Control				
AEA09-FF-01-OD-C1	463SET44-10	NA	9.96	NA
AEA09-FF-01-OD-C2	463SET44-11	NA	<LOQ	NA
AEA09-FF-02-OD-C1	463SET47-16	NA	7.88	NA
AEA09-FF-02-OD-C2	463SET47-17	NA	8.24	NA
AEA09-FF-03-OD-C1	463SET50-16	NA	<LOQ	NA
AEA09-FF-03-OD-C2	463SET50-17	NA	<LOQ	NA
AEA09-FF-04-OD-C1	463SET53-16	NA	5.72 (4.32[a])	NA
AEA09-FF-04-OD-C2	463SET53-17	NA	3.78 (<LOQ[a])	NA
AEA09-FF-05-OD-C1	463SET56-16	NA	5.44 (6.00[a])	NA
AEA09-FF-05-OD-C2	463SET56-17	NA	<LOQ	NA
AEA09-FF-06-OD-C1	463SET58-16	NA	10.5 (12.5[a])	NA
AEA09-FF-06-OD-C2	463SET58-17	NA	22.5 (26.6[a])	NA
AEA09-FF-07-OD-C1	463SET61-16	NA	20.7 (20.2[a])	NA
AEA09-FF-07-OD-C2	463SET61-17	NA	<LOQ	NA
AEA09-FF-08-OD-C1	463SET65-16	NA	16.8 (17.1[a])	NA
AEA09-FF-08-OD-C2	463SET65-17	NA	<LOQ	NA
AEA09-FF-09-OD-C1	463SET67-16	NA	<LOQ	NA
AEA09-FF-09-OD-C2	463SET68-10	NA	<LOQ	NA

LOQ = 3.00 µg/sample

[a] Reanalysis conducted to confirm residues in field control.

Table 27 Summary of Field Fortification Recoveries for Outer Dosimeters Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
Low Fortification (~12.0 µg/sample)				
AEA09-FF-01-OD-L1	463SET44-12	12.0	10.4	86.7
AEA09-FF-01-OD-L2	463SET44-13	12.0	11.3	94.2
AEA09-FF-01-OD-L3	463SET44-14	12.0	11.4	95.0
AEA09-FF-02-OD-L1	463SET47-18	12.0	15.2 (14.6[b])	127[a] (122[a,b])
AEA09-FF-02-OD-L2	463SET47-19	12.0	15.4 (14.2[b])	128[a] (118[b])
AEA09-FF-02-OD-L3	463SET47-20	12.0	12.2	102
AEA09-FF-03-OD-L1	463SET50-18	12.0	14.1	118
AEA09-FF-03-OD-L2	463SET50-19	12.0	16.4 (16.0[b])	137[a] (133[a,b])
AEA09-FF-03-OD-L3	463SET50-20	12.0	11.1	92.5
AEA09-FF-04-OD-L1	463SET53-18	12.0	13.6	113
AEA09-FF-04-OD-L2	463SET53-19	12.0	13.4	112
AEA09-FF-04-OD-L3	463SET53-20	12.0	12.2	102
AEA09-FF-05-OD-L1	463SET56-18	12.0	9.80	81.7
AEA09-FF-05-OD-L2	463SET56-19	12.0	11.3	94.2
AEA09-FF-05-OD-L3	463SET56-20	12.0	12.7	106
AEA09-FF-06-OD-L1	463SET58-18	12.0	23.4 (24.7[b])	195[a] (206[a,b])
AEA09-FF-06-OD-L2	463SET58-19	12.0	9.76	81.3
AEA09-FF-06-OD-L3	463SET58-20	12.0	13.2	110
AEA09-FF-07-OD-L1	463SET61-18	12.0	18.0 (16.0[b])	150[a] (133[a,b])
AEA09-FF-07-OD-L2	463SET61-19	12.0	12.8	107
AEA09-FF-07-OD-L3	463SET61-20	12.0	13.2	110
AEA09-FF-08-OD-L1	463SET65-18	12.0	11.2	93.3
AEA09-FF-08-OD-L2	463SET65-19	12.0	11.4	95.0
AEA09-FF-08-OD-L3	463SET65-20	12.0	24.4 (24.2[b])	203[a] (202[a,b])
AEA09-FF-09-OD-L1	463SET67-17	12.0	13.4	112
AEA09-FF-09-OD-L2	463SET67-18	12.0	12.8	107
AEA09-FF-09-OD-L3	463SET68-11	12.0	16.1 (15.7[b])	134[a] (131[a,b])
		Mean =	**13.7**	**114**
		Standard Deviation =	**3.56**	**29.6**
		CV =	**26.0**	**26.0**

LOQ = 3.00 µg/sample

[a] Percent Recovery >120%.

[b] Reanalysis conducted to confirm recoveries (not included in mean, standard deviation or coefficient of variation calculations).

Table 27 Summary of Field Fortification Recoveries for Outer Dosimeters Samples (continued)

Sample Number	Laboratory ID	Fortification Amount (µg/sample)	Sample Concentration (µg/sample)	Percent Recovery (%)
High Fortification (~1000 µg/sample)				
AEA09-FF-01-OD-H1	463SET44-15	1119	929	83.0
AEA09-FF-01-OD-H2	463SET44-16	1017	937	92.1
AEA09-FF-01-OD-H3	463SET44-17	1131	1026	90.7
AEA09-FF-02-OD-H1	463SET47-21	1041	917	88.1
AEA09-FF-02-OD-H2	463SET47-22	1023	929	90.8
AEA09-FF-02-OD-H3	463SET47-23	1053	909	86.3
AEA09-FF-03-OD-H1	463SET50-21	1077	953	88.5
AEA09-FF-03-OD-H2	463SET50-22	1089	1002	92.0
AEA09-FF-03-OD-H3	463SET50-23	1089	1054	96.8
AEA09-FF-04-OD-H1	463SET53-21	1035	1131	109
AEA09-FF-04-OD-H2	463SET53-22	1012	1018	101
AEA09-FF-04-OD-H3	463SET53-23	1029	1018	98.9
AEA09-FF-05-OD-H1	463SET56-21	1071	986	92.1
AEA09-FF-05-OD-H2	463SET56-22	1083	1034	95.5
AEA09-FF-05-OD-H3	463SET56-23	1101	990	89.9
AEA09-FF-06-OD-H1	463SET58-21	1023	974	95.2
AEA09-FF-06-OD-H2	463SET58-22	1047	957	91.4
AEA09-FF-06-OD-H3	463SET58-23	1071	1022	95.4
AEA09-FF-07-OD-H1	463SET61-21	1131	1050	92.8
AEA09-FF-07-OD-H2	463SET61-22	1035	1075	104
AEA09-FF-07-OD-H3	463SET61-23	1035	957	92.5
AEA09-FF-08-OD-H1	463SET65-21	1160	925	79.7
AEA09-FF-08-OD-H2	463SET65-22	1107	949	85.7
AEA09-FF-08-OD-H3	463SET65-23	1065	921	86.5
AEA09-FF-09-OD-H1	463SET67-19	1023	1030	101
AEA09-FF-09-OD-H2	463SET67-20	1065	945	88.7
AEA09-FF-09-OD-H3	463SET68-12	1160	1022	88.1
		Mean =	**987**	**92.4**
		Standard Deviation =	**56.1**	**6.48**
		CV =	**5.68**	**7.01**
			Overall Mean =	**103**
			Overall Standard Deviation =	**23.9**
			Overall CV =	**23.2**

LOQ = 3.00 µg/sample

Table 28 Residue Data Summary for Air Sampling Tubes

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]
ME01	463SET33-4	AEA09-BRS-01-AR	<LOQ	<LOQ
ME02	463SET34-4	AEA09-BRS-02-AR	<LOQ	<LOQ
ME03	463SET34-5	AEA09-BRS-03-AR	<LOQ	<LOQ
ME04	463SET35-4	AEA09-BRS-04-AR	<LOQ	<LOQ
ME05	463SET35-5	AEA09-BRS-05-AR	<LOQ	<LOQ
ME06	463SET37-4	AEA09-BRS-06-AR	<LOQ	<LOQ
ME07	463SET37-5	AEA09-BRS-07-AR	<LOQ	<LOQ
ME08	463SET38-4	AEA09-BRS-08-AR	<LOQ	<LOQ
ME09	463SET38-5	AEA09-BRS-09-AR	<LOQ	<LOQ
ME10	463SET39-4	AEA09-BRS-10-AR	<LOQ	<LOQ
ME11	463SET39-5	AEA09-BRS-11-AR	<LOQ	<LOQ
ME12	463SET40-4	AEA09-BRS-12-AR	<LOQ	<LOQ
ME13	463SET40-5	AEA09-BRS-13-AR	<LOQ	<LOQ
ME14	463SET41-4	AEA09-BRS-14-AR	<LOQ	<LOQ
ME15	463SET41-5	AEA09-BRS-15-AR	<LOQ	<LOQ
ME16	463SET70-4	AEA09-BRS-16-AR	<LOQ	<LOQ
ME17	463SET70-5	AEA09-BRS-17-AR	<LOQ	<LOQ
ME18	463SET70-6	AEA09-BRS-18-AR	<LOQ	<LOQ

LOQ = 0.0100 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

Table 29 Residue Data Summary for Fiberglass Filter Samples

Monitoring Event	Lab ID	Sample ID	Filter Pore Size (µm)	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	Total Corrected Residue (µg/sample)[b]
ME01	463SET24-4	AEA09-BRS-01-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET24-5	AEA09-BRS-01-RES-02	10	<LOQ	<LOQ	
	463SET24-6	AEA09-BRS-01-RES-03	2.5	<LOQ	<LOQ	
ME02	463SET25-4	AEA09-BRS-02-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET25-5	AEA09-BRS-02-RES-02	10	<LOQ	<LOQ	
	463SET25-6	AEA09-BRS-02-RES-03	2.5	<LOQ	<LOQ	
ME03	463SET25-7	AEA09-BRS-03-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET25-8	AEA09-BRS-03-RES-02	10	<LOQ	<LOQ	
	463SET25-9	AEA09-BRS-03-RES-03	2.5	<LOQ	<LOQ	
ME04	463SET26-4	AEA09-BRS-04-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET26-5	AEA09-BRS-04-RES-02	10	<LOQ	<LOQ	
	463SET26-6	AEA09-BRS-04-RES-03	2.5	<LOQ	<LOQ	
ME05	463SET26-7	AEA09-BRS-05-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET26-8	AEA09-BRS-05-RES-02	10	<LOQ	<LOQ	
	463SET26-9	AEA09-BRS-05-RES-03	2.5	<LOQ	<LOQ	
ME06	463SET27-4	AEA09-BRS-06-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET27-5	AEA09-BRS-06-RES-02	10	<LOQ	<LOQ	
	463SET27-6	AEA09-BRS-06-RES-03	2.5	<LOQ	<LOQ	
ME07	463SET27-7	AEA09-BRS-07-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET27-8	AEA09-BRS-07-RES-02	10	<LOQ	<LOQ	
	463SET27-9	AEA09-BRS-07-RES-03	2.5	<LOQ	<LOQ	
ME08	463SET28-4	AEA09-BRS-08-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET28-5	AEA09-BRS-08-RES-02	10	<LOQ	<LOQ	
	463SET28-6	AEA09-BRS-08-RES-03	2.5	<LOQ	<LOQ	
ME09	463SET28-7	AEA09-BRS-09-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET28-8	AEA09-BRS-09-RES-02	10	<LOQ	<LOQ	
	463SET28-9	AEA09-BRS-09-RES-03	2.5	<LOQ	<LOQ	
ME10	463SET29-4	AEA09-BRS-10-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET29-5	AEA09-BRS-10-RES-02	10	<LOQ	<LOQ	
	463SET29-6	AEA09-BRS-10-RES-03	2.5	<LOQ	<LOQ	
ME11	463SET29-7	AEA09-BRS-11-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET29-8	AEA09-BRS-11-RES-02	10	<LOQ	<LOQ	
	463SET29-9	AEA09-BRS-11-RES-03	2.5	<LOQ	<LOQ	

LOQ = 0.0100 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Total Residue = Sum of All Residues for that Particular Subject

Table 29 Residue Data Summary for Fiberglass Filter Samples (continued)

Monitoring Event	Lab ID	Sample ID	Filter Pore Size (µm)	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	Total Corrected Residue (µg/sample)[b]
ME12	463SET30-4	AEA09-BRS-12-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET30-5	AEA09-BRS-12-RES-02	10	<LOQ	<LOQ	
	463SET30-6	AEA09-BRS-12-RES-03	2.5	<LOQ	<LOQ	
ME13	463SET30-7	AEA09-BRS-13-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET30-8	AEA09-BRS-13-RES-02	10	<LOQ	<LOQ	
	463SET30-9	AEA09-BRS-13-RES-03	2.5	<LOQ	<LOQ	
ME14	463SET31-4	AEA09-BRS-14-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET31-5	AEA09-BRS-14-RES-02	10	<LOQ	<LOQ	
	463SET31-6	AEA09-BRS-14-RES-03	2.5	<LOQ	<LOQ	
ME15	463SET31-7	AEA09-BRS-15-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET31-8	AEA09-BRS-15-RES-02	10	<LOQ	<LOQ	
	463SET31-9	AEA09-BRS-15-RES-03	2.5	<LOQ	<LOQ	
ME16	463SET32-4	AEA09-BRS-16-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET32-5	AEA09-BRS-16-RES-02	10	<LOQ	<LOQ	
	463SET32-6	AEA09-BRS-16-RES-03	2.5	<LOQ	<LOQ	
ME17	463SET32-7	AEA09-BRS-17-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET32-8	AEA09-BRS-17-RES-02	10	<LOQ	<LOQ	
	463SET32-9	AEA09-BRS-17-RES-03	2.5	<LOQ	<LOQ	
ME18	463SET32-10	AEA09-BRS-18-RES-01	100	<LOQ	<LOQ	<LOQ
	463SET32-11	AEA09-BRS-18-RES-02	10	<LOQ	<LOQ	
	463SET32-12	AEA09-BRS-18-RES-03	2.5	<LOQ	<LOQ	

LOQ = 0.0100 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Total Residue = Sum of All Residues for that Particular Subject

Table 30 Residue Data Summary for Hand Wash Samples

Monitoring Event Conducted	Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	Residue Corrected for Removal Efficiency[b]
Low	ME-01	463SET06-4	AEA09-BRS-01-HW-01	417	434	592
	ME-02	463SET07-4	AEA09-BRS-02-HW-01	76.8	86.7	118
	ME-04	463SET08-4	AEA09-BRS-04-HW-01	76.5	82.0	112
	ME-11	463SET11-5	AEA09-BRS-11-HW-01	123	139	190
	ME-13	463SET12-5	AEA09-BRS-13-HW-01	96.9	102	139
	ME-18	463SET14-6	AEA09-BRS-18-HW-01	113	116	158
					Mean	**218**
					Standard Deviation	**185**
Mid	ME-05	463SET08-5	AEA09-BRS-05-HW-01	792	849	1271
	ME-08	463SET10-4	AEA09-BRS-08-HW-01	965	1051	1573
	ME-10	463SET11-4	AEA09-BRS-10-HW-01	125	141	211
	ME-12	463SET12-4	AEA09-BRS-12-HW-01	463	487	729
	ME-14	463SET13-4	AEA09-BRS-14-HW-01	224	250	374
	ME-15	463SET13-5	AEA09-BRS-15-HW-01	2424	2702	4045
					Mean	**1367**
					Standard Deviation	**1411**
High	ME-03	463SET07-5	AEA09-BRS-03-HW-01	1081	1220	2023
	ME-06	463SET09-7	AEA09-BRS-06-HW-01	167	183	303
	ME-07	463SET09-5	AEA09-BRS-07-HW-01	457	502	833
	ME-09	463SET10-5	AEA09-BRS-09-HW-01	114	124	206
	ME-16	463SET14-4	AEA09-BRS-16-HW-01	37.7	38.6	64.0
	ME-17	463SET14-5	AEA09-BRS-17-HW-01	542	555	920
					Mean	**725**
					Standard Deviation	**724**

LOQ = 1.00 ng/mL (0.500 µg/sample where one sample is 500 mL)

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Removal Efficiency Corrected Residue = (Corrected Residue x 100) ÷ Removal Efficiency for each level of BIT concentration of paint.

Removal efficiency for base paint (low level paint) is 73.3% and for high paint the removal efficiency is 60.3%. For mid level paint, the average of these two values is used, 66.8%. These values were determined in Removal Efficiency Study, GPL#130503. (Boatwright, M.T. 2017). For further clarification see Section 8.4

Table 31 Residue Data Summary for Face/Neck Wipe Samples from Subjects Painting with Low Level Paint

Monitoring Event Conducted	Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	PPE Corrected Residue (µg/sample)[b]	Residue Corrected for Removal Efficiency (µg/sample)[c]	Sum of Corrected Sample Residues (µg/sample)[d]
Low	ME-01	463SET15-4	AEA09-BRS-01-FW-01	<LOQ	<LOQ	<LOQ	<LOQ	0.150
		463SET15-5	AEA09-BRS-01-SW-01	<LOQ	<LOQ	<LOQ	NA	
		463SET15-6	AEA09-BRS-01-SW-02	<LOQ	<LOQ	<LOQ	NA	
	ME-02	463SET16-4	AEA09-BRS-02-FW-01	<LOQ	<LOQ	<LOQ	<LOQ	0.100
		463SET16-5	AEA09-BRS-02-SW-01	<LOQ	<LOQ	<LOQ	NA	
	ME-04	463SET17-4	AEA09-BRS-04-FW-01	0.553	0.697	0.774	1.06	1.16
		463SET17-5	AEA09-BRS-04-SW-01	<LOQ	<LOQ	<LOQ	<LOQ	
		463SET17-6	AEA09-BRS-04-SW-02	<LOQ	<LOQ	<LOQ	NA	
	ME-11	463SET20-7	AEA09-BRS-11-FW-01	<LOQ	<LOQ	<LOQ	<LOQ	0.100
		463SET20-8	AEA09-BRS-11-SW-01	<LOQ	<LOQ	<LOQ	NA	
	ME-13	463SET21-6	AEA09-BRS-13-FW-01	0.104	0.113	0.125	0.171	0.351
		463SET21-7	AEA09-BRS-13-SW-01	0.107	0.117	0.130	NA	
		463SET21-8	AEA09-BRS-13-SW-02	<LOQ	<LOQ	<LOQ	NA	
	ME-18	463SET23-6	AEA09-BRS-18-FW-01	<LOQ	<LOQ	<LOQ	<LOQ	6.01
		463SET23-7	AEA09-BRS-18-SW-01	4.73	5.32	5.91	NA	
		463SET23-8	AEA09-BRS-18-SW-02	<LOQ	<LOQ	<LOQ	NA	
							Mean	**1.31**
							Standard Deviation	**2.34**

LOQ = 0.100 µg/sample

PPE = Personal protective equipment.

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] PPE Corrected Residue = (Corrected Residue x 1.11). PPE factor of 1.11 is from the AEATF SOP.

[c] Removal Efficiency Corrected Residue = (Corrected Residue x 100) ÷ Removal efficiency for base paint (low level paint) [73.3%]. Removal Efficiency correction is only performed on wetted dressing sponge samples (FW). For sweat wipes, which are not wetted, removal efficiency factor is not applied. Value determined in Removal Efficiency Study, GPL#130503. (Boatwright, M.T. 2017). For further clarification see Section 8.4

[d] Sum of Corrected Sample Residues = (PPE Corrected Residue values if applicable for sweat wipe samples) + Residue Corrected for Removal Efficiency for face/neck wipe samples)

Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 32 Residue Data Summary for Face/Neck Wipe Samples from Subjects Painting with Mid Level Paint

Monitoring Event Conducted	Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	PPE Corrected Residue (µg/sample)[b]	Residue Corrected for Removal Efficiency (µg/sample)[c]	Sum of Corrected Sample Residues (µg/sample)[d]
Mid	ME-05	463SET17-7	AEA09-BRS-05-FW-01	7.51	9.47	10.5	15.7	15.7
	ME-08	463SET19-4	AEA09-BRS-08-FW-01	0.257	0.287	0.319	0.478	0.478
	ME-10	463SET20-4	AEA09-BRS-10-FW-01	0.609	0.716	0.795	1.19	2.83
		463SET20-5	AEA09-BRS-10-SW-01	<LOQ	<LOQ	<LOQ	NA	
		463SET20-6	AEA09-BRS-10-SW-02	1.22	1.43	1.59	NA	
	ME-12	463SET21-4	AEA09-BRS-12-FW-01	1.66	1.81	2.01	3.01	3.18
		463SET21-5	AEA09-BRS-12-SW-01	0.137	0.149	0.165	NA	
	ME-14	463SET22-4	AEA09-BRS-14-FW-01	0.551	0.623	0.692	1.04	1.19
		463SET22-5	AEA09-BRS-14-SW-01	<LOQ	<LOQ	<LOQ	NA	
		463SET22-6	AEA09-BRS-14-SW-02	<LOQ	<LOQ	<LOQ	NA	
		463SET22-7	AEA09-BRS-14-SW-03	<LOQ	<LOQ	<LOQ	NA	
	ME-15	463SET22-8	AEA09-BRS-15-FW-01	2.29	2.59	2.87	4.30	4.40
		463SET22-9	AEA09-BRS-15-SW-01	<LOQ	<LOQ	<LOQ	NA	
		463SET22-10	AEA09-BRS-15-SW-02	<LOQ	<LOQ	<LOQ	NA	
							Mean	**4.63**
							Standard Deviation	**5.60**

LOQ = 0.100 µg/sample

PPE = Personal protective equipment.

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] PPE Corrected Residue = (Corrected Residue x 1.11). PPE factor of 1.11 is from the AEATF SOP.

[c] Removal Efficiency Corrected Residue = (PPE Corrected Residue x 100) ÷ Removal efficiency for mid level paint (66.8%). Removal Efficiency correction is only performed on wetted dressing sponge samples (FW). For sweat wipes, which are not wetted, removal efficiency factor is not applied. Value determined in Removal Efficiency Study, GPL#130503. (Boatwright, M.T. 2017). For further clarification see Section 8.4

[d] Sum of Corrected Sample Residues = (PPE Corrected Residue values if applicable for sweat wipe samples) + Residue Corrected for Removal Efficiency for face/neck wipe samples)

Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 33 Residue Data Summary for Face/Neck Wipe Samples from Subjects Painting with High Level Paint

Monitoring Event Conducted	Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]	PPE Corrected Residue (µg/sample)[b]	Residue Corrected for Removal Efficiency (µg/sample)[c]	Sum of Corrected Sample Residues (µg/sample)[d]
High	ME-03	463SET16-6	AEA09-BRS-03-FW-01	5.81	6.43	7.14	11.8	11.8
	ME-06	463SET18-4	AEA09-BRS-06-FW-01	<LOQ	<LOQ	<LOQ	<LOQ	0.100
		463SET18-5	AEA09-BRS-06-SW-01	<LOQ	<LOQ	<LOQ	NA	
	ME-07	463SET18-6	AEA09-BRS-07-FW-01	0.922	1.12	1.24	2.06	2.06
	ME-09	463SET19-5	AEA09-BRS-09-FW-01	0.220	0.245	0.272	0.451	0.451
	ME-16	463SET23-4	AEA09-BRS-16-FW-01	0.233	0.262	0.291	0.483	0.483
	ME-17	463SET23-5	AEA09-BRS-17-FW-01	0.538	0.605	0.672	1.11	1.11
							Mean	**2.67**
							Standard Deviation	**4.53**

LOQ = 0.100 µg/sample

PPE = Personal protective equipment.

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] PPE Corrected Residue = (Corrected Residue x 1.11). PPE factor of 1.11 is from the AEATF SOP.

[c] Removal Efficiency Corrected Residue = (Corrected Residue x 100) ÷ Removal efficiency for high level paint (60.3%). Removal Efficiency correction is only performed on wetted dressing sponge samples (FW). For sweat wipes, which are not wetted, removal efficiency factor is not applied. Value determined in Removal Efficiency Study, GPL#130503. (Boatwright, M.T. 2017). For further clarification see Section 8.4

[d] Sum of Corrected Sample Residues = (PPE Corrected Residue values if applicable for sweat wipe samples) + Residue Corrected for Removal Efficiency for face/neck wipe samples)

Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 34 Residue Data Summary for Inner Dosimeters Samples

Monitoring Event.	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME01	463SET46-4	AEA09-BRS-01-ID-UA	192	193[b]
	463SET46-5	AEA09-BRS-01-ID-LA	227	228[b]
	463SET46-6	AEA09-BRS-01-ID-FT	374	376[b]
	463SET46-7	AEA09-BRS-01-ID-RT	336	338[b]
	463SET46-8	AEA09-BRS-01-ID-UL	344	346[b]
	463SET46-9	AEA09-BRS-01-ID-LL	394	396[b]
ME02	463SET49-4	AEA09-BRS-02-ID-UA	609	609[b]
	463SET49-5	AEA09-BRS-02-ID-LA	683	683[b]
	463SET49-6	AEA09-BRS-02-ID-FT	1138	1138[b]
	463SET49-7	AEA09-BRS-02-ID-RT	897	897[b]
	463SET49-8	AEA09-BRS-02-ID-UL	1061	1061[b]
	463SET49-9	AEA09-BRS-02-ID-LL	1197	1197[b]
ME03	463SET49-10	AEA09-BRS-03-ID-UA	<LOQ	<LOQ
	463SET49-11	AEA09-BRS-03-ID-LA	33.5	33.5
	463SET49-12	AEA09-BRS-03-ID-FT	<LOQ	<LOQ
	463SET49-13	AEA09-BRS-03-ID-RT	<LOQ	<LOQ
	463SET49-14	AEA09-BRS-03-ID-UL	<LOQ	<LOQ
	463SET49-15	AEA09-BRS-03-ID-LL	<LOQ	<LOQ
ME04	463SET52-4	AEA09-BRS-04-ID-UA	426	426[b]
	463SET52-5	AEA09-BRS-04-ID-LA	521	521[b]
	463SET52-6	AEA09-BRS-04-ID-FT	673	673[b]
	463SET52-7	AEA09-BRS-04-ID-RT	614	614[b]
	463SET52-8	AEA09-BRS-04-ID-UL	689	689[b]
	463SET52-9	AEA09-BRS-04-ID-LL	777	777[b]
ME05	463SET52-11	AEA09-BRS-05-ID-UA	<LOQ	<LOQ
	463SET52-12	AEA09-BRS-05-ID-LA	50.6	50.6
	463SET52-13	AEA09-BRS-05-ID-FT	23.9	23.9
	463SET52-14	AEA09-BRS-05-ID-RT	3.20	3.20
	463SET52-15	AEA09-BRS-05-ID-UL	4.59	4.59
	463SET52-16	AEA09-BRS-05-ID-LL	<LOQ	<LOQ
ME06	463SET55-4	AEA09-BRS-06-ID-UA	141	161[b]
	463SET55-5	AEA09-BRS-06-ID-LA	123	140[b]
	463SET55-6	AEA09-BRS-06-ID-FT	362	412[b]
	463SET55-7	AEA09-BRS-06-ID-RT	280	319[b]
	463SET55-8	AEA09-BRS-06-ID-UL	165	188[b]
	463SET55-9	AEA09-BRS-06-ID-LL	191	218[b]

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Residues attributed to background contamination in inner dosimeter garments and will not be used in data summary tables. See Section 9.0 for more information.

Table 34 Residue Data Summary for Inner Dosimeters Samples (continued)

Monitoring Event.	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME07	463SET55-10	AEA09-BRS-07-ID-UA	247	281[b]
	463SET55-11	AEA09-BRS-07-ID-LA	238	271[b]
	463SET55-12	AEA09-BRS-07-ID-FT	377	429[b]
	463SET55-13	AEA09-BRS-07-ID-RT	276	314[b]
	463SET55-14	AEA09-BRS-07-ID-UL	488	556[b]
	463SET55-15	AEA09-BRS-07-ID-LL	362	412[b]
ME08	463SET60-4	AEA09-BRS-08-ID-UA	<LOQ	<LOQ
	463SET60-5	AEA09-BRS-08-ID-LA	6.05	6.05
	463SET60-6	AEA09-BRS-08-ID-FT	<LOQ	<LOQ
	463SET60-7	AEA09-BRS-08-ID-RT	<LOQ	<LOQ
	463SET60-8	AEA09-BRS-08-ID-UL	<LOQ	<LOQ
	463SET60-9	AEA09-BRS-08-ID-LL	<LOQ	<LOQ
ME09	463SET60-10	AEA09-BRS-09-ID-UA	<LOQ	<LOQ
	463SET60-11	AEA09-BRS-09-ID-LA	4.11	4.11
	463SET60-12	AEA09-BRS-09-ID-FT	5.69	5.69
	463SET60-13	AEA09-BRS-09-ID-RT	4.13	4.13
	463SET60-14	AEA09-BRS-09-ID-UL	4.38	4.38
	463SET60-15	AEA09-BRS-09-ID-LL	5.27	5.27
ME10	463SET63-4	AEA09-BRS-10-ID-UA	285	292[b]
	463SET63-5	AEA09-BRS-10-ID-LA	421	431[b]
	463SET63-6	AEA09-BRS-10-ID-FT	665	681[b]
	463SET63-7	AEA09-BRS-10-ID-RT	732	749[b]
	463SET63-8	AEA09-BRS-10-ID-UL	685	701[b]
	463SET63-9	AEA09-BRS-10-ID-LL	723	740[b]
ME11	463SET63-11	AEA09-BRS-11-ID-UA	<LOQ	<LOQ
	463SET63-12	AEA09-BRS-11-ID-LA	5.48	5.61
	463SET63-13	AEA09-BRS-11-ID-FT	<LOQ	<LOQ
	463SET63-14	AEA09-BRS-11-ID-RT	<LOQ	<LOQ
	463SET63-15	AEA09-BRS-11-ID-UL	<LOQ	<LOQ
	463SET63-16	AEA09-BRS-11-ID-LL	<LOQ	<LOQ
ME12	463SET64-4	AEA09-BRS-12-ID-UA	456	456[b]
	463SET64-5	AEA09-BRS-12-ID-LA	524	524[b]
	463SET64-6	AEA09-BRS-12-ID-FT	792	792[b]
	463SET64-7	AEA09-BRS-12-ID-RT	608	608[b]
	463SET64-8	AEA09-BRS-12-ID-UL	944	944[b]
	463SET64-9	AEA09-BRS-12-ID-LL	797	797[b]

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Residues attributed to background contamination in inner dosimeter garments and will not be used in data summary tables. See Section 9.0 for more information.

Table 34 Residue Data Summary for Inner Dosimeters Samples (continued)

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME13	463SET64-11	AEA09-BRS-13-ID-UA	208	208[b]
	463SET64-12	AEA09-BRS-13-ID-LA	215	215[b]
	463SET64-13	AEA09-BRS-13-ID-FT	371	371[b]
	463SET64-14	AEA09-BRS-13-ID-RT	267	267[b]
	463SET64-15	AEA09-BRS-13-ID-UL	336	336[b]
	463SET64-16	AEA09-BRS-13-ID-LL	395	395[b]
ME14	463SET71-4	AEA09-BRS-14-ID-UA	<LOQ	<LOQ
	463SET71-5	AEA09-BRS-14-ID-LA	4.20	4.20
	463SET71-6	AEA09-BRS-14-ID-FT	29.7	29.7
	463SET71-7	AEA09-BRS-14-ID-RT	4.52	4.52
	463SET71-8	AEA09-BRS-14-ID-UL	6.56	6.56
	463SET71-9	AEA09-BRS-14-ID-LL	<LOQ	<LOQ
ME15	463SET71-11	AEA09-BRS-15-ID-UA	<LOQ	<LOQ
	463SET71-12	AEA09-BRS-15-ID-LA	8.03	8.03
	463SET71-13	AEA09-BRS-15-ID-FT	3.32	3.32
	463SET71-14	AEA09-BRS-15-ID-RT	3.00	3.00
	463SET71-15	AEA09-BRS-15-ID-UL	3.38	3.38
	463SET71-16	AEA09-BRS-15-ID-LL	<LOQ	<LOQ
ME16	463SET72-4	AEA09-BRS-16-ID-UA	133	133[b]
	463SET72-5	AEA09-BRS-16-ID-LA	123	123[b]
	463SET72-6	AEA09-BRS-16-ID-FT	295	295[b]
	463SET72-7	AEA09-BRS-16-ID-RT	368	368[b]
	463SET72-8	AEA09-BRS-16-ID-UL	235	235[b]
	463SET72-9	AEA09-BRS-16-ID-LL	248	248[b]
ME17	463SET72-11	AEA09-BRS-17-ID-UA	297	297[b]
	463SET72-12	AEA09-BRS-17-ID-LA	294	294[b]
	463SET72-13	AEA09-BRS-17-ID-FT	NA	NA[c]
	463SET72-14	AEA09-BRS-17-ID-RT	376	376[b]
	463SET72-15	AEA09-BRS-17-ID-UL	517	517[b]
	463SET72-16	AEA09-BRS-17-ID-LL	458	458[b]
ME18	463SET73-4	AEA09-BRS-18-ID-UA	<LOQ	<LOQ
	463SET73-5	AEA09-BRS-18-ID-LA	<LOQ	<LOQ
	463SET73-6	AEA09-BRS-18-ID-FT	<LOQ	<LOQ
	NA	AEA09-BRS-18-ID-FT	NA[d]	NA
	463SET73-7	AEA09-BRS-18-ID-UL	<LOQ	<LOQ
	463SET73-8	AEA09-BRS-18-ID-LL	<LOQ	<LOQ

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

[b] Residues attributed to background contamination in inner dosimeter garments and will not be used in data summary tables. See Section 9.0 for more information.

[c] Sample was inadvertently not analyzed after being diluted into calibration curve range due to mis-injection in the dilution analysis. Sample residue data has been generated however is greater than the calibration curve range (See Method Deviation #1).

[d] Inner dosimeter rear torso piece was not analyzed since outer dosimeter rear torso piece was <LOQ.

Table 35 Residue Data Summary for Painter's Hat Inner Dosimeter Samples

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]
ME01	463SET46-10	AEA09-BRS-01-PH-ID	5.51	5.54
ME03	463SET49-16	AEA09-BRS-03-PH-ID	15.6	15.6
ME04	463SET52-10	AEA09-BRS-04-PH-ID	14.9	14.9
ME05	463SET52-17	AEA09-BRS-05-PH-ID	12.0	12.0
ME07	463SET55-16	AEA09-BRS-07-PH-ID	15.5	17.7
ME10	463SET63-10	AEA09-BRS-10-PH-ID	15.9	16.3
ME11	463SET63-17	AEA09-BRS-11-PH-ID	12.0	12.3
ME12	463SET64-10	AEA09-BRS-12-PH-ID	17.9	17.9
ME13	463SET64-17	AEA09-BRS-13-PH-ID	14.5	14.5
ME14	463SET71B-10	AEA09-BRS-14-PH-ID	19.1	19.1
ME15	463SET71B-17	AEA09-BRS-15-PH-ID	12.6	12.6
ME16	463SET72B-10	AEA09-BRS-16-PH-ID	12.3	12.3
ME17	463SET72B-17	AEA09-BRS-17-PH-ID	17.7	17.7

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

Table 36 Residue Data Summary for Painter's Hat Samples

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample)[a]
ME01	463SET45-4	AEA09-BRS-01-PH	7.56	8.26
ME02	463SET48-4	AEA09-BRS-02-PH	<LOQ	<LOQ
ME03	463SET48-5	AEA09-BRS-03-PH	94.8	99.6
ME04	463SET51-4	AEA09-BRS-04-PH	11.9	12.8
ME05	463SET51-5	AEA09-BRS-05-PH	53.6	57.8
ME06	463SET54-4	AEA09-BRS-06-PH	<LOQ	<LOQ
ME07	463SET54-5	AEA09-BRS-07-PH	9.56	9.75
ME08	463SET57-4	AEA09-BRS-08-PH	<LOQ	<LOQ
ME09	463SET57-5	AEA09-BRS-09-PH	<LOQ	<LOQ
ME10	463SET59-4	AEA09-BRS-10-PH	6.88	8.36
ME11	463SET59-5	AEA09-BRS-11-PH	9.28	11.3
ME12	463SET62-4	AEA09-BRS-12-PH	77.6	101
ME13	463SET62-5	AEA09-BRS-13-PH	9.44	12.2
ME14	463SET66-4	AEA09-BRS-14-PH	7.40	8.89
ME15	463SET66-5	AEA09-BRS-15-PH	5.28	6.35
ME16	463SET69-4	AEA09-BRS-16-PH	27.4	31.3
ME17	463SET69-5	AEA09-BRS-17-PH	63.6	72.7
ME18	463SET69-6	AEA09-BRS-18-PH	<LOQ	<LOQ

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

Table 37 Residue Data Summary for Outer Dosimeters Samples

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME01	463SET44-4	AEA09-BRS-01-OD-UA	8.48	9.39
	463SET44-5	AEA09-BRS-01-OD-LA	62.0	68.7
	463SET44-6	AEA09-BRS-01-OD-FT	35.5	39.3
	463SET44-7	AEA09-BRS-01-OD-RT	37.2	41.2
	463SET44-8	AEA09-BRS-01-OD-UL	33.2	36.8
	463SET44-9	AEA09-BRS-01-OD-LL	6.28	6.95
ME02	463SET47-4	AEA09-BRS-02-OD-UA	5.72	5.72
	463SET47-5	AEA09-BRS-02-OD-LA	37.9	37.9
	463SET47-6	AEA09-BRS-02-OD-FT	14.1	14.1
	463SET47-7	AEA09-BRS-02-OD-RT	<LOQ	<LOQ
	463SET47-8	AEA09-BRS-02-OD-UL	12.2	12.2
	463SET47-9	AEA09-BRS-02-OD-LL	26.6	26.6
ME03	463SET47-10	AEA09-BRS-03-OD-UA	156	156
	463SET47-11	AEA09-BRS-03-OD-LA	445	445
	463SET47-12	AEA09-BRS-03-OD-FT	220	220
	463SET47-13	AEA09-BRS-03-OD-RT	40.4	40.4
	463SET47-14	AEA09-BRS-03-OD-UL	144	144
	463SET47-15	AEA09-BRS-03-OD-LL	286	286
ME04	463SET50-4	AEA09-BRS-04-OD-UA	23.8	23.8
	463SET50-5	AEA09-BRS-04-OD-LA	52.0	52.0
	463SET50-6	AEA09-BRS-04-OD-FT	58.4	58.4
	463SET50-7	AEA09-BRS-04-OD-RT	24.2	24.2
	463SET50-8	AEA09-BRS-04-OD-UL	54.4	54.4
	463SET50-9	AEA09-BRS-04-OD-LL	18.0	18.0
ME05	463SET50-10	AEA09-BRS-05-OD-UA	69.2	69.2
	463SET50-11	AEA09-BRS-05-OD-LA	210	210
	463SET50-12	AEA09-BRS-05-OD-FT	126	126
	463SET50-13	AEA09-BRS-05-OD-RT	90.0	90.0
	463SET50-14	AEA09-BRS-05-OD-UL	190	190
	463SET50-15	AEA09-BRS-05-OD-LL	130	130
ME06	463SET53-4	AEA09-BRS-06-OD-UA	4.24	4.24
	463SET53-5	AEA09-BRS-06-OD-LA	24.8	24.8
	463SET53-6	AEA09-BRS-06-OD-FT	189	189
	463SET53-7	AEA09-BRS-06-OD-RT	72.0	72.0
	463SET53-8	AEA09-BRS-06-OD-UL	90.8	90.8
	463SET53-9	AEA09-BRS-06-OD-LL	108	108

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Field Fortification Recovery contained in same analytical Set or Average Field Fortification Recovery if the set contained recoveries of a low and a high field fortification. For further clarification see Section 8.3.

Table 37 Residue Data Summary for Outer Dosimeters Samples (continued)

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME07	463SET53-10	AEA09-BRS-07-OD-UA	9.32	9.32
	463SET53-11	AEA09-BRS-07-OD-LA	209	209
	463SET53-12	AEA09-BRS-07-OD-FT	23.2	23.2
	463SET53-13	AEA09-BRS-07-OD-RT	32.6	32.6
	463SET53-14	AEA09-BRS-07-OD-UL	158	158
	463SET53-15	AEA09-BRS-07-OD-LL	114	114
ME08	463SET56-4	AEA09-BRS-08-OD-UA	18.4	19.7
	463SET56-5	AEA09-BRS-08-OD-LA	34.0	36.5
	463SET56-6	AEA09-BRS-08-OD-FT	103	111
	463SET56-7	AEA09-BRS-08-OD-RT	18.4	19.7
	463SET56-8	AEA09-BRS-08-OD-UL	57.2	61.4
	463SET56-9	AEA09-BRS-08-OD-LL	104	112
ME09	463SET56-10	AEA09-BRS-09-OD-UA	9.32	10.0
	463SET56-11	AEA09-BRS-09-OD-LA	72.8	78.1
	463SET56-12	AEA09-BRS-09-OD-FT	27.8	29.8
	463SET56-13	AEA09-BRS-09-OD-RT	7.28	7.81
	463SET56-14	AEA09-BRS-09-OD-UL	672	721
	463SET56-15	AEA09-BRS-09-OD-LL	7.72	8.28
ME10	463SET58-4	AEA09-BRS-10-OD-UA	40.0	40.0
	463SET58-5	AEA09-BRS-10-OD-LA	34.2	34.2
	463SET58-6	AEA09-BRS-10-OD-FT	25.6	25.6
	463SET58-7	AEA09-BRS-10-OD-RT	11.2	11.2
	463SET58-8	AEA09-BRS-10-OD-UL	24.0	24.0
	463SET58-9	AEA09-BRS-10-OD-LL	37.8	37.8
ME11	463SET58-10	AEA09-BRS-11-OD-UA	11.6	11.6
	463SET58-11	AEA09-BRS-11-OD-LA	38.6	38.6
	463SET58-12	AEA09-BRS-11-OD-FT	43.2	43.2
	463SET58-13	AEA09-BRS-11-OD-RT	9.16	9.16
	463SET58-14	AEA09-BRS-11-OD-UL	53.6	53.6
	463SET58-15	AEA09-BRS-11-OD-LL	28.6	28.6
ME12	463SET61-4	AEA09-BRS-12-OD-UA	43.6	43.6
	463SET61-5	AEA09-BRS-12-OD-LA	117	117
	463SET61-6	AEA09-BRS-12-OD-FT	198	198
	463SET61-7	AEA09-BRS-12-OD-RT	19.6	19.6
	463SET61-8	AEA09-BRS-12-OD-UL	48.8	48.8
	463SET61-9	AEA09-BRS-12-OD-LL	124	124

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Field Fortification Recovery contained in same analytical Set or Average Field Fortification Recovery if the set contained recoveries of a low and a high field fortification. For further clarification see Section 8.3.

Table 37 Residue Data Summary for Outer Dosimeters Samples (continued)

Monitoring Event	Lab ID	Sample ID	Residue (µg/sample)	Corrected Residue (µg/sample) [a]
ME13	463SET61-10	AEA09-BRS-13-OD-UA	13.4	13.4
	463SET61-11	AEA09-BRS-13-OD-LA	33.7	33.7
	463SET61-12	AEA09-BRS-13-OD-FT	39.8	39.8
	463SET61-13	AEA09-BRS-13-OD-RT	27.3	27.3
	463SET61-14	AEA09-BRS-13-OD-UL	27.5	27.5
	463SET61-15	AEA09-BRS-13-OD-LL	23.3	23.3
ME14	463SET65-4	AEA09-BRS-14-OD-UA	49.2	49.2
	463SET65-5	AEA09-BRS-14-OD-LA	185	185
	463SET65-6	AEA09-BRS-14-OD-FT	257	257
	463SET65-7	AEA09-BRS-14-OD-RT	15.3	15.3
	463SET65-8	AEA09-BRS-14-OD-UL	315	315
	463SET65-9	AEA09-BRS-14-OD-LL	200	200
ME15	463SET65-10	AEA09-BRS-15-OD-UA	3.99	3.99
	463SET65-11	AEA09-BRS-15-OD-LA	118	118
	463SET65-12	AEA09-BRS-15-OD-FT	171	171
	463SET65-13	AEA09-BRS-15-OD-RT	76.5	76.5
	463SET65-14	AEA09-BRS-15-OD-UL	154	154
	463SET65-15	AEA09-BRS-15-OD-LL	63.6	63.6
ME16	463SET67-4	AEA09-BRS-16-OD-UA	8.28	8.28
	463SET67-5	AEA09-BRS-16-OD-LA	24.9	24.9
	463SET67-6	AEA09-BRS-16-OD-FT	10.1	10.1
	463SET67-7	AEA09-BRS-16-OD-RT	3.57	3.57
	463SET67-8	AEA09-BRS-16-OD-UL	23.3	23.3
	463SET67-9	AEA09-BRS-16-OD-LL	24.8	24.8
ME17	463SET67-10	AEA09-BRS-17-OD-UA	43.6	43.6
	463SET67-11	AEA09-BRS-17-OD-LA	90.8	90.8
	463SET67-12	AEA09-BRS-17-OD-FT	56.0	56.0
	463SET67-13	AEA09-BRS-17-OD-RT	50.8	50.8
	463SET67-14	AEA09-BRS-17-OD-UL	38.2	38.2
	463SET67-15	AEA09-BRS-17-OD-LL	151	151
ME18	463SET68-4	AEA09-BRS-18-OD-UA	4.84	4.84
	463SET68-5	AEA09-BRS-18-OD-LA	33.6	33.6
	463SET68-6	AEA09-BRS-18-OD-FT	7.28	7.28
	463SET68-7	AEA09-BRS-18-OD-RT	<LOQ	<LOQ
	463SET68-8	AEA09-BRS-18-OD-UL	26.3	26.3
	463SET68-9	AEA09-BRS-18-OD-LL	82.8	82.8

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Field Fortification Recovery contained in same analytical Set or Average Field Fortification Recovery if the set contained recoveries of a low and a high field fortification. For further clarification see Section 8.3.

Table 38 Summary of Inner Dosimeter Garments and Range of Residues

Monitoring Event	Inner Dosimeter Garment lot #	Range of Corrected Residue[a] (µg/sample)
ME03	GPU 4 ME68	<LOQ – 33.5
ME05	GPU 6 DL77	<LOQ – 50.6
ME08	GPU 4 ME68	<LOQ – 6.05
ME09	GPU 4 MG07	<LOQ – 5.69
ME11	GPU 9 U056	<LOQ – 5.61
ME14	GPU 6 DL77	<LOQ – 29.7
ME15	GPU 6 DL77	<LOQ – 8.03
ME18	GPU 6 DL77	All <LOQ
Suspected Contaminated Garments		
ME01	GPU 14 U546	193 – 396
ME02	GPU 14 U576	609 – 1197
ME04	GPU 15 U594	426 – 777
ME06	GPU 14 U346	140 – 412
ME07	GPU 14 U546	271 – 556
ME10	GPU 14 U576	292 – 749
ME12	GPU 15 U594	456 – 944
ME13	GPU 14 U546	208 – 395
ME16	GPU 14 U346	123 – 368
ME17	GPU 15 U593	294 – 517

LOQ = 3.00 µg/sample

[a] Corrected Residue = (Residue x 100) ÷ Corresponding Average Field Fortification Recovery contained in same analytical Set. For further clarification see Section 8.3.

Table 39 Summary of Inner Dosimeter Garment Investigation Results

ID Garment Control Lot #	Garment Section	Sample Residues (µg/sample)	Total BIT Residues in Garment (µg)
GPU 4 MG07	Lower Arms	<LOQ	15.7
	Upper Arms	<LOQ	
	Front Torso	4.83	
	Rear Torso	3.11	
	Upper Legs	3.81	
	Lower Legs	3.92	
GPU 6 L74	Lower Arms	<LOQ	<LOQ
	Upper Arms	<LOQ	
	Front Torso	<LOQ	
	Rear Torso	<LOQ	
	Upper Legs	<LOQ	
	Lower Legs	<LOQ	
GPU 14 U543	Lower Arms	251	1776
	Upper Arms	206	
	Front Torso	350	
	Rear Torso	306	
	Upper Legs	358	
	Lower Legs	305	
GPU 15 U630	Lower Arms	289	2429
	Upper Arms	288	
	Front Torso	618	
	Rear Torso	400	
	Upper Legs	429	
	Lower Legs	405	

LOQ = 3.00 µg/sample

Table 40 Overall Residues (µg/sample) for Monitoring Events with Low BIT Concentration Paint

Sample	Field Fort Corrected Residues (µg/sample)						Mean ± Standard Deviation
	ME01	ME02	ME04	ME11	ME13	ME18	
Air Sampling Tubes	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (100 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (10 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (2.5 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Hand Wash[a]	592	118	112	190	139	158	218 ± 185
Face/Neck Wipe[a,b]	0.150	0.100	1.16	0.100	0.351	6.01	1.31 ± 2.34
Painter's Hat	8.26	<LOQ	12.8	11.3	12.2	<LOQ	7.93 ± 5.22
OD Upper Arm (UA)	9.39	5.72	23.8	11.6	13.4	4.84	11.5 ± 6.89
OD Lower Arm (LA)	68.7	37.9	52.0	38.6	33.7	33.6	44.1 ± 13.8
OD Front Torso (FT)	39.3	14.1	58.4	43.2	39.8	7.28	33.7 ± 19.2
OD Rear Torso (RT)	41.2	<LOQ	24.2	9.16	27.3	<LOQ	17.5 ± 16.0
OD Upper Leg (UL)	36.8	12.2	54.4	53.6	27.5	26.3	35.1 ± 16.6
OD Lower Leg (LL)	6.95	26.6	18.0	28.6	23.3	82.8	31.0 ± 26.5
ID Painter's Hat	5.54	NA	14.9	12.3	14.5	NA	11.8 ± 4.33
ID Upper Arm (UA)	<LOQ[c]	<LOQ[c]	<LOQ[c]	<LOQ	<LOQ[c]	<LOQ	<LOQ ± NA
ID Lower Arm (LA)	8.45[c]	4.66[c]	6.40[c]	5.61	4.15[c]	<LOQ	5.13 ± 2.33
ID Front Torso (FT)	4.83[c]	<LOQ[c]	7.18[c]	<LOQ	4.90[c]	<LOQ	3.57 ± 2.42
ID Rear Torso (RT)	5.07[c]	<LOQ[c]	<LOQ[c]	<LOQ	3.36[c]	NA	2.59 ± 1.61
ID Upper Leg (UL)	4.53[c]	<LOQ[c]	6.69[c]	<LOQ	3.38[c]	<LOQ	3.18 ± 2.13
ID Lower Leg (LL)	<LOQ[c]	3.27[c]	<LOQ[c]	<LOQ	<LOQ[c]	<LOQ	1.80 ± 0.723

[a] Values were corrected for removal efficiency. See Tables 30-33 for details.

[b] Residue represents the sum of all samples collected if more than one sample was generated.

[c] Samples from suspected contaminated garments. Reported values are based on 12.3% penetration factor through corresponding outer dosimeter piece (Penetration factor ID residue = (Corresponding OD section) x 12.3%. See report section 9.2 for details.

Residues that are <LOQ are represented as half the matrix LOQ, when calculating mean and standard deviation.

Air Sampling Tube LOQ = 0.0100 µg/sample, Fiberglass Filters LOQ = 0.0100 µg/sample, Hand Wash LOQ = 1.00 ng/mL (0.500 µg/sample (sample size = 500 mL), Face/Neck Wipe LOQ = 0.100 µg/sample, Outer Dosimeter LOQ = 3.00 µg/sample, Inner Dosimeter LOQ = 3.00 µg/sample, Painter's Hat LOQ = 3.00 µg/sample.

Table 41 Overall Residues (µg/sample) for Monitoring Events with Mid BIT Concentration Paint

Sample	Field Fort Corrected Residues (µg/sample)						Mean ± Standard Deviation
	ME05	ME08	ME10	ME12	ME14	ME15	
Air Sampling Tubes	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (100 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (10 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (2.5 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Hand Wash[a]	1271	1573	211	729	374	4045	1367 ± 1411
Face/Neck Wipe[a,b]	15.7	0.478	2.83	3.18	1.19	4.40	4.63 ± 5.60
Painter's Hat	57.8	<LOQ	8.36	101	8.89	6.35	30.7 ± 40.2
OD Upper Arm (UA)	69.2	19.7	40.0	43.6	49.2	3.99	37.6 ± 22.9
OD Lower Arm (LA)	210	36.5	34.2	117	185	118	117 ± 73.0
OD Front Torso (FT)	126	111	25.6	198	257	171	148 ± 79.7
OD Rear Torso (RT)	90.0	19.7	11.2	19.6	15.3	76.5	38.7 ± 34.9
OD Upper Leg (UL)	190	61.4	24.0	48.8	315	154	132 ± 110
OD Lower Leg (LL)	130	112	37.8	124	200	63.6	111 ± 56.7
ID Painter's Hat	12.0	NA	16.3	17.9	19.1	12.6	15.6 ± 3.16
ID Upper Arm (UA)	<LOQ	<LOQ	4.92[c]	5.36[c]	<LOQ	<LOQ	2.71 ± 1.88
ID Lower Arm (LA)	50.6	6.05	4.21[c]	14.4[c]	4.20	8.03	14.6 ± 18.0
ID Front Torso (FT)	23.9	<LOQ	3.15[c]	24.4[c]	29.7	3.32	14.3 ± 13.0
ID Rear Torso (RT)	3.20	<LOQ	<LOQ[c]	<LOQ[c]	4.52	3.00	2.54 ± 1.25
ID Upper Leg (UL)	4.59	<LOQ	<LOQ[c]	6.00[c]	6.56	3.38	3.92 ± 2.18
ID Lower Leg (LL)	<LOQ	<LOQ	4.65[c]	15.3[c]	<LOQ	<LOQ	4.33 ± 5.52

[a] Values were corrected for removal efficiency. See Tables 30-33 for details.

[b] Residue represents the sum of all samples collected if more than one sample was generated.

[c] Samples from suspected contaminated garments. Reported values are based on 12.3% penetration factor through corresponding outer dosimeter piece (Penetration factor ID residue = (Corresponding OD section) x 12.3%. See report section 9.2 for details.

Residues that are <LOQ are represented as half the matrix LOQ, when calculating mean and standard deviation.

Air Sampling Tube LOQ = 0.0100 µg/sample, Fiberglass Filters LOQ = 0.0100 µg/sample, Hand Wash LOQ = 1.00 ng/mL (0.500 µg/sample (sample size = 500 mL), Face/Neck Wipe LOQ = 0.100 µg/sample, Outer Dosimeter LOQ = 3.00 µg/sample, Inner Dosimeter LOQ = 3.00 µg/sample, Painter's Hat LOQ = 3.00 µg/sample.

Table 42 Overall Residues (µg/sample) for Monitoring Events with High BIT Concentration Paint

Sample	Field Fort Corrected Residues (µg/sample)						Mean ± Standard Deviation
	ME03	ME06	ME07	ME09	ME16	ME17	
Air Sampling Tubes	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (100 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (10 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Fiberglass Filter (2.5 µm)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Hand Wash[a]	2023	303	833	206	64.0	920	725 ± 724
Face/Neck Wipe[a,b]	11.8	0.100	2.06	0.451	0.483	1.11	2.67 ± 4.53
Painter's Hat	99.6	<LOQ	9.75	<LOQ	31.3	72.7	36.1 ± 41.2
OD Upper Arm (UA)	156	4.24	9.32	10.0	8.28	43.6	38.6 ± 59.3
OD Lower Arm (LA)	445	24.8	209	78.1	24.9	90.8	145 ± 161
OD Front Torso (FT)	220	189	23.2	29.8	10.1	56.0	88.0 ± 92.0
OD Rear Torso (RT)	40.4	72.0	32.6	7.81	3.57	50.8	34.5 ± 26.0
OD Upper Leg (UL)	144	90.8	158	721	23.3	38.2	196 ± 263
OD Lower Leg (LL)	286	108	114	8.28	24.8	151	115 ± 100
ID Painter's Hat	15.6	NA[d]	17.7	NA[d]	12.3	17.7	15.8 ± 2.55
ID Upper Arm (UA)	<LOQ	<LOQ[c]	<LOQ[c]	<LOQ	<LOQ[c]	5.36[c]	2.14 ± 1.58
ID Lower Arm (LA)	33.5	3.05[c]	25.7[c]	4.11	3.06[c]	11.2[c]	13.4 ± 13.1
ID Front Torso (FT)	<LOQ	23.2[c]	<LOQ[c]	5.69	<LOQ[c]	6.89[c]	6.71 ± 8.42
ID Rear Torso (RT)	<LOQ	8.86[c]	4.01[c]	4.13	<LOQ[c]	6.25[c]	4.38 ± 2.84
ID Upper Leg (UL)	<LOQ	11.2[c]	19.4[c]	4.38	<LOQ[c]	4.70[c]	7.11 ± 6.99
ID Lower Leg (LL)	<LOQ	13.3[c]	14.0[c]	5.27	3.05[c]	18.6[c]	9.29 ± 6.94

[a] Values were corrected for removal efficiency. See Tables 30-33 for details.

[b] Residue represents the sum of all samples collected if more than one sample was generated.

[c] Samples from suspected contaminated garments. Reported values are based on 12.3% penetration factor through corresponding outer dosimeter piece (Penetration factor ID residue = (Corresponding OD section) x 12.3%. See report section 9.2 for details.

[d] Sample not analyzed since corresponding outer sample was <LOQ, thus inner sample is not analyzed.

Residues that are <LOQ are represented as half the matrix LOQ, when calculating mean and standard deviation.

Air Sampling Tube LOQ = 0.0100 µg/sample, Fiberglass Filters LOQ = 0.0100 µg/sample, Hand Wash LOQ = 1.00 ng/mL (0.500 µg/sample (sample size = 500 mL), Face/Neck Wipe LOQ = 0.100 µg/sample, Outer Dosimeter LOQ = 3.00 µg/sample, Inner Dosimeter LOQ = 3.00 µg/sample, Painter's Hat LOQ = 3.00 µg/sample.

Table 43 Dermal Residues and Potential Dermal Exposure During Monitoring Events for Brush and Roller Painting (with hat included to represent unprotected head exposure)

BIT Level in Paint Applied	ME	Lb BIT Handled	Face/ Neck[a,b] (µg)	Hand Wash[a] (µg)	Painter's Hat (µg)	Painter's Hat ID (µg)	ID UA (µg)	ID LA (µg)	ID FT (µg)	ID RT (µg)	ID UL (µg)	ID LL (µg)	Total Dermal Exposure (µg)	Dermal Unit Exposure (µg/lb ai)
Low	1	0.00308	0.150	592	8.26	5.54	<LOQ	8.45[c]	4.83[c]	5.07[c]	4.53[c]	<LOQ	632	205195
	2	0.00272	0.100	118	<LOQ	NA[d]	<LOQ	4.66[c]	<LOQ	<LOQ	<LOQ	3.27[c]	134	49265
	4	0.00305	1.16	112	12.8	14.9	<LOQ	6.40[c]	7.18[c]	<LOQ	6.69[c]	<LOQ	166	54426
	11	0.00308	0.100	190	11.3	12.3	<LOQ	5.61	<LOQ	<LOQ	<LOQ	<LOQ	227	73701
	13	0.00287	0.351	139	12.2	14.5	<LOQ	4.15	4.90	3.36	3.38	<LOQ	185	64460
	18	0.00276	6.01	158	<LOQ	NA[d]	<LOQ	<LOQ	<LOQ	NA	<LOQ	<LOQ	173	62681
	Average	**0.00293**	**1.31**	**218**	**7.93**	**11.8**	**<LOQ**	**5.13**	**3.57**	**2.59**	**3.18**	**1.80**	**253**	**84955**
	Std Dev	**0.000165**	**2.34**	**185**	**5.22**	**4.33**	**NA**	**2.33**	**2.42**	**1.61**	**2.13**	**0.723**	**188**	**59508**
Mid	5	0.00808	15.7	1271	57.8	12.0	<LOQ	50.6	23.9	3.20	4.59	<LOQ	1442	178465
	8	0.00766	0.478	1573	<LOQ	NA[d]	<LOQ	6.05	<LOQ	<LOQ	<LOQ	<LOQ	1589	207441
	10	0.00787	2.83	211	8.36	16.3	4.92[c]	4.21[c]	3.15[c]	<LOQ	<LOQ	4.65[c]	258	32783
	12	0.00753	3.18	729	101	17.9	5.36[c]	14.4[c]	24.4[c]	<LOQ	6.00[c]	15.3[c]	918	121912
	14	0.00712	1.19	374	8.89	19.1	<LOQ	4.20	29.7	4.52	6.56	<LOQ	451	63343
	15	0.00777	4.40	4045	6.35	12.6	<LOQ	8.03	3.32	3.00	3.38	<LOQ	4089	526255
	Average	**0.00767**	**4.63**	**1367**	**30.7**	**15.6**	**2.71**	**14.6**	**14.3**	**2.54**	**3.92**	**4.33**	**1458**	**188367**
	Std Dev	**0.000329**	**5.60**	**1411**	**40.2**	**3.16**	**1.88**	**18.0**	**13.0**	**1.25**	**2.18**	**5.52**	**1392**	**178260**
High	3	0.0141	11.8	2023	99.6	15.6	<LOQ	33.5	<LOQ	<LOQ	<LOQ	<LOQ	2191	155390
	6	0.0128	0.100	303	<LOQ	NA[d]	<LOQ	3.05[c]	23.2[c]	8.86[c]	11.2[c]	13.3[c]	366	28594
	7	0.0130	2.06	833	9.75	17.7	<LOQ	25.7[c]	<LOQ	4.01[c]	19.4[c]	14.0[c]	929	71462
	9	0.0120	0.451	206	<LOQ	NA[d]	<LOQ	4.11	5.69	4.13	4.38	5.27	233	19417
	16	0.0124	0.483	64.0	31.3	12.3	<LOQ	3.06[c]	<LOQ	<LOQ	<LOQ	3.05[c]	120	9677
	17	0.0132	1.11	920	72.7	17.7	5.36[c]	11.2[c]	6.89[c]	6.25[c]	4.70[c]	18.6[c]	1065	80682
	Average	**0.0129**	**2.67**	**725**	**36.1**	**15.8**	**2.14**	**13.4**	**6.71**	**4.38**	**7.11**	**9.29**	**817**	**60870**
	Std Dev	**0.000722**	**4.53**	**724**	**41.2**	**2.55**	**1.58**	**13.1**	**8.42**	**2.84**	**6.99**	**6.94**	**774**	**54442**
									OVERALL			**Average**	**843**	**111397**
												Std Dev	**1006**	**120408**

[a] Values were calculated using residues that were corrected for removal efficiency in Tables 30-33.
[b] Residue represents the sum of all samples collected if more than one sample was generated.
[c] Penetration factor corrected residues.
[d] Sample not analyzed since corresponding outer sample was <LOQ, thus inner sample is not analyzed.
Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 44 Dermal Residues and Potential Dermal Exposure During Monitoring Events for Brush and Roller Painting (without hat included to represent protected head exposure)

BIT Level in Paint Applied	ME	Lb BIT Handled	Face/ Neck (µg)	Hand Wash (µg)	Painter's Hat ID (µg)	ID UA (µg)	ID LA (µg)	ID FT (µg)	ID RT (µg)	ID UL (µg)	ID LL (µg)	Total Dermal Exposure (µg)	Dermal Unit Exposure (µg/lb ai)
Low	1	0.00308	0.150	592	5.54	<LOQ	8.45[c]	4.83[c]	5.07[c]	4.53[c]	<LOQ	624	202597
	2	0.00272	0.100	118	NA[d]	<LOQ	4.66[c]	<LOQ	<LOQ	<LOQ	3.27[c]	132	48529
	4	0.00305	1.16	112	14.9	<LOQ	6.40[c]	7.18[c]	<LOQ	6.69[c]	<LOQ	153	50164
	11	0.00308	0.100	190	12.3	<LOQ	5.61	<LOQ	<LOQ	<LOQ	<LOQ	216	70130
	13	0.00287	0.351	139	14.5	<LOQ	4.15	4.90	3.36	3.38	<LOQ	173	60279
	18	0.00276	6.01	158	NA[d]	<LOQ	<LOQ	<LOQ	NA	<LOQ	<LOQ	172	62319
	Average	**0.00293**	**1.31**	**218**	**11.8**	**<LOQ**	**5.13**	**3.57**	**2.59**	**3.18**	**1.80**	**245**	**82336**
	Std Dev	**0.000165**	**2.34**	**185**	**4.33**	**NA**	**2.33**	**2.42**	**1.61**	**2.13**	**0.723**	**188**	**59459**
Mid	5	0.00808	15.7	1271	12.0	<LOQ	50.6	23.9	3.20	4.59	<LOQ	1384	171287
	8	0.00766	0.478	1573	NA[d]	<LOQ	6.05	<LOQ	<LOQ	<LOQ	<LOQ	1587	207180
	10	0.00787	2.83	211	16.3	4.92[c]	4.21[c]	3.15[c]	<LOQ	<LOQ	4.65[c]	250	31766
	12	0.00753	3.18	729	17.9	5.36[c]	14.4[c]	24.4[c]	<LOQ	6.00[c]	15.3[c]	817	108499
	14	0.00712	1.19	374	19.1	<LOQ	4.20	29.7	4.52	6.56	<LOQ	442	62079
	15	0.00777	4.40	4045	12.6	<LOQ	8.03	3.32	3.00	3.38	<LOQ	4083	525483
	Average	**0.00767**	**4.63**	**1367**	**15.6**	**2.71**	**14.6**	**14.3**	**2.54**	**3.92**	**4.33**	**1427**	**184382**
	Std Dev	**0.000329**	**5.60**	**1411**	**3.16**	**1.88**	**18.0**	**13.0**	**1.25**	**2.18**	**5.52**	**1401**	**179471**
High	3	0.0141	11.8	2023	15.6	<LOQ	33.5	<LOQ	<LOQ	<LOQ	<LOQ	2091	148298
	6	0.0128	0.100	303	NA[d]	<LOQ	3.05[c]	23.2[c]	8.86[c]	11.2[c]	13.3[c]	364	28438
	7	0.0130	2.06	833	17.7	<LOQ	25.7[c]	<LOQ	4.01[c]	19.4[c]	14.0[c]	919	70692
	9	0.0120	0.451	206	NA[d]	<LOQ	4.11	5.69	4.13	4.38	5.27	232	19333
	16	0.0124	0.483	64.0	12.3	<LOQ	3.06[c]	<LOQ	<LOQ	<LOQ	3.05[c]	89	7177
	17	0.0132	1.11	920	17.7	5.36[c]	11.2[c]	6.89[c]	6.25[c]	4.70[c]	18.6[c]	992	75152
	Average	**0.0129**	**2.67**	**725**	**15.8**	**2.14**	**13.4**	**6.71**	**4.38**	**7.11**	**9.29**	**781**	**58182**
	Std Dev	**0.000722**	**4.53**	**724**	**2.55**	**1.58**	**13.1**	**8.42**	**2.84**	**6.99**	**6.94**	**739**	**52078**
OVERALL										**Average**		**818**	**108300**
										Std Dev		**998**	**120326**

[a] Values were calculated using residues that were corrected for removal efficiency in Tables 30-33.
[b] Residue represents the sum of all samples collected if more than one sample was generated.
[c] Penetration factor corrected residues.
[d] Sample not analyzed since corresponding outer sample was <LOQ, thus inner sample is not analyzed.
Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 45 Personal Air Pump Flow Rates for Air Sampling Tubes and RespiCon™ Filters during Monitoring Events

Subject Number	Sample Number	Pump ID	Flow Rates (L/min)		
			Start	Finish	Average
ME-01	AEA09-BRS-01-AR	PMP-23	2.017	1.944	1.981
	AEA09-BRS-01-RES-01	882222	3.100	3.103	3.102
	AEA09-BRS-01-RES-02				
	AEA09-BRS-01-RES-03				
ME-02	AEA09-BRS-02-AR	PMP-23	2.011	2.064	2.038
	AEA09-BRS-02-RES-01	882222	3.109	2.907	3.008
	AEA09-BRS-02-RES-02				
	AEA09-BRS-02-RES-03				
ME-03	AEA09-BRS-03-AR	PMP-33	2.028	1.861	1.944
	AEA09-BRS-03-RES-01	814467	3.093	3.075	3.084
	AEA09-BRS-03-RES-02				
	AEA09-BRS-03-RES-03				
ME-04	AEA09-BRS-04-AR	PMP-23	2.012	1.652	1.832
	AEA09-BRS-04-RES-01	882222	3.113	3.032	3.072
	AEA09-BRS-04-RES-02				
	AEA09-BRS-04-RES-03				
ME-05	AEA09-BRS-05-AR	PMP-33	2.015	1.929	1.972
	AEA09-BRS-05-RES-01	814467	3.104	3.013	3.059
	AEA09-BRS-05-RES-02				
	AEA09-BRS-05-RES-03				
ME-06	AEA09-BRS-06-AR	PMP-23	2.028	2.055	2.042
	AEA09-BRS-06-RES-01	882222	3.102	3.127	3.115
	AEA09-BRS-06-RES-02				
	AEA09-BRS-06-RES-03				

Table 45 Personal Air Pump Flow Rates for Air Sampling Tubes and RespiCon™ Filters during Monitoring Events (continued)

Subject Number	Sample Number	Pump ID	Flow Rates (L/min)		
			Start	Finish	Average
ME-07	AEA09-BRS-07-AR	PMP-33	2.013	1.829	1.921
	AEA09-BRS-07-RES-01	745473	3.107	3.129	3.118
	AEA09-BRS-07-RES-02				
	AEA09-BRS-07-RES-03				
ME-08	AEA09-BRS-08-AR	PMP-23	2.013	2.049	2.031
	AEA09-BRS-08-RES-01	882222	3.133	3.137	3.135
	AEA09-BRS-08-RES-02				
	AEA09-BRS-08-RES-03				
ME-09	AEA09-BRS-09-AR	PMP-33	2.013	2.007	2.010
	AEA09-BRS-09-RES-01	745473	3.113	3.081	3.097
	AEA09-BRS-09-RES-02				
	AEA09-BRS-09-RES-03				
ME-10	AEA09-BRS-10-AR	PMP-23	2.001	1.994	1.998
	AEA09-BRS-10-RES-01	882222	3.115	3.127	3.121
	AEA09-BRS-10-RES-02				
	AEA09-BRS-10-RES-03				
ME-11	AEA09-BRS-11-AR	PMP-33	2.001	2.038	2.020
	AEA09-BRS-11-RES-01	745473	3.107	3.106	3.107
	AEA09-BRS-11-RES-02				
	AEA09-BRS-11-RES-03				
ME-12	AEA09-BRS-12-AR	PMP-14	2.014	1.825	1.920
	AEA09-BRS-12-RES-01	882262	3.118	3.022	3.070
	AEA09-BRS-12-RES-02				
	AEA09-BRS-12-RES-03				

Table 45 Personal Air Pump Flow Rates for Air Sampling Tubes and RespiCon™ Filters during Monitoring Events (continued)

Subject Number	Sample Number	Pump ID	Flow Rates (L/min)		
			Start	Finish	Average
ME-13	AEA09-BRS-13-AR	PMP-5	2.017	2.009	2.013
	AEA09-BRS-13-RES-01	882206	3.107	3.121	3.114
	AEA09-BRS-13-RES-02				
	AEA09-BRS-13-RES-03				
ME-14	AEA09-BRS-14-AR	PMP-5	2.006	2.043	2.025
	AEA09-BRS-14-RES-01	882262	3.115	3.155	3.135
	AEA09-BRS-14-RES-02				
	AEA09-BRS-14-RES-03				
ME-15	AEA09-BRS-15-AR	PMP-23	2.017	2.042	2.030
	AEA09-BRS-15-RES-01	882206	3.109	3.242	3.176
	AEA09-BRS-15-RES-02				
	AEA09-BRS-15-RES-03				
ME-16	AEA09-BRS-16-AR	PMP-37	2.010	1.927	1.969
	AEA09-BRS-16-RES-01	882222	3.091	3.131	3.111
	AEA09-BRS-16-RES-02				
	AEA09-BRS-16-RES-03				
ME-17	AEA09-BRS-17-AR	PMP-5	2.009	2.055	2.032
	AEA09-BRS-17-RES-01	882262	3.106	3.194	3.150
	AEA09-BRS-17-RES-02				
	AEA09-BRS-17-RES-03				
ME-18	AEA09-BRS-18-AR	PMP-23	2.012	1.978	1.995
	AEA09-BRS-18-RES-01	882206	3.110	3.122	3.116
	AEA09-BRS-18-RES-02				
	AEA09-BRS-18-RES-03				

Table 46 Total Air Pumping Time for All Subjects

Subject Number	Time Pumps Turned On	Time Pumps Turned Off	Total Time Pumps were On (min)
ME-01	9:50 am	11:54 am	124
ME-02	9:00 am	10:39 am	99
ME-03	10:17 am	12:33 pm	136
ME-04	8:41 am	10:31 am	110
ME-05	11:28 am	1:34 pm	126
ME-06	9:25 am	11:00 am	95
ME-07	10:11 am	12:55 pm	164
ME-08	8:43 am	11:35 am	172
ME-09	9:36 am	12:16 pm	160
ME-10	9:04 am	11:17 am	133
ME-11	10:55 am	12:43 pm	108
ME-12	9:40 am	10:45 am	65
ME-13	10:23 am	11:57 am	94
ME-14	8:57 am	9:45 am	48
ME-15	10:39 am	11:36 am	57
ME-16	7:58 am	8:57 am	59
ME-17	9:05 am	10:09 am	64
ME-18	10:19 am	12:12 pm	113

Table 47 Air Concentrations for Subjects

BIT Level in Paint Applied	Monitoring Event	Sampling Time (min)[a]	Corrected Residue (µg)	BIT Handled (lb)	Average Pump Flow Rate (L/min)	Amount of Air Drawn[b] (m^3)	Inhalation Concentration[c] (µg/m^3)	Inhalation Unit Exposure[d] (µg BIT/lb ai handled)
Low	ME-01	124	<LOQ	0.00308	1.981	0.246	0.0203	13.7
	ME-02	99	<LOQ	0.00272	2.038	0.202	0.0248	15.1
	ME-04	110	<LOQ	0.00305	1.832	0.202	0.0248	14.9
	ME-11	108	<LOQ	0.00308	2.020	0.218	0.0229	13.4
	ME-13	94	<LOQ	0.00287	2.013	0.189	0.0265	14.5
	ME-18	113	<LOQ	0.00276	1.995	0.225	0.0222	15.2
Mean		108	<LOQ	0.00293	1.98	0.214	0.0236	14.5
Standard Deviation		10.6	NA	0.000165	0.0751	0.0204	0.00222	0.755
Mid	ME-05	126	<LOQ	0.00808	1.972	0.248	0.0202	5.24
	ME-08	172	<LOQ	0.00766	2.031	0.349	0.0143	5.37
	ME-10	133	<LOQ	0.00787	1.998	0.266	0.0188	5.31
	ME-12	65	<LOQ	0.00753	1.920	0.125	0.0400	5.78
	ME-14	48	<LOQ	0.00712	2.025	0.0972	0.0514	5.79
	ME-15	57	<LOQ	0.00777	2.030	0.116	0.0431	5.29
Mean		100	<LOQ	0.00767	2.00	0.200	0.0313	5.46
Standard Deviation		50.5	NA	0.000329	0.0438	0.102	0.0154	0.253
High	ME-03	136	<LOQ	0.0141	1.944	0.264	0.0189	3.05
	ME-06	95	<LOQ	0.0128	2.042	0.194	0.0258	3.19
	ME-07	164	<LOQ	0.0130	1.921	0.315	0.0159	3.34
	ME-09	160	<LOQ	0.0120	2.010	0.322	0.0155	3.46
	ME-16	59	<LOQ	0.0124	1.969	0.116	0.0431	3.42
	ME-17	64	<LOQ	0.0132	2.032	0.130	0.0385	3.11
Mean		113	<LOQ	0.0129	1.99	0.224	0.0263	3.26
Standard Deviation		46.9	NA	0.000722	0.0492	0.0904	0.0119	0.169
OVERALL						**Mean**	0.0271	7.73
						Standard Deviation	0.0111	5.01

LOQ = 0.0100 µg/sample.

[a] Total time pump was on

[b] Amount of Air Drawn (m^3) = Sampling Time (min) x Average Pump Flow Rate (L/min) x (1 m^3/1000 L).

[c] Inhalation Concentration (µg/m^3) = (Corrected residue (µg))/((Average Pump Flow Rate (L/min) x Sampling Time (min) x (1 m^3/1000 L).

[d] Inhalation Unit Exposure (µg BIT/lb ai handled) = ((Corrected residue (µg) x (EPA Std Adult Breathing Rate for light work (16.7 L/min))/(Average Pump Flow Rate (L/min) x BIT Handled (lb)).

Note: Results less than the LOQ were assigned a value of ½ LOQ for statistical purposes.

Table 48 Size Distribution of Particles of BIT

Monitoring Event Conducted	Monitoring Event	Sampling Time (min)[a]	Total Corrected Residue (µg)	Average Pump Flow Rate (L/min)	Amount of Air Drawn (m^3)[b]	Total BIT Air Concentration (µg/m^3)	% of Total Residue Captured on 100 µm Filter	% of Total Residue Captured on 10 µm Filter	% of Total Residue Captured on 2.5 µm Filter
Low	ME-01	124	<LOQ	3.102	0.385	<LOQ	NA	NA	NA
	ME-02	99	<LOQ	3.008	0.298	<LOQ	NA	NA	NA
	ME-04	110	<LOQ	3.072	0.338	<LOQ	NA	NA	NA
	ME-11	108	<LOQ	3.107	0.336	<LOQ	NA	NA	NA
	ME-13	94	<LOQ	3.114	0.293	<LOQ	NA	NA	NA
	ME-18	113	<LOQ	3.116	0.352	<LOQ	NA	NA	NA
Mean		**108**	**<LOQ**	**3.09**	**0.334**	**<LOQ**	**NA**	**NA**	**NA**
Standard Deviation		**10.6**	**NA**	**0.0416**	**0.0344**	**NA**	**NA**	**NA**	**NA**
Mid	ME-05	126	<LOQ	3.059	0.385	<LOQ	NA	NA	NA
	ME-08	172	<LOQ	3.135	0.539	<LOQ	NA	NA	NA
	ME-10	133	<LOQ	3.121	0.415	<LOQ	NA	NA	NA
	ME-12	65	<LOQ	3.070	0.200	<LOQ	NA	NA	NA
	ME-14	48	<LOQ	3.135	0.150	<LOQ	NA	NA	NA
	ME-15	57	<LOQ	3.176	0.181	<LOQ	NA	NA	NA
Mean		**100**	**<LOQ**	**3.12**	**0.312**	**<LOQ**	**NA**	**NA**	**NA**
Standard Deviation		**50.5**	**NA**	**0.0441**	**0.157**	**NA**	**NA**	**NA**	**NA**
High	ME-03	136	<LOQ	3.084	0.419	<LOQ	NA	NA	NA
	ME-06	95	<LOQ	3.115	0.296	<LOQ	NA	NA	NA
	ME-07	164	<LOQ	3.118	0.511	<LOQ	NA	NA	NA
	ME-09	160	<LOQ	3.097	0.496	<LOQ	NA	NA	NA
	ME-16	59	<LOQ	3.111	0.184	<LOQ	NA	NA	NA
	ME-17	64	<LOQ	3.150	0.202	<LOQ	NA	NA	NA
Mean		**113**	**<LOQ**	**3.11**	**0.351**	**<LOQ**	**NA**	**NA**	**NA**
Standard Deviation		**46.9**	**NA**	**0.0223**	**0.144**	**NA**	**NA**	**NA**	**NA**

[a] Total time pump was on

[b] Amount of Air Drawn (m^3) = Sampling Time (min) x Average Pump Flow Rate (L/min) x (1 m^3/1000 L).

APPENDIX A.

PROTOCOL INCLUDING AMENDMENTS AND DEVIATIONS

PROTOCOL

05 January 2016

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

February 2016

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEA09

GPL Study Number

120463

Total Number of Pages: 150

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No: AEA09
GPL Study No: 120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date: February 2016

Proposed Experimental Termination Date: July 2016

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
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2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 360 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 360 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all personal protective equipment (PPE, i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable, thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized

with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as outlined in section 4 of the scenario design document. Generally, from a regulatory

perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is limited incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: (*954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish.

Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California Department of Pesticide Review (DPR) and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations,

and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data available to EPA from the PHED, the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or isopropyl alcohol (IPA) will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own gender. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The subjects will be painting using equipment such as extension poles and ladders. There is a risk of injury from dropped equipment or falling. These risks will be reduced by continuous observation from the research team and assistance with supporting ladders.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 360 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 360 ppm and 600 ppm.
A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study for each preparation of the test substance including colorant.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantitation of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint types.

The table below lists the proposed limit of quantitation (LOQ) for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample
Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Subjects will be provided a smaller container (paint cup) and edger to use at their preference for brush painting. If subjects use the paint cup they will transfer paint from the secondary container to the paint cup. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue. Subjects will be provided dry

cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at ambient room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting

rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary the amount of active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).

Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 6 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 12 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. The ceiling exhaust fan will be operated continuously during each ME. Room airflow (ACH) will be measured and included in the final study report. Photographs of the painting rooms will be maintained in the raw data. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment

used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The AiAH will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Painters to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates.

At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24 initially selected are required, randomized subject 25 will be contacted followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate painters (or 'workers') for the MEs. This includes the planned 18 surrogate painters needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment

materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Subject Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire about the health of the subject. The investigator will answer any questions the subject may have. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee

will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 24 subjects have

been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and

Subject Self-Reporting Demographic Form

- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands, face, or neck (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies or sensitivities to latex paint, soaps, BIT, isopropyl alcohol or other chemical products.
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Other health conditions that make participation difficult or unsafe (e.g. broken bone)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential appliers of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study

sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of six will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal

Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed, research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink. The on-site health professional will immediately be contacted for further medical

management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an

approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same gender. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer dosimeter shirt will be tucked into the pants.

A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation, and the subject will retain the key during their ME.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. A piece of inner dosimeter cloth will be placed underneath the painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on and ensure proper placement.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections. Ceiling ventilation fans will remain on while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be provided additional test substance until they

have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks. Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same gender. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

a. The researcher will help subjects take off the painter's hat plus underlying dosimeter and save them for analysis.

b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse by pouring the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

f. The researcher will help subjects take off the long underwear, and save it for analysis.

g. When all samples have been collected, subjects will dress again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat and underlying dosimeter cloth will be removed with the assistance of a researcher (study team member) of the same gender, placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing,

sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™ filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be

collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same gender and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in “gross violation” or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be

based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.

5. Prepare field fortification samples.
6. Monitor temperature and humidity, ensure room vent fans are on during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site (e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 ng/mL and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at $\leq$ -10° C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be added to the raw data
Purity:	to be added to the raw data
Date Received:	to be added to the raw data
Expiration Date:	to be added to the raw data

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The limit of quantitation (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the remaining samples. Any sample not bracketed by the standard curve concentrations will be re-diluted and re-analyzed unless it is below the LOQ when at the minimum method dilution.

Each analytical set will include two laboratory fortified matrix samples, a solvent blank and an unfortified matrix control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal

standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantitation

Chromatographic quantitation (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);
12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study, except study subject personal information, will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be maintained in a separate location at GPL and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts (Appendix H), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for

changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the quality

assurance unit (QAU). The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Study Director and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.
9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.

13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with California DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

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19. PROTOCOL APPROVALS

Has Shah March 15, 2016
Has Shah, Ph.D. Date
Sponsor's Representative

03/15/16
Robert J. Testman, M.B.A. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

03/15/16
Megan T. Boatwright, B.S. Date
Field Coordinator (English)
Golden Pacific Laboratories, LLC

03/15/16
Kimon P. Acedo, B.S. Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Reviewed By:

03/15/16
Margaret A. Hamelin, B.S., RQAP-GLP Date
Quality Assurance
Golden Pacific Laboratories, LLC

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol*. Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012 Complies with:			
OTC	Yes	LEED®09 CI	Yes
SCAQMD	Yes	LEED®09 NC	Yes
CARB	Yes	LEED®09 CS	Yes
CARB SCM 2007	Yes	LEED®09 H	Yes
MPI #	53	NGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer
Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry
Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent
Flash Point: N/A
Finish: 0-5 units @ 85°
Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic
A86W00151
VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12
Volume Solids: 43 ± 2%
Weight Solids: 61 ± 2%
Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

continued on back

SHERWIN WILLIAMS.

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SUPERPAINT®

Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE: Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
HOTW 03/25/2013 A86W00151 09:47

The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

Desde el 01/12/2012, cumple con:			
OTC	SI	LEED® 09 CI	SI
SCAQMD	SI	LEED® 09 NC	SI
CARB	SI	LEED® 09 CS	SI
CARB SCM 2007	SI	LEED® 09 H	SI
MPI N.°	53	NGBS	SI

CARACTERÍSTICAS

SuperPaint Interior Latex Flat se utiliza en paneles y maderas vírgenes, imprimados o con pintura previa, así como en revoque imprimado, mampostería y metales. SuperPaint permite cubrir con una capa cualquier color en superficies lisas y ofrece un acabado duradero que se puede lavar y fregar.

Color: Disponible en la mayoría de los colores
Para optimizar la cobertura y la coloración, utilice siempre el imprimador P-Shade recomendado.

Rendimiento: 350-40 ft²/gal (7,2-8,1 m²/L) a 4 mils húmedo; 1,6 mils seco

Tiempo de secado a 77 °F (25 °C) y 50 % RH:
Tacto: 1 hora
Repintado: 4 horas
Los plazos de secado y repintado dependen de la temperatura, la humedad y el espesor de la capa.

Punto de inflamación: N/C

Acabado: 0-5 unidades a 85º

Tinturas con CCE:

Base	oz/gal	Fuerte
Extrablanco	0-6	125 %
Base profunda	4-12	100 %
Blanco de alta reflectividad	0-5	125 %

Tipo de vehículo: Acrílico vinilo
A86W00151

COV (salvo solventes exentos): <50 g/L; 0,42 lb/gal
Conforme al Código de Reglamentos Federales [CFR], Título 40, Artículo 59.406, y a las Regulaciones de Productos Orgánicos [SOR] 2009-264, art. 12

Sólidos por volumen: 43 ± 2 %

Sólidos por peso: 61 ± 2 %

Peso por galón: 12,1 lb (5,4 kg)

ESPECIFICACIONES

SuperPaint Interior Latex se puede aplicar directamente sobre revestimientos previos o sobre paneles de yeso sin pintar, revoque (curado con un pH menor a 9), mampostería (curada con un pH menor a 9), madera sin sangrado.

Panel de yeso
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Mampostería/bloques
(se pueden rellenar para obtener una superficie lisa o imprimar si se trata de un sustrato con un pH alto)
1 capa Loxon Block Surfacer
o
1 capa Loxon Concrete & Masonry Primer
2 capas SuperPaint Interior Latex

Revoque
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Madera
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex
Si la madera presenta sangrados (como taninos u orificios de nudos), aplique una capa de imprimador con Multi-Surface Primer.

Otros imprimadores podrían ser adecuados.

Cuando volver a pintar implique un cambio de color drástico, la presencia de una capa de imprimador mejorará el poder cubritivo del revestimiento de color definitivo.

PREPARACIÓN DE LA SUPERFICIE

¡ADVERTENCIA! La eliminación de la pintura vieja mediante lija, raspaje u otro medio podría generar polvo o vapores que contengan plomo. La exposición al polvo y vapores con plomo podría causar un daño cerebral u otros problemas de salud, especialmente en el caso de niños y embarazadas. Para controlar la exposición al plomo y otras sustancias peligrosas se necesita utilizar equipos de protección adecuados, como un respirador bien ajustado (aprobado por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) y una contención y limpieza correctos. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-LEAD (en los EE. UU.) o comuníquese con la autoridad sanitaria local.

Elimine de las superficies cualquier tipo de contaminación lavándolas con un limpiador adecuado, enjuague minuciosamente y deje que se sequen. La pintura descascarada o marcada se debería rasquetear y lijar hasta lograr una superficie sólida. Las superficies brillantes se deberían lijar hasta quitarles el brillo. Las manchas causadas por agua, humo, tinta, lápiz, grasa, etc. se deberían sellar utilizando el imprimador/sellador adecuado.

Panel de yeso
Llene las grietas y perforaciones con enduido/masilla y lije hasta que la superficie quede lisa. Los compuestos para juntas se deben curar y lijar hasta que la superficie quede lisa. Elimine todo el polvo producido al lijar.

Mampostería, concreto, cemento, bloques
Todas las superficies nuevas se deben curar según las recomendaciones del proveedor (normalmente, durante unos 30 días). Elimine todo tipo de agente desmoldante y de curado. Las superficies ásperas se deben empastar para obtener una superficie lisa. Si no pudiera esperar 30 días para comenzar a pintar, deje que la superficie se cure durante 7 días y luego imprima la superficie con Loxon Concrete & Masonry Primer.

SHERWIN WILLIAMS.

101.02

SUPERPAINT®
Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

PREPARACIÓN DE LA SUPERFICIE

Revoque
El revoque sin pintar se debe curar y dejar endurecer. El revoque texturado, blando, poroso o granulado debería tratarse con una solución de 1 pinta (473 cm^3) de vinagre de uso doméstico y 1 galón (3,79 L) de agua. Repita hasta que la superficie esté dura, luego enjuague con agua limpia y deje que se seque.

Madera
Lije la madera expuesta para lograr una superficie indemne. Emparche todos los orificios e imperfecciones con masilla o enduido para madera y lije hasta que la superficie quede lisa.

Moho
Antes de pintar, elimine el moho con una solución de 1 parte de blanqueador líquido y 3 partes de agua. Aplique la solución y friegue el área mohosa. Deje trabajar la solución sobre la superficie durante 10 minutos. Enjuague minuciosamente con agua y deje secar la superficie antes de pintarla. Utilice gafas protectoras, guantes impermeables y vestimenta de protección. Enjuague sin demora cualquier resto de la mezcla que tenga contacto con su piel. No agregue detergentes ni amoníaco a la solución de blanqueador y agua.

Enmasillado
Los espacios en las paredes, cielorrasos, molduras de cornisas y otros contramarcos internos se pueden rellenar con la masilla adecuada después de imprimar la superficie.

APLICACIÓN

Aplicar a temperaturas superiores a 50 °F (10 °C).
No es necesario diluir.
Brocha
Utilice brochas de nailon/poliéster.
Rodillo
Utilice rodillos de felpa sintética de 3/8" a 3/4" (0,95 a 1,90 cm).
Pistola de pulverización sin aire
Presión ..... 2000 psi
Boquilla..... .017"-.021"

INFORMACIÓN SOBRE LIMPIEZA

Use jabón y agua tibia para limpiar derrames, salpicaduras, manos y herramientas inmediatamente después de utilizar el producto. Después de limpiar, haga correr alcohol mineral por el equipo de la pistola para evitar que se oxide. Siga las recomendaciones de seguridad del fabricante siempre que utilice alcoholes minerales.

PRECAUCIONES

Únicamente para uso en interiores.
Proteja contra el frío.
Sin reacción fotoquímica.

ETIQUETA DE PRECAUCIÓN
PRECAUCIÓN: contiene SÍLICE CRISTALINA. Utilice únicamente con una ventilación adecuada. Para evitar una exposición excesiva, abra las puertas y ventanas o utilice otros medios para garantizar la circulación de aire fresco durante la aplicación y el secado. Si le llora la vista, le duele la cabeza o sufre mareos, aumente la circulación de aire fresco, utilice protección respiratoria (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) o abandone el lugar. Deberá haber una ventilación adecuada cuando se lije o desgaste la película seca. Si no pudiera proporcionarse una ventilación adecuada, utilice una máscara antipartículas (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH). Siga las instrucciones del fabricante de la máscara. Evite el contacto con ojos y la piel. Lávese las manos después de usar el producto. Mantenga el recipiente cerrado cuando no lo esté utilizando. No transfiera el contenido a otros recipientes para almacenarlo. PRIMEROS AUXILIOS: En caso de contacto ocular, enjuáguese minuciosamente con una gran cantidad de agua. Consulte a su médico si la irritación persiste. En caso de ingerir el producto, llame de inmediato al Centro de Toxicología, una sala de emergencias hospitalaria o a un médico. EFECTOS RETARDADOS CAUSADOS POR UNA EXPOSICIÓN EXCESIVA PROLONGADA: El desgaste o lijado de la película seca podría liberar sílice cristalino que, según se ha comprobado, puede provocar daños pulmonares y cáncer en caso de exposición prolongada. ADVERTENCIA: Este producto contiene sustancias químicas que, según el Estado de California, provocan cáncer y defectos congénitos u otros daños reproductivos. NO INGERIR. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.
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La información y recomendaciones en la Hoja de Datos del Producto se basan en las pruebas realizadas por The Sherwin-Williams Company o en representación de ella. La información y recomendaciones mencionadas están sujetas a cambios y corresponden al producto ofrecido al momento de su publicación. Consulte a un representante de Sherwin-Williams para obtener la Hoja de Datos del Producto más reciente.

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or, absorbed through skin. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles or face shield) long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latices, Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Car Care Products Including Car Washes, Car Waxes, And Silicone Emulsions, Home Care Cleaning Products Including Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	**5383-121**
EPA Establishment Number	**5383-NJ-1**

ACTIVE INGREDIENT:	**% Weight**
1,2-Benzisothiazolin-3(2H)-One	**19.18%**
INERT INGREDIENTS	**80.82%**
TOTAL	**100.0%**

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:
[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

®MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

GENERAL INFORMATION

APPLICATION RATE: Mergal® BIT 20 is an effective preservative for most aqueous applications. Mergal® BIT 20 is suggested for use in aqueous or water-containing products and systems, including industrial and institutional products to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% w/w/t of Mergal® BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below.

FOR FOOD-CONTACT PAPER AND PAPERBOARD COATINGS: Follow the FDA clearances cited below. Use Mergal® BIT 20 at a level not to exceed 0.1% (1000 mg/kg) of dried paper and paperboard intended for contact with dry foods and 0.1 mg/in² (0.0168 mg/cm²) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal® BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 –	Components for Adhesives
21 CFR 176.170 –	Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 –	Components of Paper and Paperboard in contact with dry food
21 CFR 176-300 –	Slimicides (in the manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 –	Rubber articles intended for repeated use: follow instructions in package (GMP)

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polymer and micellar/polymer waterfloods: Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning,If available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection
To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

    When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks
If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA09) Estudio para medir la potencial exposición dérmica y por inhalación durante la aplicación con brocha y rodillo de una pintura de látex que contiene un producto pesticida antimicrobiano en superficies interiores

Investigador principal: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Coordinadores de campo:

Megan T. Boatwright (inglés)
Coordinadora de campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Natan R. Chavez (inglés y español)
Asociado de investigaciones en el campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate, M.S. (inglés)
Asociado de investigaciones en el campo
Gerente general
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Instalaciones en el campo: (Lugar de la entrevista para el consentimiento informado del sujeto)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Lugar de los procedimientos del estudio)
Un edificio comercial vacante en Fresno County, CA

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono las 24 horas: 949-939-3585 (Robert Testman)

Le estamos pidiendo que considere participar en un estudio de investigación porque tiene experiencia pintando con brocha y rodillo. Su participación es voluntaria. Este formulario de consentimiento informado explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar y comentarlo con sus amigos o familia antes de decidir si desea participar en el estudio. Si tiene alguna pregunta o si no entiende algo de este formulario, pida a uno de nosotros que se lo expliquemos. Si prefiere hablar en español, por favor indíquelo así. Le podemos explicar el estudio en inglés o en español.

Schulman Institutional Review Board, Inc. (Schulman), un comité institucional de revisión, ha aprobado la información que contiene este documento de consentimiento y ha autorizado al médico del estudio para que efectúe el estudio. Un comité institucional de revisión (Institutional Review Board o IRB, por sus siglas en inglés) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado que usted participe en el estudio. Es a usted a quien corresponde examinar la información de este documento de consentimiento y, seguidamente, decidir si desea participar en el estudio.

Finalidad de este estudio

Golden Pacific Laboratories está llevando a cabo esta investigación. Nos gustaría saber cuánta sustancia química puede caer en su piel cuando aplica una pintura de látex para interiores con una brocha y un rodillo. Mediremos la cantidad de la sustancia química que le cae en la ropa que usa y en sus manos, cara y cuello. Le pediremos que pinte superficies interiores como paredes, cielorraso y molduras. También nos gustaría saber la cantidad de la sustancia química que se encuentra en el aire que usted respira durante el estudio. Esta información se proporcionará a la Agencia de Protección Ambiental de EE. UU. o EPA por sus siglas en inglés. La EPA usará esta información para evaluar los niveles de exposición a las sustancias químicas de la pintura de este estudio y de otras pinturas similares a ella.

Un grupo de compañías que fabrica productos para reducir la cantidad de microorganismos paga este estudio. Este grupo de compañías se llama Grupo Operativo de Evaluación de la Exposición a Agentes Antimicrobianos II (Antimicrobial Exposure Assessment Task Force II). La EPA ha registrado estos productos como pesticidas.

Robert Testman, Thomas Moate, Megan Boatwright y Natan Chavez trabajan en Golden Pacific Laboratories. Robert Testman está a cargo del estudio. Thomas Moate, Megan Boatwright y Natan Chavez también están capacitados para explicar el estudio y contestar cualquier pregunta que pudiera tener. Natan Chavez habla español. Él será el principal investigador de habla hispana.

Producto de prueba
El producto de prueba es una pintura de látex para interiores de Sherwin-Williams. Esta es una pintura de uso común. Este producto se usa para pintar paredes y molduras en casas y empresas. El producto de prueba contiene una sustancia química conocida como BIT que ayuda a evitar el crecimiento bacteriano. Hemos añadido una cantidad adicional de BIT a la pintura para este estudio, pero no más que la necesaria para evaluar su exposición a este producto. Se le entregará una copia de la etiqueta del producto. También le daremos la hoja de datos de seguridad del material, o "MSDS" por sus siglas en inglés, de este producto, si lo desea.

Selección de sujetos
Para participar en el estudio debe estar sano y tener 18 años de edad o más. Debe poder leer y hablar inglés o español. Necesitará comprobar su edad con un documento de identidad con fotografía expedido por el gobierno, como una licencia para conducir o un pasaporte. Debe tener experiencia pintando con brocha y rodillo, pero no ser pintor profesional. Debe querer participar en este estudio. Debe estar dispuesto a firmar este consentimiento, el formulario Declaración de derechos de los sujetos participantes en experimentos y una ficha de calificación. Le pediremos que proporcione cierta información personal adicional y que siga las instrucciones de los investigadores.

No podrá participar en esta investigación si es empleado o cónyuge de un empleado de Golden Pacific Laboratories, de cualquiera de las compañías que pagan esta investigación, del Consejo Americano de Química (American Chemistry Council) o de un fabricante de pinturas; si está embarazada o lactando; si ha tenido reacciones alérgicas al jabón, alcohol isopropílico, productos de pintura o productos químicos (incluido el BIT); si tiene psoriasis, eccema, llagas o cortaduras abiertas en la piel; si tiene problemas cardiacos o respiratorios; o si tiene otros problemas médicos que dificultaran su participación.

En este estudio participarán entre dieciocho y veinticuatro personas. Inscribiremos a unas pocas personas más que las que necesitamos en caso de que alguien no pueda participar el día de la prueba.

Haremos el estudio en un edificio vacante aquí en Fresno County. Puede participar en el estudio solamente una vez. Si en un día usted es el suplente y no se lo selecciona, es posible que pueda participar en el estudio otro día.

Inscripción en el estudio
Hoy se va a reunir con el investigador principal, Robert Testman, con los coordinadores de campo, Megan Boatwright o Thomas Moate; o si lo prefiere, con un investigador que habla español. Ellos le darán más información sobre lo que debe esperar durante el estudio y lo que se espera de usted. También contestarán cualquier pregunta que tenga sobre el estudio. Usted puede decidir hoy si desea participar en el estudio o puede llevarse a casa este formulario para conversarlo con su familia y amigos antes de tomar su decisión.

Le preguntaremos sobre su experiencia como pintor y sobre su salud general. Le preguntaremos su nombre y edad, y si tiene alguna afección en la piel de sus manos. Si decidimos que es apto, y si usted decide que quiere participar en el estudio, le pediremos que firme este consentimiento informado y el formulario Declaración de derechos de los sujetos participantes en experimentos. Luego le preguntaremos su estatura y peso y la talla de su ropa.

Si lo inscribimos en el estudio, le pediremos que venga al sitio del estudio cierto día y a cierta hora. Lo llamaremos un día antes para recordarle y asegurarnos de que aún desea participar en el estudio. También le pediremos que se asegure de tomar una ducha o darse un baño antes de ir al sitio del estudio.

Procedimiento del estudio
Si se lo selecciona, hará la prueba en cuartos pequeños construidos dentro de un edificio vacante ubicado en Fresno County. La prueba durará 3 o 4 horas en un día. Después de que llegue se pondrá ropa especial para la prueba y se le colocarán dos bombas pequeñas para tomar muestras del aire que respira. Luego le pediremos que pinte las paredes, los cielorrasos, los zócalos, la moldura de la ventana y la moldura de la puerta con una brocha y un rodillo de pintura. Le proporcionaremos todo el equipo que usará, como una brocha, un rodillo, una bandeja para el rodillo, trapos para pintura, etc. Usted pintará como lo hace normalmente cuando pinta una habitación en su propia casa. Se le pedirá que use aproximadamente dos galones de pintura en varios cuartos. Puede descansar entre cuartos si lo necesita. El tiempo real que pasará pintando puede ser de varias horas. Después recogeremos la ropa especial que usó, usted se pondrá su propia ropa, recibirá su pago y se irá.

Esto es exactamente lo que sucederá.

1. El día del estudio usted irá al sitio del estudio a la hora que se le dijo, y se reunirá con el equipo de estudio.

2. Robert Testman y el equipo de investigación revisarán con usted y con los otros participantes lo que sucederá, y usted tendrá otra oportunidad de hacer preguntas. Le recordaremos que en cualquier momento, antes o después de que comience el estudio, puede cambiar de parecer con respecto a su participación en el estudio. Todo lo que necesita hacer es decirnos que cambió de parecer. No sufrirá sanciones de ningún tipo si decide abandonar el estudio.

3. Dado que es importante que usted NO participe en este estudio si está embarazada, el día de la prueba cada voluntaria pasará a un área privada y recibirá un kit de prueba de embarazo como los que puede comprar en la farmacia. Una investigadora le explicará cómo usarlo y contestará sus preguntas. Después de hacerse la prueba le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no se le preguntará la razón y no se registrarán los resultados de la prueba. Se le pagarán $100 por venir al sitio de la prueba y entonces podrá irse. Si desea permanecer en el estudio, una investigadora capacitada verificará los resultados con usted. Nadie aparte de usted verá los resultados pero nosotros haremos una nota indicando que la prueba se hizo.

4. Antes de que comience la prueba se lavará las manos y la cara con jabón Ivory y agua, y se las secará con toallas de papel. Revisaremos sus manos para asegurarnos de que no tiene cortaduras, raspaduras ni ninguna afección que pudiera aumentar el riesgo de que sufra problemas en la piel durante la prueba.

5. Una persona de su mismo sexo lo llevará a un área limpia y privada para que se cambie y se prepare para el estudio. Le pediremos que se quite su ropa excepto la ropa interior. Luego se pondrá calzoncillos largos de algodón (*long johns*), una camiseta de algodón de mangas largas y pantalones largos de algodón. Nosotros le proporcionaremos toda esta ropa. Es posible que tengamos que recortar el reborde de las mangas o de las piernas de los calzoncillos largos para que no sobresalgan. Colocará su propia ropa y sus objetos de valor en un área de almacenamiento bajo llave, y usted conservará la llave. Usará su propio calzado, pero si quiere le daremos cubiertas para evitar que le caiga pintura en los zapatos.

6. Le daremos una gorra de pintor y gafas de seguridad para que las use mientras pinta. Debe usar estos artículos mientras pinta con la brocha o el rodillo.

7. Le instalaremos en el cinturón, alrededor de su cintura, dos pequeñas bombas para muestreo de aire. Si no lleva cinturón le proporcionaremos uno para que lo use. Le colocaremos un pequeño tubo en el cuello de la camisa y lo conectaremos en una de las bombas. Instalaremos un pequeño tomador de muestras de aire en la otra bomba y lo colocaremos frente a usted con una pequeña correa alrededor de su pecho. Ambas bombas tomarán muestras del aire que respira mientras pinta. Cada bomba es del tamaño aproximado de un radio portátil. El tubo es del tamaño de un lápiz, y el tomador de muestras de aire es aproximadamente del tamaño de una bola de tenis.

8. Le mostraremos el equipo que usará para pintar, incluido el pequeño cubo que contiene la pintura, la brocha, el rodillo, la bandeja para el rodillo, el mango de extensión y los trapos para pintura. También contaremos con ribeteadores de pintura y pequeños vasos de pintura por si desea usarlos. Le preguntaremos si tiene alguna pregunta.

9. Lo llevaremos a uno de los cuartos pequeños en donde comenzará a trabajar. Encenderemos las bombas de aire que le colocamos y le pediremos que se ponga la gorra y las gafas de seguridad. Le entregaremos una lata de pintura cerrada que contiene pintura. Quitará la tapa de la lata de pintura con un abridor. Usará una brocha con la lata de pintura para pintar las molduras de una o más paredes. Verterá algo de pintura de la lata en la bandeja para el rodillo y pintará con el rodillo el cielorraso y las paredes. Cuando se termine la pintura de la lata, le daremos una lata nueva hasta que haya usado la cantidad asignada. Uno de nosotros lo observará mientras trabaja, anotando el tiempo que trabaja y la cantidad de superficie que pinta. También podemos tomar fotografías o grabar videos para mostrar lo que sucedió en el estudio, pero en el informe final, tales fotografías no mostrarán rostros, tatuajes ni otras características identificadoras. **Si no desea que se le tomen fotografías, no debe participar en este estudio.**

10. Le pediremos que aplique aproximadamente dos galones de pintura. Trabajará en tantos cuartos como sea necesario para usar la cantidad asignada de pintura. Puede tomar un breve descanso en cualquier momento que desee, tal como lo haría en el trabajo. No podrá fumar ni comer durante la prueba, pero puede consumir una bebida fría durante su descanso. Si necesita usar el baño, uno de los investigadores le limpiará sus manos antes de que vaya, para recoger cualquier pintura que pueda tener en ellas.

11. Cuando termine de pintar, un investigador de su mismo sexo lo llevará al área donde se cambia la ropa y le tomará muestras:

    a. El investigador le quitará la gorra de pintor, las bombas tomadoras de muestras de aire y el equipo.

    b. El investigador frotará sus manos con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua, se las enjuagará con la misma solución y guardará la solución del enjuague.

    c. El investigador le limpiará la cara y el cuello con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua para recoger cualquier pintura que pudiera tener en la piel.

    d. El investigador lo ayudará a quitarse los zapatos (y los calcetines si lo desea).

    e. El investigador lo ayudará a quitarse la camiseta y los pantalones y los guardará para analizarlos.

    f. El investigador lo ayudará a quitarse los calzoncillos largos y los guardará para analizarlos.

Cuando hayamos tomado todas estas muestras, se vestirá otra vez con su propia ropa. Revisaremos sus manos antes de que se vaya para ver si las tiene enrojecidas o muestra otros signos de irritación. Le pagaremos $100 en efectivo y podrá irse.

Riesgos
Si participa el este estudio estaría expuesto a varias clases de riesgos:

1. El riesgo de una reacción a la pintura de látex o al ingrediente de pesticida (BIT) de la pintura. El contacto directo con la pintura puede causar enrojecimiento de los ojos, dolor e inflamación o irritación de la piel, de manera temporal, y la respiración del vapor puede causar tos e irritar su garganta. Usará gafas de seguridad para evitar que le caiga pintura en los ojos, y camiseta de manga larga y pantalones para evitar que le caiga pintura en la piel. También podría tener una reacción alérgica a la pintura. Pudiera sentirse mareado o tener dolor de cabeza. Si anteriormente ha tenido una reacción a un producto de pintura, asegúrese de decírnoslo. Si nota enrojecimiento o comezón, se siente mareado o piensa que le cayó pintura en los ojos, deje de pintar inmediatamente y dígaselo al investigador.

2. Riesgo de molestia Las bombas de aire instaladas en su cinturón y las mangueras de aire usadas para muestrear el aire que respira pueden causarle incomodidad. También pudiera resultarle incómodo usar dos capas de ropa.

3. Riesgo de lesiones Se le pedirá que use equipo para pintura y unas escaleras para pintar los cuartos. Si perdiera el equilibrio y cayera pudiera resultar herido. Si piensa que necesita ayuda para evitar lesionarse, o pudiera haberse lesionado, dígaselo a un miembro del equipo de investigación.

4. Riesgo de escozor causado por el lavado con alcohol y las toallitas El alcohol isopropílico diluido usado para frotar y enjuagar sus manos y limpiar su cara y cuello puede causarle escozor si tiene alguna cortadura o abrasiones en las manos o en la cara.

5. Riesgo de calor Como usará una capa adicional de ropa, pudiera tener demasiado calor. Supervisaremos la temperatura y la humedad durante la prueba, y detendremos el estudio si aumenta demasiado la temperatura para su seguridad. Si siente desvanecerse o demasiado calor, o está sudando mucho, deje de pintar inmediatamente y notifíquelo a un miembro del equipo de investigación.

6. Riesgo de sentir vergüenza Es posible que sienta vergüenza que un investigador esté presente mientras se cambia de ropa. Esto es necesario para asegurarnos de que la ropa le queda adecuadamente y que no se ensucie cuando termine la prueba. El investigador que lo ayudará será de su mismo sexo y será la única persona presente con usted. Usted usará su propia ropa interior en todo momento.

7. Si es mujer, le podría sorprender enterarse el día de la investigación que está embarazada. Solamente usted sabrá si los resultados de la prueba muestran que está embarazada, y no se registrarán estos resultados.

Riesgos desconocidos o imprevisibles
La participación en este estudio pudiera conllevar otros riesgos que desconocemos o que no podemos predecir. Si nos enteramos de algo nuevo que pudiera influenciar su decisión de participar, se lo notificaremos inmediatamente.

Lesiones relacionadas con la investigación
Si se lesiona o enferma mientras participa en el estudio, se le proporcionará atención en una instalación médica cercana. Si es necesario lo llevaremos ahí. AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no pague su propio seguro o el seguro de un tercero en el cual tenga cobertura. El investigador principal, en consulta con el profesional médico del sitio, decidirán si usted sufre una lesión o enfermedad que se debe a su participación en el estudio. Si dentro del período de 24 horas de su participación en el estudio experimenta una reacción en la piel u otro efecto adverso que usted cree que se relaciona con su participación en el estudio, debe buscar tratamiento médico y llamar al investigador principal, Robert Testman, a Golden Pacific Laboratories (559 275-9091) tan pronto como sea posible. Ningún expediente médico formará parte del estudio.

Al firmar este formulario no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio será porque usted quiere hacerlo. No recibirá un beneficio directo si decide participar y no sufrirá daños si decide no participar. Es su decisión.

Beneficios
Su participación en este estudio no le producirá beneficios directos. Lo que aprendamos de este estudio nos ayudará a asegurarnos de que los productos de pintura como la pintura de látex de Sherwin-Williams se puede usar con seguridad. Usted se pudiera beneficiar si pide sus resultados de este estudio, pues se puede enterar de cuánta pintura le cayó en el cuerpo en comparación con otros trabajadores que hicieron la misma tarea. Las personas que pagan el estudio también se beneficiarán del mismo, ya que ellos necesitan hacer este estudio para mantener en el mercado sus productos antibacterianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede formularlas en cualquier momento, antes durante o después del estudio. Simplemente hágalas a Robert Testman o a cualquier otro miembro del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico. Schulman IRB está a cargo de proteger sus derechos. Puede encontrar más información sobre sus derechos y el papel de los investigadores en el sitio web de Schulman IRB, www.sairb.com.

Costos y pagos
No le costará nada participar en este estudio. Al final de la entrevista para el consentimiento informado se le pagarán $20 en efectivo por su tiempo y las inconveniencias de venir a nuestra oficina. Si se lo selecciona para el estudio y va al sitio del estudio asignado, se le pagarán $100 en efectivo cuando termine el día, independientemente de si participa o no.

Confidencialidad
Le daremos un número de ID especial para este estudio y registraremos e informaremos todos los datos usando este número. Solo conservaremos un registro que relacione su nombre con este número de ID, y lo guardaremos separado de otros datos, en un gabinete bajo llave. No lo identificaremos por su nombre ni de ninguna otra manera en los informes del estudio. Ninguna fotografía suya que se use en un informe de este estudio mostrará su cara ni ninguna otra característica que lo identifique (como tatuajes).

Restringiremos el acceso a los expedientes de este estudio a solo unas pocas personas. Pero las personas que pagan el estudio, las agencias gubernamentales que revisarán los informes, y SAIRB, Inc., que vigila su seguridad, pueden revisar los expedientes del estudio. Debido a esto no podemos garantizar completamente la confidencialidad. Puede obtener una copia de sus propios expedientes con el investigador principal si la solicita.

Derecho a retirarse del estudio
Puede retirarse de este estudio en cualquier momento, por cualquier motivo. Simplemente notifíquelo a cualquier miembro del equipo de investigación. Si decide no participar en este estudio o retirarse del mismo, no se lo penalizará de ninguna manera ni perderá ningún beneficio.

Retiro del estudio
Robert Testman, el investigador principal a cargo de este estudio, puede retirarlo del estudio aunque usted desee permanecer en él. Lo pudiera retirar si, por ejemplo:

- Piensa que si usted permanece en el estudio correría riesgos.
- Usted no sigue las indicaciones de los investigadores.
- El estudio se detiene porque aumenta mucho la temperatura para continuar de forma segura, o por otra razón.

Si se lo retira del estudio o si se detiene todo el estudio, se le pagará de todas maneras por su tiempo e inconveniencias.

FORMULARIO DECLARACIÓN DE DERECHOS DE LOS SUJETOS PARTICIPANTES EN EXPERIMENTOS

Los siguientes son los derechos de cualquier persona a la que se pide que participe en un estudio de investigación. Como sujeto de un experimento, tengo los siguientes derechos:

1. Que se me diga el propósito del estudio.
2. Que se me diga lo que me sucederá y si cualquiera de los procedimientos, pesticidas o dispositivos es diferente del que se utilizaría en la práctica normal.
3. Que se me informe acerca de los riesgos, efectos secundarios o malestares frecuentes e/o importantes, o de las cosas que me sucederán durante el estudio.
4. Que se me informe si puedo esperar algún beneficio de mi participación y, de ser así, cuál podría ser el beneficio.
5. Que se me digan las alternativas a participar en el estudio.
6. Que se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el curso del estudio.
7. Que se me diga qué tipo de tratamiento médico está disponible en caso de que surjan complicaciones.
8. Rehusarme absolutamente a participar o cambiar de parecer acerca de mi participación después de que el estudio haya comenzado. Esta decisión no afectará mi estado con mi empleador.
9. Recibir una copia del formulario de consentimiento firmado y fechado; y
10. No ser presionado cuando esté considerando si deseo participar en el estudio;

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico.

Si tiene otras preguntas, debe formularlas al investigador principal o a los investigadores del estudio.

Contactos telefónicos:

Investigador principal: Robert Testman (559) 275-9091 o (949) 939-3585

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de Derechos de los Sujetos, y todas mis preguntas han sido contestadas en un idioma que entiendo bien. Acepto voluntariamente participar en este estudio como sujeto de investigación. Al firmar este formulario no renuncio a ninguno de mis derechos legales. Recibiré mi propia copia de este formulario con todas las firmas.

Fecha y hora: _____ _____
Firma del sujeto

_____
Nombre del sujeto (en letra de imprenta)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

SchulmanIRB

CERTIFICATION OF TRANSLATION

Protocol Number: AEA09
IRB Number: 201307318
PI: Robert J. Testman, M.B.A.
Material Type (if applicable): Informed Consent
Description (if applicable):
This is to certify that this Spanish translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Diane Barrett

Translated from English source document approved 03/04/2016

Diane Barrett 03/10/2016

ata A Corporate Member of the American Translators Association
Schulman Associates, IRB, Inc. (ATA Member No. 252187)

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA09: Interior Latex Paint Application with Brush and Roller Scenario

| **Part I: *Interview questions*** | | |

Hoja de trabajo para calificación

Estudio sobre la exposición en trabajadores AEA09 de la AEATF (*Antimicrobial Exposure Assessment Task Force*, Grupo de trabajo de evaluación de la exposición antimicrobiana): Situación de aplicación de pintura de látex para interiores con brocha y rodillo

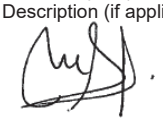
Parte I: ***Preguntas de la entrevista***	***C/NC***
1. ¿Tiene algún problema de la piel en las manos (por ejemplo, psoriasis, eczema, etc.)? □ Sí □ No	
2.¿Tiene dificultad para respirar? ¿Enfisema o asma moderada o grave? □ Sí □ No	
3. ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio, derrame cerebral o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta no controlada? □ Sí □ No	
4. ¿Tiene algún otro problema de salud que pueda dificultar su participación en este estudio tal como se describió? □ Sí □ No	
5. ¿Es empleado o está casado con un empleado de una compañía de AEATF, GPL, un fabricante de pinturas o el ACC? (el entrevistador explicará las iniciales de las distintas entidades) □ Sí □ No	

Parte II: ***Para que la llene el candidato***			
6. Nombre		9. Peso: libras	
7. Dirección		10. Estatura: pies pulgadas	
		11. Talla de camisa: □ **P** □ **M** □ **G** □ **XG** □ **XXG** □ **XXXG**	
8. Ciudad, estado, código postal		12. Cintura: □ 24-28 pulgadas □ 28-32 pulgadas □ 32-36 pulgadas □ 36-40 pulgadas □ 40-44 pulgadas □ 44-50 pulgadas	
13. Teléfono(s)			
14. Edad en años =	15. Fecha de nacimiento:	16. Sexo □ M □ F	
17. ¿Es residente del condado de Fresno? □ Sí □ No		18. ¿Pintó con brocha y rodillo los últimos 5 años? □ Sí □ No	
		19. ¿Trabajó como pintor profesional los últimos 10 años? □ Sí □ No	
20. Idioma de preferencia: □ Inglés □ Español		21. Lee: □ Inglés □ Español	
22. ¿Está embarazada? □ NC □ Sí □ No		23. ¿Está amamantando? □ NC □ Sí □ No	
24. ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio tal como se describió? □ Sí □ No			
25. ¿El olor de la pintura para interiores o la sensación en la piel de la pintura para interiores le molesta más que a sus familiares o amigos? □ Sí □ No			
26. ¿Frotarse la piel con alcohol o jabón le molesta más que a sus familiares o amigos? □ Sí □ No			
Verificación de la edad mediante documento de identificación realizada por el entrevistador: □ Sí □ No _____ _____ Firma del sujeto Fecha			
Idioma de la entrevista: □ Inglés □ Español	Nombre del entrevistador:		
Fecha de la entrevista:	Firma del entrevistador:		

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Subject Information Sheet – MA1601860-0
Description (if applicable): Subject Self-Reporting Demographic Form



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
**for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)*	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	**Cristobalite**		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	**Calcium Carbonate**		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	**Titanium Dioxide**		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.
EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.
SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

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SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

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SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable
CONDITIONS TO AVOID
None known.
INCOMPATIBILITY
None known.
HAZARDOUS DECOMPOSITION PRODUCTS
By fire: Carbon Dioxide, Carbon Monoxide
HAZARDOUS POLYMERIZATION
Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS

Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.

IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD

Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.

Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

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SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

HOJA DE DATOS SOBRE LA SEGURIDAD DEL MATERIAL

A86W151
12 00

FECHA DE PREPARACIÓN
30-dic-2014

SECCIÓN 1 — PRODUCTO Y COMPAÑÍA IDENTIFICATIÓN

NÚMERO DEL PRODUCTO
A86W151
NOMBRE DEL PRODUCTO
SUPERPAINT® Interior Flat Latex Wall Paint, Extra White
NOMBRE DEL FABRICANTE
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

NÚMEROS DE TELÉFONOS Y SITIOS WEB

Información sobre el producto	www.sherwin-williams.com
Información reguladora	(216) 566-2902 www.paintdocs.com
Emergencia médica	(216) 566-2917
Emergencia de transporte*	(800) 424-9300
**para una emergencia química SOLAMENTE (derrame, fuga, fuego, exposición o accidente)*	

SECCIÓN 2 — INGREDIENTES DEL PRODUCTO

% por peso	CAS No.	INGREDIENTE	UNIDADES	PRESION DE VAPOR
15	14808-60-7	**Cuarzo**		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,1 mg/m3 Resp. de Polvo	
1	14464-46-1	**cristobalita**		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,05 mg/m3 Resp. de Polvo	
2	1332-58-7	**Kaolin**		
		ACGIH TLV	No Disponible	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	13463-67-7	**Dioxido de Titanio**		
		ACGIH TLV	10 mg/m3 de Polvo	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECCIÓN 3 — EFECTOS POTENCIALES PARA LA SALUD

VÍAS DE EXPOSICIÓN
INHALACIÓN de vapor o de la niebla para la atomización.
Contacto del producto, del vapor o de la niebla para la atomización con los OJOS o la PIEL.

HMIS Codes

Salud	1*
Inflamabilidad	0
Reactividad	0

EFECTOS DE LA SOBREEXPOSICIÓN
OJOS: Irritación.
PIEL: Una exposición prolongada y repetida puede causar irritación.
INHALACIÓN: Irritación del sistema respiratorio superior.

En un recinto cerrado, los vapores en alta concentración pueden causar dolor de cabeza, náusea o mareo.

SEÑALES Y SÍNTOMAS DE LA SOBREEXPOSISCIÓN
La rojez, la picazón o la sensación de ardor indican exposición excesiva de los ojos o la piel.

CONDICIONES MÉDICAS EMPEORADAS POR LA SOBREEXPOSICIÓN
Ninguno generalmente reconocido.

CANCER INFORMATION
Vea la Sección 11.

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SECCIÓN 4 — PRIMEROS AUXILIOS

OJOS: Lávese los ojos durante 15 minutos usando mucha agua. Consulte con un médico.
PIEL: Lávese bien la parte afectada con agua y jabón.
Quítese la ropa contaminada y lávela antes de volverla a usar.
INHALACIÓN: Si le afecta, salga del lugar contaminado. Respire. Manténgase abrigado y tranquilo.
INGESTIÓN: No induza o vomito. Consulte inmediatamente con un médico.

SECCIÓN 5 — PROCEDIMIENTOS DE EXTINCIÓN

PUNTO DE INFLAMACIÓN	LEL	UEL	CLASIFICACIÓN DE INFLAMACIÓN
No corresponde	No corresponde	No corresponde	No corresponde

PRODUCTOS PARA COMBATIR EL FUEGO
Anhídrido carbónico, producto químico seco, espuma de alcohol
PELIGROS DE EXPLOSIÓN E INCENDIO INUSUALES
Los envases cerrados pueden reventar (debido al acumulamiento de presión) cuando expuestos a calor intenso.
En casos de emergencias, la exposición prolongada a productos de su descomposición puede causar un peligro a la salud. Puede ser que los síntomas no se manifiesten de inmediato. Obtenga atención médica.
PROCEDIMIENTOS ESPECIALES PARA COMBATIR EL FUEGO
Debe usarse equipos de protección total, incluyendo aparatos respiratorios autocontenidos.
La atomización de agua puede resultar ineficaz. Si se usa agua, es preferible usar boquillas de neblina. Se puede usar agua para enfriar los envases cerrados a modo de prevenir el aumento de presión y la posible autoignición o explosión cuando expuesto a calor extremado.

SECCIÓN 6 — ACCIÓN EN CASO DE ACCIDENTES

PASOS A SEGUIR EN CASO QUE OCURRA UN DERRAME O FUGA DE MATERIAL
Elimine todas las fuentes de ignición. Ventile el lugar.
Elimine con absorbente inerte.

SECCIÓN 7 — MANEJO SEGURO Y ALMACENAMIENTO

CATEGORÍA DE ALMACENAMIENTO DEPT. TRAVAJO
No corresponde
PRECAUCIONES QUE DEBEN TOMARSE DURANTE EL MANEJO Y ALMACENAMIENTO
Mantenga cerrado el envase cuando no se usa. Transfiéralo únicamente a envases aprobados colocando todas las etiquetas con las indicaciones apropiadas. No es para uso interno. Manténgalo fuera del alcance de los niños.

SECCIÓN 8 — PROTECCIÓN PERSONAL

PRECAUCIONES A TOMARSE DURANTE EL USO
Use solamente con ventilación adecuada.
Evite el contacto con la piel y los ojos. Evite respirar el vapor y la niebla producida por la atomización.
Lávese las manos después de usar.
Este recubrimiento puede contener materiales clasificados como "partículas molestosas" (listadas como "polvo" en la Sección 2) las cuales puede que estén presentes a niveles peligrosos únicamente durante el lijado o el pulido de película seca. Si la Sección 2 no menciona polvos específicos, los límites aplicables para los "polvos molestosos" son ACGIH TLV 10 mg/m3 (total de polvo), 3 mg/m3 (fracción respirable), OSHA PEL 15 mg/m3 (total de polvo), 5 mg/m3 (fracción respirable).
Remover la pintura vieja ya sea lijando, raspando, gastando o de cualquier otra manera creará polvo o gases que pueden contener plomo. La exposición al polvo o a los gases que contengan plomo puede causar daños al cerebro o causar otros efectos adversos a la salud, especialmente en personas menores de edad y mujeres embarazadas. Para controlar la exposición al plomo y a otras substancias peligrodas, será necesario el uso de equipos de protección tales como un respirador apropiado aprobado por NIOSH, como así también el uso de procedimientos correctos de contención y limpieza. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-5323 (en los EE.UU.) o consulte con una autoridad competente en temas de salud a nivel local.
VENTILACIÓN
El escape de ventilación local es preferible. El escape general es aceptable si la exposición a los materiales en la Sección 2 se mantiene debajo de los límites de exposición aplicables. Recurra a los Estándares de OSHA 1910.94, 1910.107, 1910.108.
PROTECCIÓN RESPIRATORIA
Si la exposición individual no puede ser controlada debajo de los límites aplicables por medio de la ventilación, use un respirador apropiado para vapor orgánico/partículas aprobado por NIOSH/MSHA para protección contra los materiales mencionados en la Sección 2.
Cuando lije o pula la película seca, use un respirador para polvo/niebla aprobado por NIOSH/MSHA para protección contra el polvo que pueda generarse de este producto, de la capa anterior de pintura o del abrasivo utilizado.
GUANTES DE PROTECCIÓN
Use guantes apropiados para protección contra los materiales de la Sección 2.
PROTECCIÓN DE LOS OJOS
Use anteojos de seguridad con protectores laterales sin perforación.

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SECCIÓN 9 — PROPIEDADES FISICAS Y QUIMICAS

PESO DEL PRODUCTO	12,05 lb/gal	1443 g/l
PESO ESPECÍFICO	1,45	
PUNTOS DE EBULLICIÓN	212 - 213 °F	100 - 100 °C
PUNTO DE FUSIÓN	No disponible	
% VOLÁTIL VOLUMEN	57%	
COEFICIENTE DE EVAPORACIÓN	Más lento que el éter	
DENSIDAD DE VAPOR	Más pesado que el aire	
SOLUBILIDAD EN AGUA	No disponible	
pH	9,3	

COV (Teorético)

0,35 lb/gal	42 g/l	Less Water and Federally Exempt Solventes
0,16 lb/gal	19 g/l	Emitido COV

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0,41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

SECCIÓN 10 — ESTABILIDAD Y REACTIVIDAD

ESTABILIDAD — Estable
CONDICIONES A EVITAR
Ninguno conocido.
INCOMPATIBILIDAD
Ninguno conocido.
PRODUCTOS DE DESCOMPOSICIÓN PELIGROSA
Por el fuego: Dióxido de carbono, monóxido de carbono
POLIMERIZACIÓN PELIGROSA
No ocurrirá.

SECCIÓN 11 — INFORMACIÓN TOXICOLOGICA

PELIGROS CRÓNICOS PARA LA SALUD
La silice cristalina (cuarzo, cristobalita) aparece en la lista IARC y NTP. La exposición por mucho tiempo a altos niveles de polvo de sílica, que ocurre solamente cuando se lija o pule la película seca, puede causar daño al pulmón (silicosis) y quizas cáncer.
La Agencia Internacional de Investigación del Cáncer reporta en su Monografía No. 93 que existen evidencias suficientes para afirmar que el dióxido de titanio provoca cáncer en ratas de laboratorio, pero que no hay evidencias de que provoque cáncer en los seres humanos y lo clasifica dentro del Grupo 2B. Además, el resumen de la agencia IARC concluye que "No se cree que exista una exposición significativa al dióxido de titanio durante el uso de productos donde el titanio se junta con otros materiales, como en el caso de la pintura."

INFORMACIÓN TOXICOLOGIA

CAS No.	INGREDIENTE			
14808-60-7	Cuarzo			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
14464-46-1	cristobalita			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
1332-58-7	Kaolin			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
13463-67-7	Dioxido de Titanio			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible

SECCIÓN 12 — INFORMACIÓN ECOLÓGICA

ECOTOXICOLÓGICA INFORMACIÓN
Ningunos datos disponibles.

SECCIÓN 13 — CONSIDERACIONES DE DESECHO

MÉTODO PARA EL DESCARTE DE RESIDUOS
El residuo de este producto no es peligroso tal como lo define la Ley de Conservación y Recuperación de Recursos ("RCRA") 40 CFR 261.
Incinérelo en los lugares autorizados. No incinere envases cerrados. Descártelo de acuerdo con las regulaciones locales, estatales y federales concernientes a la polución.

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SECCIÓN 14 — INFORMACIÓN DE TRANSPORTE

Las descripciones de envío multimodal se proporcionan a título informativo, y no tienen en cuenta el tamaño de los recipientes. La presencia de una descripción de envío para un modo de transporte en particular (mar, aire, etc.) no indica que el producto esté envasado de forma adecuada para ese modo de transporte. La idoneidad de todos los envases se debe revisar antes de los envíos y el cumplimiento de todos los reglamentos pertinentes es responsabilidad exclusiva de la persona que ofrece el producto para su transporte. El personal que carga y descarga materiales o sustancias peligrosos debe contar con formación sobre todos los riesgos derivados de dichas sustancias y sobre las medidas necesarias en caso de emergencia.

US Ground (DOT)
No regulado.
Canada (TDG)
No regulado.
IMO
No regulado.
IATA/ICAO
No regulado.

SECCIÓN 15 — INFORMACIÓN REGLAMENTARIA

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICACIÓN

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

Ningún ingrediente en este producto está sujeto a la notificación por parte del proveedor bajo la ley SARA 313 (40 CFR 372.65C).

CALIFORNIA PROPOSITION 65
CUIDADO: Este producto contiene químicos que a conocimiento del estado de California puede causar cáncer defectos de nacimiento u otros daños reproductivos.

TSCA INFORMACIÓN
Todos los quimicos en este producto estan en la lista o son exhonerado de la lista de inventario de TSCA.

SECCIÓN 16 — INFORMACIÓN MISCELÁNEA

La información anterior se refiere a este producto tal como ha sido recientemente formulado, y está basada en información disponible a la fecha. La adición de reductores u otros aditivos a este producto puede substancialmente alterar la composición y los peligros del producto. Debido a que las condiciones de uso están fuera de nuestro control, no damos ningún tipo de garantía, expresa o implícita, ni asumimos responsabilidad en conexión con el uso de cualquier parte de esta información.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

SE BUSCAN PINTORES AFICIONADOS

Se buscan voluntarios que deseen participar en un estudio de investigación que evalúa la exposición a componentes de la pintura al pintar en el interior con una brocha y un rodillo. Los voluntarios recibirán una compensación de hasta $120 por las molestias de participar. No se aceptan pintores profesionales.

Comuníquese con Robert Testman (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español)
al 559-275-9091
para obtener más información.

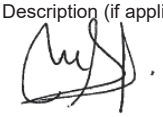
Estudio patrocinado por *Antimicrobial Exposure Assessment Task Force* (AEATF, Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos); administrado por *American Chemistry Council* (ACC, Consejo Estadounidense de Química) y dirigido por Golden Pacific Laboratories (GPL) de Fresno, CA.
559-275-9091

Versión: 04/11/2013

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Ad-Print - MA1601862-0
Description (if applicable): N/A



_____ _MMB_ 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

Guión de invitación a participar para el sujeto

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

Queremos determinar la cantidad de productos químicos que se encuentra en el aire que respira o que puede entrar en contacto con la piel cuando aplica productos de pintura con una brocha y un rodillo. Mediremos la cantidad de compuestos de pintura que quede en la ropa que vista y en las manos, cara y cuello. Además, mediremos la cantidad presente en el aire que respira en el momento que pinte habitaciones.

El producto de prueba será la PINTURA DE LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

Debe haber pintado con una brocha y un rodillo en los últimos cinco años, pero no haber trabajado como pintor profesional en los últimos diez años.

Su participación en el estudio durará alrededor de medio día. Le proporcionaremos una ropa especial que deberá usar durante la prueba. Le colocaremos una pequeña bomba de aire para tomar muestras del aire que respira. Luego, se le pedirá que pinte paredes, molduras y zócalos con los productos de prueba. Deberá usar una brocha y un rodillo para aplicar dos galones de pintura. Cuando termine, deberá cambiarse para volver a ponerse su ropa y devolver la ropa especial al equipo de investigación.

¿Le gustaría saber más sobre este proyecto?

(If no, thank them for their time.)

(If yes, instruct them as follows)

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del día del estudio. Para reunir los requisitos para participar, debe mostrar una identificación con foto para comprobar su edad. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni amamantando.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está ubicada en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con el investigador principal, Robert Testman. Si prefiere, podemos realizar la entrevista en español. La entrevista se programará para la fecha y hora que le resulte más conveniente, incluso durante un fin de semana. Le explicaremos el estudio en detalle, entre otras cosas, qué puede esperar y qué se espera de usted. Responderemos todas sus preguntas. La primera visita durará alrededor de una hora. Deberá traer un documento de identificación con foto emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

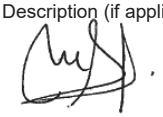
(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Phone Screen - MA1601861-0
Description (if applicable): Subject Invitation to Participate Script



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.
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Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:
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1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA09-BRS-01-PH	Brush and Roller Worker Sample, ME 01, Painter's Hat
AEA09-BRS-01-PH-ID	Brush and Roller Worker Sample, ME 01, Painter's Hat Dosimeter
AEA09-BRS-01-AR	Brush and Roller Worker Sample, ME 01, Air Sampling Tube
AEA09-BRS-01-RES-01	Brush and Roller Worker Sample, ME 01, RespiCon™ 100 µm
AEA09-BRS-01-RES-02	Brush and Roller Worker Sample, ME 01, RespiCon™ 10 µm
AEA09-BRS-01-RES-03	Brush and Roller Worker Sample, ME 01, RespiCon™ 2.5 µm
AEA09-BRS-01-HW-01	Brush and Roller Worker Sample, ME 01, Hand Wash
AEA09-BRS-01-FW-01	Brush and Roller Worker Sample, ME 01, Face and Neck Wipe
AEA09-BRS-01-ID-UA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-01-ID-LA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Arm
AEA09-BRS-01-ID-FT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Front Torso
AEA09-BRS-01-ID-RT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Rear Torso
AEA09-BRS-01-ID-UL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Leg
AEA09-BRS-01-ID-LL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Leg
AEA09-BRS-01-OD-UA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Arm
AEA09-BRS-01-OD-LA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-01-OD-FT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Front Torso
AEA09-BRS-01-OD-RT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Rear Torso
AEA09-BRS-01-OD-UL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Leg
AEA09-BRS-01-OD-LL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Leg
AEA09-BRS-02-PH	Brush and Roller Worker Sample, ME 02, Painter's Hat
AEA09-BRS-02-PH-ID	Brush and Roller Worker Sample, ME 02, Painter's Hat Dosimeter
AEA09-BRS-02-AR	Brush and Roller Worker Sample, ME 02, Air Sampling Tube
AEA09-BRS-02-RES-01	Brush and Roller Worker Sample, ME 02, RespiCon™ 100 µm
AEA09-BRS-02-RES-02	Brush and Roller Worker Sample, ME 02, RespiCon™ 10 µm
AEA09-BRS-02-RES-03	Brush and Roller Worker Sample, ME 02, RespiCon™ 2.5 µm
AEA09-BRS-02-HW-01	Brush and Roller Worker Sample, ME 02, Hand Wash
AEA09-BRS-02-FW-01	Brush and Roller Worker Sample, ME 02, Face and Neck Wipe
AEA09-BRS-02-ID-UA	Brush and Roller Worker Sample, ME 02, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-02-ID-LA	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Arm
AEA09-BRS-02-ID-FT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-02-ID-RT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Rear Torso
AEA09-BRS-02-ID-UL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Upper Leg
AEA09-BRS-02-ID-LL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Leg
AEA09-BRS-02-OD-UA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Arm
AEA09-BRS-02-OD-LA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Arm
AEA09-BRS-02-OD-FT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Front Torso
AEA09-BRS-02-OD-RT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Rear Torso
AEA09-BRS-02-OD-UL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Leg
AEA09-BRS-02-OD-LL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Leg
AEA09-BRS-03-PH	Brush and Roller Worker Sample, ME 03, Painter's Hat
AEA09-BRS-03-PH-ID	Brush and Roller Worker Sample, ME 03, Painter's Hat Dosimeter
AEA09-BRS-03-AR	Brush and Roller Worker Sample, ME 03, Air Sampling Tube
AEA09-BRS-03-RES-01	Brush and Roller Worker Sample, ME 03, RespiCon™ 100 µm
AEA09-BRS-03-RES-02	Brush and Roller Worker Sample, ME 03, RespiCon™ 10 µm
AEA09-BRS-03-RES-03	Brush and Roller Worker Sample, ME 03, RespiCon™ 2.5 µm
AEA09-BRS-03-HW-01	Brush and Roller Worker Sample, ME 03, Hand Wash
AEA09-BRS-03-FW-01	Brush and Roller Worker Sample, ME 03, Face and Neck Wipe
AEA09-BRS-03-ID-UA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Arm
AEA09-BRS-03-ID-LA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Arm
AEA09-BRS-03-ID-FT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Front Torso
AEA09-BRS-03-ID-RT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Rear Torso
AEA09-BRS-03-ID-UL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Leg
AEA09-BRS-03-ID-LL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Leg
AEA09-BRS-03-OD-UA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Arm
AEA09-BRS-03-OD-LA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Arm
AEA09-BRS-03-OD-FT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Front Torso
AEA09-BRS-03-OD-RT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-03-OD-UL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Leg
AEA09-BRS-03-OD-LL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Leg
AEA09-BRS-04-PH	Brush and Roller Worker Sample, ME 04, Painter's Hat
AEA09-BRS-04-PH-ID	Brush and Roller Worker Sample, ME 04, Painter's Hat Dosimeter
AEA09-BRS-04-AR	Brush and Roller Worker Sample, ME 04, Air Sampling Tube
AEA09-BRS-04-RES-01	Brush and Roller Worker Sample, ME 04, RespiCon™ 100 µm
AEA09-BRS-04-RES-02	Brush and Roller Worker Sample, ME 04, RespiCon™ 10 µm
AEA09-BRS-04-RES-03	Brush and Roller Worker Sample, ME 04, RespiCon™ 2.5 µm
AEA09-BRS-04-HW-01	Brush and Roller Worker Sample, ME 04, Hand Wash
AEA09-BRS-04-FW-01	Brush and Roller Worker Sample, ME 04, Face and Neck Wipe
AEA09-BRS-04-ID-UA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Arm
AEA09-BRS-04-ID-LA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Arm
AEA09-BRS-04-ID-FT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Front Torso
AEA09-BRS-04-ID-RT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Rear Torso
AEA09-BRS-04-ID-UL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Leg
AEA09-BRS-04-ID-LL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Leg
AEA09-BRS-04-OD-UA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Arm
AEA09-BRS-04-OD-LA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Arm
AEA09-BRS-04-OD-FT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Front Torso
AEA09-BRS-04-OD-RT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Rear Torso
AEA09-BRS-04-OD-UL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Leg
AEA09-BRS-04-OD-LL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Leg
AEA09-BRS-05-PH	Brush and Roller Worker Sample, ME 05, Painter's Hat
AEA09-BRS-05-PH-ID	Brush and Roller Worker Sample, ME 05, Painter's Hat Dosimeter
AEA09-BRS-05-AR	Brush and Roller Worker Sample, ME 05, Air Sampling Tube
AEA09-BRS-05-RES-01	Brush and Roller Worker Sample, ME 05, RespiCon™ 100 µm
AEA09-BRS-05-RES-02	Brush and Roller Worker Sample, ME 05, RespiCon™ 10 µm
AEA09-BRS-05-RES-03	Brush and Roller Worker Sample, ME 05, RespiCon™ 2.5 µm
AEA09-BRS-05-HW-01	Brush and Roller Worker Sample, ME 05, Hand Wash
AEA09-BRS-05-FW-01	Brush and Roller Worker Sample, ME 05, Face and Neck Wipe
AEA09-BRS-05-ID-UA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Arm

Sample ID Number	Description
AEA09-BRS-05-ID-LA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Arm
AEA09-BRS-05-ID-FT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Front Torso
AEA09-BRS-05-ID-RT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Rear Torso
AEA09-BRS-05-ID-UL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Leg
AEA09-BRS-05-ID-LL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Leg
AEA09-BRS-05-OD-UA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Arm
AEA09-BRS-05-OD-LA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Arm
AEA09-BRS-05-OD-FT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Front Torso
AEA09-BRS-05-OD-RT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Rear Torso
AEA09-BRS-05-OD-UL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Leg
AEA09-BRS-05-OD-LL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Leg
AEA09-BRS-06-PH	Brush and Roller Worker Sample, ME 06, Painter's Hat
AEA09-BRS-06-PH-ID	Brush and Roller Worker Sample, ME 06, Painter's Hat Dosimeter
AEA09-BRS-06-AR	Brush and Roller Worker Sample, ME 06, Air Sampling Tube
AEA09-BRS-06-RES-01	Brush and Roller Worker Sample, ME 06, RespiCon™ 100 µm
AEA09-BRS-06-RES-02	Brush and Roller Worker Sample, ME 06, RespiCon™ 10 µm
AEA09-BRS-06-RES-03	Brush and Roller Worker Sample, ME 06, RespiCon™ 2.5 µm
AEA09-BRS-06-HW-01	Brush and Roller Worker Sample, ME 06, Hand Wash
AEA09-BRS-06-FW-01	Brush and Roller Worker Sample, ME 06, Face and Neck Wipe
AEA09-BRS-06-ID-UA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Arm
AEA09-BRS-06-ID-LA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Arm
AEA09-BRS-06-ID-FT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Front Torso
AEA09-BRS-06-ID-RT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Rear Torso
AEA09-BRS-06-ID-UL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Leg
AEA09-BRS-06-ID-LL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Leg
AEA09-BRS-06-OD-UA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Arm
AEA09-BRS-06-OD-LA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Arm

Sample ID Number	Description
AEA09-BRS-06-OD-FT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Front Torso
AEA09-BRS-06-OD-RT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Rear Torso
AEA09-BRS-06-OD-UL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Leg
AEA09-BRS-06-OD-LL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Leg
AEA09-BRS-07-PH	Brush and Roller Worker Sample, ME 07, Painter's Hat
AEA09-BRS-07-PH-ID	Brush and Roller Worker Sample, ME 07, Painter's Hat Dosimeter
AEA09-BRS-07-AR	Brush and Roller Worker Sample, ME 07, Air Sampling Tube
AEA09-BRS-07-RES-01	Brush and Roller Worker Sample, ME 07, RespiCon™ 100 µm
AEA09-BRS-07-RES-02	Brush and Roller Worker Sample, ME 07, RespiCon™ 10 µm
AEA09-BRS-07-RES-03	Brush and Roller Worker Sample, ME 07, RespiCon™ 2.5 µm
AEA09-BRS-07-HW-01	Brush and Roller Worker Sample, ME 07, Hand Wash
AEA09-BRS-07-FW-01	Brush and Roller Worker Sample, ME 07, Face and Neck Wipe
AEA09-BRS-07-ID-UA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Arm
AEA09-BRS-07-ID-LA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Arm
AEA09-BRS-07-ID-FT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Front Torso
AEA09-BRS-07-ID-RT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Rear Torso
AEA09-BRS-07-ID-UL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Leg
AEA09-BRS-07-ID-LL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Leg
AEA09-BRS-07-OD-UA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Arm
AEA09-BRS-07-OD-LA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Arm
AEA09-BRS-07-OD-FT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Front Torso
AEA09-BRS-07-OD-RT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Rear Torso
AEA09-BRS-07-OD-UL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Leg
AEA09-BRS-07-OD-LL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Leg
AEA09-BRS-08-PH	Brush and Roller Worker Sample, ME 08, Painter's Hat
AEA09-BRS-08-PH-ID	Brush and Roller Worker Sample, ME 08, Painter's Hat Dosimeter
AEA09-BRS-08-AR	Brush and Roller Worker Sample, ME 08, Air Sampling Tube
AEA09-BRS-08-RES-01	Brush and Roller Worker Sample, ME 08, RespiCon™ 100 µm
AEA09-BRS-08-RES-02	Brush and Roller Worker Sample, ME 08, RespiCon™ 10 µm
AEA09-BRS-08-RES-03	Brush and Roller Worker Sample, ME 08, RespiCon™ 2.5 µm

Sample ID Number	Description
AEA09-BRS-08-HW-01	Brush and Roller Worker Sample, ME 08, Hand Wash
AEA09-BRS-08-FW-01	Brush and Roller Worker Sample, ME 08, Face and Neck Wipe
AEA09-BRS-08-ID-UA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Arm
AEA09-BRS-08-ID-LA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Arm
AEA09-BRS-08-ID-FT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Front Torso
AEA09-BRS-08-ID-RT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Rear Torso
AEA09-BRS-08-ID-UL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Leg
AEA09-BRS-08-ID-LL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Leg
AEA09-BRS-08-OD-UA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Arm
AEA09-BRS-08-OD-LA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Arm
AEA09-BRS-08-OD-FT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Front Torso
AEA09-BRS-08-OD-RT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Rear Torso
AEA09-BRS-08-OD-UL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Leg
AEA09-BRS-08-OD-LL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Leg
AEA09-BRS-09-PH	Brush and Roller Worker Sample, ME 09, Painter's Hat
AEA09-BRS-09-PH-ID	Brush and Roller Worker Sample, ME 09, Painter's Hat Dosimeter
AEA09-BRS-09-AR	Brush and Roller Worker Sample, ME 09, Air Sampling Tube
AEA09-BRS-09-RES-01	Brush and Roller Worker Sample, ME 09, RespiCon™ 100 µm
AEA09-BRS-09-RES-02	Brush and Roller Worker Sample, ME 09, RespiCon™ 10 µm
AEA09-BRS-09-RES-03	Brush and Roller Worker Sample, ME 09, RespiCon™ 2.5 µm
AEA09-BRS-09-HW-01	Brush and Roller Worker Sample, ME 09, Hand Wash
AEA09-BRS-09-FW-01	Brush and Roller Worker Sample, ME 09, Face and Neck Wipe
AEA09-BRS-09-ID-UA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Arm
AEA09-BRS-09-ID-LA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Arm
AEA09-BRS-09-ID-FT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Front Torso
AEA09-BRS-09-ID-RT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Rear Torso
AEA09-BRS-09-ID-UL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Leg
AEA09-BRS-09-ID-LL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-BRS-09-OD-UA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Arm
AEA09-BRS-09-OD-LA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Arm
AEA09-BRS-09-OD-FT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Front Torso
AEA09-BRS-09-OD-RT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Rear Torso
AEA09-BRS-09-OD-UL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Leg
AEA09-BRS-09-OD-LL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Leg
AEA09-BRS-10-PH	Brush and Roller Worker Sample, ME 10, Painter's Hat
AEA09-BRS-10-PH-ID	Brush and Roller Worker Sample, ME 10, Painter's Hat Dosimeter
AEA09-BRS-10-AR	Brush and Roller Worker Sample, ME 10, Air Sampling Tube
AEA09-BRS-10-RES-01	Brush and Roller Worker Sample, ME 10, RespiCon™ 100 µm
AEA09-BRS-10-RES-02	Brush and Roller Worker Sample, ME 10, RespiCon™ 10 µm
AEA09-BRS-10-RES-03	Brush and Roller Worker Sample, ME 10, RespiCon™ 2.5 µm
AEA09-BRS-10-HW-01	Brush and Roller Worker Sample, ME 10, Hand Wash
AEA09-BRS-10-FW-01	Brush and Roller Worker Sample, ME 10, Face and Neck Wipe
AEA09-BRS-10-ID-UA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Arm
AEA09-BRS-10-ID-LA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Arm
AEA09-BRS-10-ID-FT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Front Torso
AEA09-BRS-10-ID-RT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Rear Torso
AEA09-BRS-10-ID-UL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Leg
AEA09-BRS-10-ID-LL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Leg
AEA09-BRS-10-OD-UA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Arm
AEA09-BRS-10-OD-LA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Arm
AEA09-BRS-10-OD-FT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Front Torso
AEA09-BRS-10-OD-RT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Rear Torso
AEA09-BRS-10-OD-UL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Leg
AEA09-BRS-10-OD-LL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Leg
AEA09-BRS-11-PH	Brush and Roller Worker Sample, ME 11, Painter's Hat
AEA09-BRS-11-PH-ID	Brush and Roller Worker Sample, ME 11, Painter's Hat Dosimeter

Sample ID Number	Description
AEA09-BRS-11-AR	Brush and Roller Worker Sample, ME 11, Air Sampling Tube
AEA09-BRS-11-RES-01	Brush and Roller Worker Sample, ME 11, RespiCon™ 100 µm
AEA09-BRS-11-RES-02	Brush and Roller Worker Sample, ME 11, RespiCon™ 10 µm
AEA09-BRS-11-RES-03	Brush and Roller Worker Sample, ME 11, RespiCon™ 2.5 µm
AEA09-BRS-11-HW-01	Brush and Roller Worker Sample, ME 11, Hand Wash
AEA09-BRS-11-FW-01	Brush and Roller Worker Sample, ME 11, Face and Neck Wipe
AEA09-BRS-11-ID-UA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Arm
AEA09-BRS-11-ID-LA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Arm
AEA09-BRS-11-ID-FT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Front Torso
AEA09-BRS-11-ID-RT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Rear Torso
AEA09-BRS-11-ID-UL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Leg
AEA09-BRS-11-ID-LL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Leg
AEA09-BRS-11-OD-UA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Arm
AEA09-BRS-11-OD-LA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Arm
AEA09-BRS-11-OD-FT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Front Torso
AEA09-BRS-11-OD-RT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Rear Torso
AEA09-BRS-11-OD-UL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Leg
AEA09-BRS-11-OD-LL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Leg
AEA09-BRS-12-PH	Brush and Roller Worker Sample, ME 12, Painter's Hat
AEA09-BRS-12-PH-ID	Brush and Roller Worker Sample, ME 12, Painter's Hat Dosimeter
AEA09-BRS-12-AR	Brush and Roller Worker Sample, ME 12, Air Sampling Tube
AEA09-BRS-12-RES-01	Brush and Roller Worker Sample, ME 12, RespiCon™ 100 µm
AEA09-BRS-12-RES-02	Brush and Roller Worker Sample, ME 12, RespiCon™ 10 µm
AEA09-BRS-12-RES-03	Brush and Roller Worker Sample, ME 12, RespiCon™ 2.5 µm
AEA09-BRS-12-HW-01	Brush and Roller Worker Sample, ME 12, Hand Wash
AEA09-BRS-12-FW-01	Brush and Roller Worker Sample, ME 12, Face and Neck Wipe
AEA09-BRS-12-ID-UA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Arm
AEA09-BRS-12-ID-LA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Arm
AEA09-BRS-12-ID-FT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Front Torso
AEA09-BRS-12-ID-RT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-12-ID-UL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Leg
AEA09-BRS-12-ID-LL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Leg
AEA09-BRS-12-OD-UA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Arm
AEA09-BRS-12-OD-LA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Arm
AEA09-BRS-12-OD-FT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Front Torso
AEA09-BRS-12-OD-RT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Rear Torso
AEA09-BRS-12-OD-UL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Leg
AEA09-BRS-12-OD-LL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Leg
AEA09-BRS-13-PH	Brush and Roller Worker Sample, ME 13, Painter's Hat
AEA09-BRS-13-PH-ID	Brush and Roller Worker Sample, ME 13, Painter's Hat Dosimeter
AEA09-BRS-13-AR	Brush and Roller Worker Sample, ME 13, Air Sampling Tube
AEA09-BRS-13-RES-01	Brush and Roller Worker Sample, ME 13, RespiCon™ 100 µm
AEA09-BRS-13-RES-02	Brush and Roller Worker Sample, ME 13, RespiCon™ 10 µm
AEA09-BRS-13-RES-03	Brush and Roller Worker Sample, ME 13, RespiCon™ 2.5 µm
AEA09-BRS-13-HW-01	Brush and Roller Worker Sample, ME 13, Hand Wash
AEA09-BRS-13-FW-01	Brush and Roller Worker Sample, ME 13, Face and Neck Wipe
AEA09-BRS-13-ID-UA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Arm
AEA09-BRS-13-ID-LA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Arm
AEA09-BRS-13-ID-FT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Front Torso
AEA09-BRS-13-ID-RT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Rear Torso
AEA09-BRS-13-ID-UL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Leg
AEA09-BRS-13-ID-LL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Leg
AEA09-BRS-13-OD-UA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Arm
AEA09-BRS-13-OD-LA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Arm
AEA09-BRS-13-OD-FT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Front Torso
AEA09-BRS-13-OD-RT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Rear Torso
AEA09-BRS-13-OD-UL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Leg

Sample ID Number	Description
AEA09-BRS-13-OD-LL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Leg
AEA09-BRS-14-PH	Brush and Roller Worker Sample, ME 14, Painter's Hat
AEA09-BRS-14-PH-ID	Brush and Roller Worker Sample, ME 14, Painter's Hat Dosimeter
AEA09-BRS-14-AR	Brush and Roller Worker Sample, ME 14, Air Sampling Tube
AEA09-BRS-14-RES-01	Brush and Roller Worker Sample, ME 14, RespiCon™ 100 µm
AEA09-BRS-14-RES-02	Brush and Roller Worker Sample, ME 14, RespiCon™ 10 µm
AEA09-BRS-14-RES-03	Brush and Roller Worker Sample, ME 14, RespiCon™ 2.5 µm
AEA09-BRS-14-HW-01	Brush and Roller Worker Sample, ME 14, Hand Wash
AEA09-BRS-14-FW-01	Brush and Roller Worker Sample, ME 14, Face and Neck Wipe
AEA09-BRS-14-ID-UA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Arm
AEA09-BRS-14-ID-LA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Arm
AEA09-BRS-14-ID-FT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Front Torso
AEA09-BRS-14-ID-RT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Rear Torso
AEA09-BRS-14-ID-UL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Leg
AEA09-BRS-14-ID-LL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Leg
AEA09-BRS-14-OD-UA	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Arm
AEA09-BRS-14-OD-LA	Brush and Roller Worker Sample, ME 14, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-14-OD-FT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Front Torso
AEA09-BRS-14-OD-RT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Rear Torso
AEA09-BRS-14-OD-UL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Leg
AEA09-BRS-14-OD-LL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Lower Leg
AEA09-BRS-15-PH	Brush and Roller Worker Sample, ME 15, Painter's Hat
AEA09-BRS-15-PH-ID	Brush and Roller Worker Sample, ME 15, Painter's Hat Dosimeter
AEA09-BRS-15-AR	Brush and Roller Worker Sample, ME 15, Air Sampling Tube
AEA09-BRS-15-RES-01	Brush and Roller Worker Sample, ME 15, RespiCon™ 100 µm
AEA09-BRS-15-RES-02	Brush and Roller Worker Sample, ME 15, RespiCon™ 10 µm
AEA09-BRS-15-RES-03	Brush and Roller Worker Sample, ME 15, RespiCon™ 2.5 µm
AEA09-BRS-15-HW-01	Brush and Roller Worker Sample, ME 15, Hand Wash
AEA09-BRS-15-FW-01	Brush and Roller Worker Sample, ME 15, Face and Neck Wipe
AEA09-BRS-15-ID-UA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Arm
AEA09-BRS-15-ID-LA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Arm

Sample ID Number	Description
AEA09-BRS-15-ID-FT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Front Torso
AEA09-BRS-15-ID-RT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Rear Torso
AEA09-BRS-15-ID-UL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Leg
AEA09-BRS-15-ID-LL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Leg
AEA09-BRS-15-OD-UA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Arm
AEA09-BRS-15-OD-LA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Arm
AEA09-BRS-15-OD-FT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Front Torso
AEA09-BRS-15-OD-RT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Rear Torso
AEA09-BRS-15-OD-UL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Leg
AEA09-BRS-15-OD-LL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Leg
AEA09-BRS-16-PH	Brush and Roller Worker Sample, ME 16, Painter's Hat
AEA09-BRS-16-PH-ID	Brush and Roller Worker Sample, ME 16, Painter's Hat Dosimeter
AEA09-BRS-16-AR	Brush and Roller Worker Sample, ME 16, Air Sampling Tube
AEA09-BRS-16-RES-01	Brush and Roller Worker Sample, ME 16, RespiCon™ 100 µm
AEA09-BRS-16-RES-02	Brush and Roller Worker Sample, ME 16, RespiCon™ 10 µm
AEA09-BRS-16-RES-03	Brush and Roller Worker Sample, ME 16, RespiCon™ 2.5 µm
AEA09-BRS-16-HW-01	Brush and Roller Worker Sample, ME 16, Hand Wash
AEA09-BRS-16-FW-01	Brush and Roller Worker Sample, ME 16, Face and Neck Wipe
AEA09-BRS-16-ID-UA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Arm
AEA09-BRS-16-ID-LA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Arm
AEA09-BRS-16-ID-FT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Front Torso
AEA09-BRS-16-ID-RT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Rear Torso
AEA09-BRS-16-ID-UL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Leg
AEA09-BRS-16-ID-LL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Leg
AEA09-BRS-16-OD-UA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Arm
AEA09-BRS-16-OD-LA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Arm
AEA09-BRS-16-OD-FT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-16-OD-RT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Rear Torso
AEA09-BRS-16-OD-UL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Leg
AEA09-BRS-16-OD-LL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Leg
AEA09-BRS-17-PH	Brush and Roller Worker Sample, ME 17, Painter's Hat
AEA09-BRS-17-PH-ID	Brush and Roller Worker Sample, ME 17, Painter's Hat Dosimeter
AEA09-BRS-17-AR	Brush and Roller Worker Sample, ME 17, Air Sampling Tube
AEA09-BRS-17-RES-01	Brush and Roller Worker Sample, ME 17, RespiCon™ 100 µm
AEA09-BRS-17-RES-02	Brush and Roller Worker Sample, ME 17, RespiCon™ 10 µm
AEA09-BRS-17-RES-03	Brush and Roller Worker Sample, ME 17, RespiCon™ 2.5 µm
AEA09-BRS-17-HW-01	Brush and Roller Worker Sample, ME 17, Hand Wash
AEA09-BRS-17-FW-01	Brush and Roller Worker Sample, ME 17, Face and Neck Wipe
AEA09-BRS-17-ID-UA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Arm
AEA09-BRS-17-ID-LA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Arm
AEA09-BRS-17-ID-FT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Front Torso
AEA09-BRS-17-ID-RT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Rear Torso
AEA09-BRS-17-ID-UL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Leg
AEA09-BRS-17-ID-LL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Leg
AEA09-BRS-17-OD-UA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Arm
AEA09-BRS-17-OD-LA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Arm
AEA09-BRS-17-OD-FT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Front Torso
AEA09-BRS-17-OD-RT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Rear Torso
AEA09-BRS-17-OD-UL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Leg
AEA09-BRS-17-OD-LL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Leg
AEA09-BRS-18-PH	Brush and Roller Worker Sample, ME 18, Painter's Hat
AEA09-BRS-18-PH-ID	Brush and Roller Worker Sample, ME 18, Painter's Hat Dosimeter
AEA09-BRS-18-AR	Brush and Roller Worker Sample, ME 18, Air Sampling Tube
AEA09-BRS-18-RES-01	Brush and Roller Worker Sample, ME 18, RespiCon™ 100 µm
AEA09-BRS-18-RES-02	Brush and Roller Worker Sample, ME 18, RespiCon™ 10 µm
AEA09-BRS-18-RES-03	Brush and Roller Worker Sample, ME 18, RespiCon™ 2.5 µm
AEA09-BRS-18-HW-01	Brush and Roller Worker Sample, ME 18, Hand Wash
AEA09-BRS-18-FW-01	Brush and Roller Worker Sample, ME 18, Face and Neck Wipe

Sample ID Number	**Description**
AEA09-BRS-18-ID-UA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Arm
AEA09-BRS-18-ID-LA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Arm
AEA09-BRS-18-ID-FT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Front Torso
AEA09-BRS-18-ID-RT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Rear Torso
AEA09-BRS-18-ID-UL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Leg
AEA09-BRS-18-ID-LL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Leg
AEA09-BRS-18-OD-UA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Arm
AEA09-BRS-18-OD-LA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Arm
AEA09-BRS-18-OD-FT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Front Torso
AEA09-BRS-18-OD-RT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Rear Torso
AEA09-BRS-18-OD-UL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Leg
AEA09-BRS-18-OD-LL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-FF-01-PH-C1	Fortification Sample, ME 01, Painter's Hat, 1st Control
AEA09-FF-01-PH-C2	Fortification Sample, ME 01, Painter's Hat, 2nd Control
AEA09-FF-01-PH-L1	Fortification Sample, ME 01, Painter's Hat, 1st Low Level
AEA09-FF-01-PH-L2	Fortification Sample, ME 01, Painter's Hat, 2nd Low Level
AEA09-FF-01-PH-L3	Fortification Sample, ME 01, Painter's Hat, 3rd Low Level
AEA09-FF-01-PH-H1	Fortification Sample, ME 01, Painter's Hat, 1st High Level
AEA09-FF-01-PH-H2	Fortification Sample, ME 01, Painter's Hat, 2nd High Level
AEA09-FF-01-PH-H3	Fortification Sample, ME 01, Painter's Hat, 3rd High Level
AEA09-FF-01-AR-C1	Fortification Sample, ME 01, Air Sampling Tube, 1st Control
AEA09-FF-01-AR-C2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Control
AEA09-FF-01-AR-L1	Fortification Sample, ME 01, Air Sampling Tube, 1st Low Level
AEA09-FF-01-AR-L2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Low Level
AEA09-FF-01-AR-L3	Fortification Sample, ME 01, Air Sampling Tube, 3rd Low Level
AEA09-FF-01-AR-H1	Fortification Sample, ME 01, Air Sampling Tube, 1st High Level
AEA09-FF-01-AR-H2	Fortification Sample, ME 01, Air Sampling Tube, 2nd High Level
AEA09-FF-01-AR-H3	Fortification Sample, ME 01, Air Sampling Tube, 3rd High Level
AEA09-FF-01-RES-C1	Fortification Sample, ME 01, RespiCon, 1st Control
AEA09-FF-01-RES-C2	Fortification Sample, ME 01, RespiCon, 2nd Control
AEA09-FF-01-RES-L1	Fortification Sample, ME 01, RespiCon, 1st Low Level
AEA09-FF-01-RES-L2	Fortification Sample, ME 01, RespiCon, 2nd Low Level
AEA09-FF-01-RES-L3	Fortification Sample, ME 01, RespiCon, 3rd Low Level
AEA09-FF-01-RES-H1	Fortification Sample, ME 01, RespiCon, 1st High Level
AEA09-FF-01-RES-H2	Fortification Sample, ME 01, RespiCon, 2nd High Level
AEA09-FF-01-RES-H3	Fortification Sample, ME 01, RespiCon, 3rd High Level
AEA09-FF-01-HW-C1	Fortification Sample, ME 01, Hand Wash, 1st Control
AEA09-FF-01-HW-C2	Fortification Sample, ME 01, Hand Wash, 2nd Control
AEA09-FF-01-HW-L1	Fortification Sample, ME 01, Hand Wash, 1st Low Level
AEA09-FF-01-HW-L2	Fortification Sample, ME 01, Hand Wash, 2nd Low Level
AEA09-FF-01-HW-L3	Fortification Sample, ME 01, Hand Wash, 3rd Low Level
AEA09-FF-01-HW-H1	Fortification Sample, ME 01, Hand Wash, 1st High Level
AEA09-FF-01-HW-H2	Fortification Sample, ME 01, Hand Wash, 2nd High Level
AEA09-FF-01-HW-H3	Fortification Sample, ME 01, Hand Wash, 3rd High Level
AEA09-FF-01-FW-C1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Control
AEA09-FF-01-FW-C2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Control
AEA09-FF-01-FW-L1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Low Level
AEA09-FF-01-FW-L2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Low Level
AEA09-FF-01-FW-L3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd Low Level
AEA09-FF-01-FW-H1	Fortification Sample, ME 01, Face and Neck Wipe, 1st High Level
AEA09-FF-01-FW-H2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd High Level
AEA09-FF-01-FW-H3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd High Level

Sample ID Number	Description
AEA09-FF-01-ID-C1	Fortification Sample, ME 01, Inner Dosimeter, 1st Control
AEA09-FF-01-ID-C2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Control
AEA09-FF-01-ID-L1	Fortification Sample, ME 01, Inner Dosimeter, 1st Low Level
AEA09-FF-01-ID-L2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Low Level
AEA09-FF-01-ID-L3	Fortification Sample, ME 01, Inner Dosimeter, 3rd Low Level
AEA09-FF-01-ID-H1	Fortification Sample, ME 01, Inner Dosimeter, 1st High Level
AEA09-FF-01-ID-H2	Fortification Sample, ME 01, Inner Dosimeter, 2nd High Level
AEA09-FF-01-ID-H3	Fortification Sample, ME 01, Inner Dosimeter, 3rd High Level
AEA09-FF-01-OD-C1	Fortification Sample, ME 01, Outer Dosimeter, 1st Control
AEA09-FF-01-OD-C2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Control
AEA09-FF-01-OD-L1	Fortification Sample, ME 01, Outer Dosimeter, 1st Low Level
AEA09-FF-01-OD-L2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Low Level
AEA09-FF-01-OD-L3	Fortification Sample, ME 01, Outer Dosimeter, 3rd Low Level
AEA09-FF-01-OD-H1	Fortification Sample, ME 01, Outer Dosimeter, 1st High Level
AEA09-FF-01-OD-H2	Fortification Sample, ME 01, Outer Dosimeter, 2nd High Level
AEA09-FF-01-OD-H3	Fortification Sample, ME 01, Outer Dosimeter, 3rd High Level
AEA09-FF-02-PH-C1	Fortification Sample, ME 02, Painter's Hat, 1st Control
AEA09-FF-02-PH-C2	Fortification Sample, ME 02, Painter's Hat, 2nd Control
AEA09-FF-02-PH-L1	Fortification Sample, ME 02, Painter's Hat, 1st Low Level
AEA09-FF-02-PH-L2	Fortification Sample, ME 02, Painter's Hat, 2nd Low Level
AEA09-FF-02-PH-L3	Fortification Sample, ME 02, Painter's Hat, 3rd Low Level
AEA09-FF-02-PH-H1	Fortification Sample, ME 02, Painter's Hat, 1st High Level
AEA09-FF-02-PH-H2	Fortification Sample, ME 02, Painter's Hat, 2nd High Level
AEA09-FF-02-PH-H3	Fortification Sample, ME 02, Painter's Hat, 3rd High Level
AEA09-FF-02-AR-C1	Fortification Sample, ME 02, Air Sampling Tube, 1st Control
AEA09-FF-02-AR-C2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Control
AEA09-FF-02-AR-L1	Fortification Sample, ME 02, Air Sampling Tube, 1st Low Level
AEA09-FF-02-AR-L2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Low Level
AEA09-FF-02-AR-L3	Fortification Sample, ME 02, Air Sampling Tube, 3rd Low Level
AEA09-FF-02-AR-H1	Fortification Sample, ME 02, Air Sampling Tube, 1st High Level
AEA09-FF-02-AR-H2	Fortification Sample, ME 02, Air Sampling Tube, 2nd High Level
AEA09-FF-02-AR-H3	Fortification Sample, ME 02, Air Sampling Tube, 3rd High Level
AEA09-FF-02-RES-C1	Fortification Sample, ME 02, RespiCon, 1st Control
AEA09-FF-02-RES-C2	Fortification Sample, ME 02, RespiCon, 2nd Control
AEA09-FF-02-RES-L1	Fortification Sample, ME 02, RespiCon, 1st Low Level
AEA09-FF-02-RES-L2	Fortification Sample, ME 02, RespiCon, 2nd Low Level
AEA09-FF-02-RES-L3	Fortification Sample, ME 02, RespiCon, 3rd Low Level
AEA09-FF-02-RES-H1	Fortification Sample, ME 02, RespiCon, 1st High Level
AEA09-FF-02-RES-H2	Fortification Sample, ME 02, RespiCon, 2nd High Level
AEA09-FF-02-RES-H3	Fortification Sample, ME 02, RespiCon, 3rd High Level
AEA09-FF-02-HW-C1	Fortification Sample, ME 02, Hand Wash, 1st Control
AEA09-FF-02-HW-C2	Fortification Sample, ME 02, Hand Wash, 2nd Control
AEA09-FF-02-HW-L1	Fortification Sample, ME 02, Hand Wash, 1st Low Level
AEA09-FF-02-HW-L2	Fortification Sample, ME 02, Hand Wash, 2nd Low Level
AEA09-FF-02-HW-L3	Fortification Sample, ME 02, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-02-HW-H1	Fortification Sample, ME 02, Hand Wash, 1st High Level
AEA09-FF-02-HW-H2	Fortification Sample, ME 02, Hand Wash, 2nd High Level
AEA09-FF-02-HW-H3	Fortification Sample, ME 02, Hand Wash, 3rd High Level
AEA09-FF-02-FW-C1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Control
AEA09-FF-02-FW-C2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Control
AEA09-FF-02-FW-L1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Low Level
AEA09-FF-02-FW-L2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Low Level
AEA09-FF-02-FW-L3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd Low Level
AEA09-FF-02-FW-H1	Fortification Sample, ME 02, Face and Neck Wipe, 1st High Level
AEA09-FF-02-FW-H2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd High Level
AEA09-FF-02-FW-H3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd High Level
AEA09-FF-02-ID-C1	Fortification Sample, ME 02, Inner Dosimeter, 1st Control
AEA09-FF-02-ID-C2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Control
AEA09-FF-02-ID-L1	Fortification Sample, ME 02, Inner Dosimeter, 1st Low Level
AEA09-FF-02-ID-L2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Low Level
AEA09-FF-02-ID-L3	Fortification Sample, ME 02, Inner Dosimeter, 3rd Low Level
AEA09-FF-02-ID-H1	Fortification Sample, ME 02, Inner Dosimeter, 1st High Level
AEA09-FF-02-ID-H2	Fortification Sample, ME 02, Inner Dosimeter, 2nd High Level
AEA09-FF-02-ID-H3	Fortification Sample, ME 02, Inner Dosimeter, 3rd High Level
AEA09-FF-02-OD-C1	Fortification Sample, ME 02, Outer Dosimeter, 1st Control
AEA09-FF-02-OD-C2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Control
AEA09-FF-02-OD-L1	Fortification Sample, ME 02, Outer Dosimeter, 1st Low Level
AEA09-FF-02-OD-L2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Low Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-02-OD-H1	Fortification Sample, ME 02, Outer Dosimeter, 1st High Level
AEA09-FF-02-OD-H2	Fortification Sample, ME 02, Outer Dosimeter, 2nd High Level
AEA09-FF-02-OD-H3	Fortification Sample, ME 02, Outer Dosimeter, 3rd High Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-03-PH-C1	Fortification Sample, ME 03, Painter's Hat, 1st Control
AEA09-FF-03-PH-C2	Fortification Sample, ME 03, Painter's Hat, 2nd Control
AEA09-FF-03-PH-L1	Fortification Sample, ME 03, Painter's Hat, 1st Low Level
AEA09-FF-03-PH-L2	Fortification Sample, ME 03, Painter's Hat, 2nd Low Level
AEA09-FF-03-PH-L3	Fortification Sample, ME 03, Painter's Hat, 3rd Low Level
AEA09-FF-03-PH-H1	Fortification Sample, ME 03, Painter's Hat, 1st High Level
AEA09-FF-03-PH-H2	Fortification Sample, ME 03, Painter's Hat, 2nd High Level
AEA09-FF-03-PH-H3	Fortification Sample, ME 03, Painter's Hat, 3rd High Level
AEA09-FF-03-AR-C1	Fortification Sample, ME 03, Air Sampling Tube, 1st Control
AEA09-FF-03-AR-C2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Control
AEA09-FF-03-AR-L1	Fortification Sample, ME 03, Air Sampling Tube, 1st Low Level
AEA09-FF-03-AR-L2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Low Level
AEA09-FF-03-AR-L3	Fortification Sample, ME 03, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-AR-H1	Fortification Sample, ME 03, Air Sampling Tube, 1st High Level
AEA09-FF-03-AR-H2	Fortification Sample, ME 03, Air Sampling Tube, 2nd High Level
AEA09-FF-03-AR-H3	Fortification Sample, ME 03, Air Sampling Tube, 3rd High Level
AEA09-FF-03-RES-C1	Fortification Sample, ME 03, RespiCon, 1st Control
AEA09-FF-03-RES-C2	Fortification Sample, ME 03, RespiCon, 2nd Control
AEA09-FF-03-RES-L1	Fortification Sample, ME 03, RespiCon, 1st Low Level
AEA09-FF-03-RES-L2	Fortification Sample, ME 03, RespiCon, 2nd Low Level
AEA09-FF-03-RES-L3	Fortification Sample, ME 03, RespiCon, 3rd Low Level
AEA09-FF-03-RES-H1	Fortification Sample, ME 03, RespiCon, 1st High Level
AEA09-FF-03-RES-H2	Fortification Sample, ME 03, RespiCon, 2nd High Level
AEA09-FF-03-RES-H3	Fortification Sample, ME 03, RespiCon, 3rd High Level
AEA09-FF-03-HW-C1	Fortification Sample, ME 03, Hand Wash, 1st Control
AEA09-FF-03-HW-C2	Fortification Sample, ME 03, Hand Wash, 2nd Control
AEA09-FF-03-HW-L1	Fortification Sample, ME 03, Hand Wash, 1st Low Level
AEA09-FF-03-HW-L2	Fortification Sample, ME 03, Hand Wash, 2nd Low Level
AEA09-FF-03-HW-L3	Fortification Sample, ME 03, Hand Wash, 3rd Low Level
AEA09-FF-03-HW-H1	Fortification Sample, ME 03, Hand Wash, 1st High Level
AEA09-FF-03-HW-H2	Fortification Sample, ME 03, Hand Wash, 2nd High Level
AEA09-FF-03-HW-H3	Fortification Sample, ME 03, Hand Wash, 3rd High Level
AEA09-FF-03-FW-C1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Control
AEA09-FF-03-FW-C2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Control
AEA09-FF-03-FW-L1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Low Level
AEA09-FF-03-FW-L2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Low Level
AEA09-FF-03-FW-L3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd Low Level
AEA09-FF-03-FW-H1	Fortification Sample, ME 03, Face and Neck Wipe, 1st High Level
AEA09-FF-03-FW-H2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd High Level
AEA09-FF-03-FW-H3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd High Level
AEA09-FF-03-ID-C1	Fortification Sample, ME 03, Inner Dosimeter, 1st Control
AEA09-FF-03-ID-C2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Control
AEA09-FF-03-ID-L1	Fortification Sample, ME 03, Inner Dosimeter, 1st Low Level
AEA09-FF-03-ID-L2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Low Level
AEA09-FF-03-ID-L3	Fortification Sample, ME 03, Inner Dosimeter, 3rd Low Level
AEA09-FF-03-ID-H1	Fortification Sample, ME 03, Inner Dosimeter, 1st High Level
AEA09-FF-03-ID-H2	Fortification Sample, ME 03, Inner Dosimeter, 2nd High Level
AEA09-FF-03-ID-H3	Fortification Sample, ME 03, Inner Dosimeter, 3rd High Level
AEA09-FF-03-OD-C1	Fortification Sample, ME 03, Outer Dosimeter, 1st Control
AEA09-FF-03-OD-C2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Control
AEA09-FF-03-OD-L1	Fortification Sample, ME 03, Outer Dosimeter, 1st Low Level
AEA09-FF-03-OD-L2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Low Level
AEA09-FF-03-OD-L3	Fortification Sample, ME 03, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description

AEA09-FF-03-OD-H1	Fortification Sample, ME 03, Outer Dosimeter, 1st High Level
AEA09-FF-03-OD-H2	Fortification Sample, ME 03, Outer Dosimeter, 2nd High Level
AEA09-FF-03-OD-H3	Fortification Sample, ME 03, Outer Dosimeter, 3rd High Level
AEA09-FF-04-PH-C1	Fortification Sample, ME 04, Painter's Hat, 1st Control
AEA09-FF-04-PH-C2	Fortification Sample, ME 04, Painter's Hat, 2nd Control
AEA09-FF-04-PH-L1	Fortification Sample, ME 04, Painter's Hat, 1st Low Level
AEA09-FF-04-PH-L2	Fortification Sample, ME 04, Painter's Hat, 2nd Low Level
AEA09-FF-04-PH-L3	Fortification Sample, ME 04, Painter's Hat, 3rd Low Level
AEA09-FF-04-PH-H1	Fortification Sample, ME 04, Painter's Hat, 1st High Level
AEA09-FF-04-PH-H2	Fortification Sample, ME 04, Painter's Hat, 2nd High Level
AEA09-FF-04-PH-H3	Fortification Sample, ME 04, Painter's Hat, 3rd High Level
AEA09-FF-04-AR-C1	Fortification Sample, ME 04, Air Sampling Tube, 1st Control
AEA09-FF-04-AR-C2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Control
AEA09-FF-04-AR-L1	Fortification Sample, ME 04, Air Sampling Tube, 1st Low Level
AEA09-FF-04-AR-L2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Low Level
AEA09-FF-04-AR-L3	Fortification Sample, ME 04, Air Sampling Tube, 3rd Low Level
AEA09-FF-04-AR-H1	Fortification Sample, ME 04, Air Sampling Tube, 1st High Level
AEA09-FF-04-AR-H2	Fortification Sample, ME 04, Air Sampling Tube, 2nd High Level
AEA09-FF-04-AR-H3	Fortification Sample, ME 04, Air Sampling Tube, 3rd High Level
AEA09-FF-04-RES-C1	Fortification Sample, ME 04, RespiCon, 1st Control
AEA09-FF-04-RES-C2	Fortification Sample, ME 04, RespiCon, 2nd Control
AEA09-FF-04-RES-L1	Fortification Sample, ME 04, RespiCon, 1st Low Level
AEA09-FF-04-RES-L2	Fortification Sample, ME 04, RespiCon, 2nd Low Level
AEA09-FF-04-RES-L3	Fortification Sample, ME 04, RespiCon, 3rd Low Level
AEA09-FF-04-RES-H1	Fortification Sample, ME 04, RespiCon, 1st High Level
AEA09-FF-04-RES-H2	Fortification Sample, ME 04, RespiCon, 2nd High Level
AEA09-FF-04-RES-H3	Fortification Sample, ME 04, RespiCon, 3rd High Level
AEA09-FF-04-HW-C1	Fortification Sample, ME 04, Hand Wash, 1st Control
AEA09-FF-04-HW-C2	Fortification Sample, ME 04, Hand Wash, 2nd Control
AEA09-FF-04-HW-L1	Fortification Sample, ME 04, Hand Wash, 1st Low Level
AEA09-FF-04-HW-L2	Fortification Sample, ME 04, Hand Wash, 2nd Low Level
AEA09-FF-04-HW-L3	Fortification Sample, ME 04, Hand Wash, 3rd Low Level
AEA09-FF-04-HW-H1	Fortification Sample, ME 04, Hand Wash, 1st High Level
AEA09-FF-04-HW-H2	Fortification Sample, ME 04, Hand Wash, 2nd High Level
AEA09-FF-04-HW-H3	Fortification Sample, ME 04, Hand Wash, 3rd High Level
AEA09-FF-04-FW-C1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Control
AEA09-FF-04-FW-C2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Control
AEA09-FF-04-FW-L1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Low Level
AEA09-FF-04-FW-L2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Low Level
AEA09-FF-04-FW-L3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd Low Level
AEA09-FF-04-FW-H1	Fortification Sample, ME 04, Face and Neck Wipe, 1st High Level
AEA09-FF-04-FW-H2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd High Level

Sample ID Number	Description
AEA09-FF-04-FW-H3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd High Level
AEA09-FF-04-ID-C1	Fortification Sample, ME 04, Inner Dosimeter, 1st Control
AEA09-FF-04-ID-C2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Control
AEA09-FF-04-ID-L1	Fortification Sample, ME 04, Inner Dosimeter, 1st Low Level
AEA09-FF-04-ID-L2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Low Level
AEA09-FF-04-ID-L3	Fortification Sample, ME 04, Inner Dosimeter, 3rd Low Level
AEA09-FF-04-ID-H1	Fortification Sample, ME 04, Inner Dosimeter, 1st High Level
AEA09-FF-04-ID-H2	Fortification Sample, ME 04, Inner Dosimeter, 2nd High Level
AEA09-FF-04-ID-H3	Fortification Sample, ME 04, Inner Dosimeter, 3rd High Level
AEA09-FF-04-OD-C1	Fortification Sample, ME 04, Outer Dosimeter, 1st Control
AEA09-FF-04-OD-C2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Control
AEA09-FF-04-OD-L1	Fortification Sample, ME 04, Outer Dosimeter, 1st Low Level
AEA09-FF-04-OD-L2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Low Level
AEA09-FF-04-OD-L3	Fortification Sample, ME 04, Outer Dosimeter, 3rd Low Level
AEA09-FF-04-OD-H1	Fortification Sample, ME 04, Outer Dosimeter, 1st High Level
AEA09-FF-04-OD-H2	Fortification Sample, ME 04, Outer Dosimeter, 2nd High Level
AEA09-FF-04-OD-H3	Fortification Sample, ME 04, Outer Dosimeter, 3rd High Level
AEA09-FF-05-PH-C1	Fortification Sample, ME 05, Painter's Hat, 1st Control
AEA09-FF-05-PH-C2	Fortification Sample, ME 05, Painter's Hat, 2nd Control
AEA09-FF-05-PH-L1	Fortification Sample, ME 05, Painter's Hat, 1st Low Level
AEA09-FF-05-PH-L2	Fortification Sample, ME 05, Painter's Hat, 2nd Low Level
AEA09-FF-05-PH-L3	Fortification Sample, ME 05, Painter's Hat, 3rd Low Level
AEA09-FF-05-PH-H1	Fortification Sample, ME 05, Painter's Hat, 1st High Level
AEA09-FF-05-PH-H2	Fortification Sample, ME 05, Painter's Hat, 2nd High Level
AEA09-FF-05-PH-H3	Fortification Sample, ME 05, Painter's Hat, 3rd High Level
AEA09-FF-05-AR-C1	Fortification Sample, ME 05, Air Sampling Tube, 1st Control
AEA09-FF-05-AR-C2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Control
AEA09-FF-05-AR-L1	Fortification Sample, ME 05, Air Sampling Tube, 1st Low Level
AEA09-FF-05-AR-L2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Low Level
AEA09-FF-05-AR-L3	Fortification Sample, ME 05, Air Sampling Tube, 3rd Low Level
AEA09-FF-05-AR-H1	Fortification Sample, ME 05, Air Sampling Tube, 1st High Level
AEA09-FF-05-AR-H2	Fortification Sample, ME 05, Air Sampling Tube, 2nd High Level
AEA09-FF-05-AR-H3	Fortification Sample, ME 05, Air Sampling Tube, 3rd High Level
AEA09-FF-05-RES-C1	Fortification Sample, ME 05, RespiCon, 1st Control
AEA09-FF-05-RES-C2	Fortification Sample, ME 05, RespiCon, 2nd Control
AEA09-FF-05-RES-L1	Fortification Sample, ME 05, RespiCon, 1st Low Level
AEA09-FF-05-RES-L2	Fortification Sample, ME 05, RespiCon, 2nd Low Level
AEA09-FF-05-RES-L3	Fortification Sample, ME 05, RespiCon, 3rd Low Level
AEA09-FF-05-RES-H1	Fortification Sample, ME 05, RespiCon, 1st High Level
AEA09-FF-05-RES-H2	Fortification Sample, ME 05, RespiCon, 2nd High Level
AEA09-FF-05-RES-H3	Fortification Sample, ME 05, RespiCon, 3rd High Level
AEA09-FF-05-HW-C1	Fortification Sample, ME 05, Hand Wash, 1st Control
AEA09-FF-05-HW-C2	Fortification Sample, ME 05, Hand Wash, 2nd Control
AEA09-FF-05-HW-L1	Fortification Sample, ME 05, Hand Wash, 1st Low Level
AEA09-FF-05-HW-L2	Fortification Sample, ME 05, Hand Wash, 2nd Low Level
AEA09-FF-05-HW-L3	Fortification Sample, ME 05, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-05-HW-H1	Fortification Sample, ME 05, Hand Wash, 1st High Level
AEA09-FF-05-HW-H2	Fortification Sample, ME 05, Hand Wash, 2nd High Level
AEA09-FF-05-HW-H3	Fortification Sample, ME 05, Hand Wash, 3rd High Level
AEA09-FF-05-FW-C1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Control
AEA09-FF-05-FW-C2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Control
AEA09-FF-05-FW-L1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Low Level
AEA09-FF-05-FW-L2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Low Level
AEA09-FF-05-FW-L3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd Low Level
AEA09-FF-05-FW-H1	Fortification Sample, ME 05, Face and Neck Wipe, 1st High Level
AEA09-FF-05-FW-H2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd High Level
AEA09-FF-05-FW-H3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd High Level
AEA09-FF-05-ID-C1	Fortification Sample, ME 05, Inner Dosimeter, 1st Control
AEA09-FF-05-ID-C2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Control
AEA09-FF-05-ID-L1	Fortification Sample, ME 05, Inner Dosimeter, 1st Low Level
AEA09-FF-05-ID-L2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Low Level
AEA09-FF-05-ID-L3	Fortification Sample, ME 05, Inner Dosimeter, 3rd Low Level
AEA09-FF-05-ID-H1	Fortification Sample, ME 05, Inner Dosimeter, 1st High Level
AEA09-FF-05-ID-H2	Fortification Sample, ME 05, Inner Dosimeter, 2nd High Level
AEA09-FF-05-ID-H3	Fortification Sample, ME 05, Inner Dosimeter, 3rd High Level
AEA09-FF-05-OD-C1	Fortification Sample, ME 05, Outer Dosimeter, 1st Control
AEA09-FF-05-OD-C2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Control
AEA09-FF-05-OD-L1	Fortification Sample, ME 05, Outer Dosimeter, 1st Low Level
AEA09-FF-05-OD-L2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Low Level
AEA09-FF-05-OD-L3	Fortification Sample, ME 05, Outer Dosimeter, 3rd Low Level
AEA09-FF-05-OD-H1	Fortification Sample, ME 05, Outer Dosimeter, 1st High Level
AEA09-FF-05-OD-H2	Fortification Sample, ME 05, Outer Dosimeter, 2nd High Level
AEA09-FF-05-OD-H3	Fortification Sample, ME 05, Outer Dosimeter, 3rd High Level
AEA09-FF-06-PH-C1	Fortification Sample, ME 06, Painter's Hat, 1st Control
AEA09-FF-06-PH-C2	Fortification Sample, ME 06, Painter's Hat, 2nd Control
AEA09-FF-06-PH-L1	Fortification Sample, ME 06, Painter's Hat, 1st Low Level
AEA09-FF-06-PH-L2	Fortification Sample, ME 06, Painter's Hat, 2nd Low Level
AEA09-FF-06-PH-L3	Fortification Sample, ME 06, Painter's Hat, 3rd Low Level
AEA09-FF-06-PH-H1	Fortification Sample, ME 06, Painter's Hat, 1st High Level
AEA09-FF-06-PH-H2	Fortification Sample, ME 06, Painter's Hat, 2nd High Level
AEA09-FF-06-PH-H3	Fortification Sample, ME 06, Painter's Hat, 3rd High Level
AEA09-FF-06-AR-C1	Fortification Sample, ME 06, Air Sampling Tube, 1st Control
AEA09-FF-06-AR-C2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Control
AEA09-FF-06-AR-L1	Fortification Sample, ME 06, Air Sampling Tube, 1st Low Level
AEA09-FF-06-AR-L2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Low Level
AEA09-FF-06-AR-L3	Fortification Sample, ME 06, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-AR-H1	Fortification Sample, ME 06, Air Sampling Tube, 1st High Level
AEA09-FF-06-AR-H2	Fortification Sample, ME 06, Air Sampling Tube, 2nd High Level
AEA09-FF-06-AR-H3	Fortification Sample, ME 06, Air Sampling Tube, 3rd High Level
AEA09-FF-06-RES-C1	Fortification Sample, ME 06, RespiCon, 1st Control
AEA09-FF-06-RES-C2	Fortification Sample, ME 06, RespiCon, 2nd Control
AEA09-FF-06-RES-L1	Fortification Sample, ME 06, RespiCon, 1st Low Level
AEA09-FF-06-RES-L2	Fortification Sample, ME 06, RespiCon, 2nd Low Level
AEA09-FF-06-RES-L3	Fortification Sample, ME 06, RespiCon, 3rd Low Level
AEA09-FF-06-RES-H1	Fortification Sample, ME 06, RespiCon, 1st High Level
AEA09-FF-06-RES-H2	Fortification Sample, ME 06, RespiCon, 2nd High Level
AEA09-FF-06-RES-H3	Fortification Sample, ME 06, RespiCon, 3rd High Level
AEA09-FF-06-HW-C1	Fortification Sample, ME 06, Hand Wash, 1st Control
AEA09-FF-06-HW-C2	Fortification Sample, ME 06, Hand Wash, 2nd Control
AEA09-FF-06-HW-L1	Fortification Sample, ME 06, Hand Wash, 1st Low Level
AEA09-FF-06-HW-L2	Fortification Sample, ME 06, Hand Wash, 2nd Low Level
AEA09-FF-06-HW-L3	Fortification Sample, ME 06, Hand Wash, 3rd Low Level
AEA09-FF-06-HW-H1	Fortification Sample, ME 06, Hand Wash, 1st High Level
AEA09-FF-06-HW-H2	Fortification Sample, ME 06, Hand Wash, 2nd High Level
AEA09-FF-06-HW-H3	Fortification Sample, ME 06, Hand Wash, 3rd High Level
AEA09-FF-06-FW-C1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Control
AEA09-FF-06-FW-C2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Control
AEA09-FF-06-FW-L1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Low Level
AEA09-FF-06-FW-L2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Low Level
AEA09-FF-06-FW-L3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd Low Level
AEA09-FF-06-FW-H1	Fortification Sample, ME 06, Face and Neck Wipe, 1st High Level
AEA09-FF-06-FW-H2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd High Level
AEA09-FF-06-FW-H3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd High Level
AEA09-FF-06-ID-C1	Fortification Sample, ME 06, Inner Dosimeter, 1st Control
AEA09-FF-06-ID-C2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Control
AEA09-FF-06-ID-L1	Fortification Sample, ME 06, Inner Dosimeter, 1st Low Level
AEA09-FF-06-ID-L2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Low Level
AEA09-FF-06-ID-L3	Fortification Sample, ME 06, Inner Dosimeter, 3rd Low Level
AEA09-FF-06-ID-H1	Fortification Sample, ME 06, Inner Dosimeter, 1st High Level
AEA09-FF-06-ID-H2	Fortification Sample, ME 06, Inner Dosimeter, 2nd High Level
AEA09-FF-06-ID-H3	Fortification Sample, ME 06, Inner Dosimeter, 3rd High Level
AEA09-FF-06-OD-C1	Fortification Sample, ME 06, Outer Dosimeter, 1st Control
AEA09-FF-06-OD-C2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Control
AEA09-FF-06-OD-L1	Fortification Sample, ME 06, Outer Dosimeter, 1st Low Level
AEA09-FF-06-OD-L2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Low Level
AEA09-FF-06-OD-L3	Fortification Sample, ME 06, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-OD-H1	Fortification Sample, ME 06, Outer Dosimeter, 1st High Level
AEA09-FF-06-OD-H2	Fortification Sample, ME 06, Outer Dosimeter, 2nd High Level
AEA09-FF-06-OD-H3	Fortification Sample, ME 06, Outer Dosimeter, 3rd High Level
AEA09-FF-07-PH-C1	Fortification Sample, ME 07, Painter's Hat, 1st Control
AEA09-FF-07-PH-C2	Fortification Sample, ME 07, Painter's Hat, 2nd Control
AEA09-FF-07-PH-L1	Fortification Sample, ME 07, Painter's Hat, 1st Low Level
AEA09-FF-07-PH-L2	Fortification Sample, ME 07, Painter's Hat, 2nd Low Level
AEA09-FF-07-PH-L3	Fortification Sample, ME 07, Painter's Hat, 3rd Low Level
AEA09-FF-07-PH-H1	Fortification Sample, ME 07, Painter's Hat, 1st High Level
AEA09-FF-07-PH-H2	Fortification Sample, ME 07, Painter's Hat, 2nd High Level
AEA09-FF-07-PH-H3	Fortification Sample, ME 07, Painter's Hat, 3rd High Level
AEA09-FF-07-AR-C1	Fortification Sample, ME 07, Air Sampling Tube, 1st Control
AEA09-FF-07-AR-C2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Control
AEA09-FF-07-AR-L1	Fortification Sample, ME 07, Air Sampling Tube, 1st Low Level
AEA09-FF-07-AR-L2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Low Level
AEA09-FF-07-AR-L3	Fortification Sample, ME 07, Air Sampling Tube, 3rd Low Level
AEA09-FF-07-AR-H1	Fortification Sample, ME 07, Air Sampling Tube, 1st High Level
AEA09-FF-07-AR-H2	Fortification Sample, ME 07, Air Sampling Tube, 2nd High Level
AEA09-FF-07-AR-H3	Fortification Sample, ME 07, Air Sampling Tube, 3rd High Level
AEA09-FF-07-RES-C1	Fortification Sample, ME 07, RespiCon, 1st Control
AEA09-FF-07-RES-C2	Fortification Sample, ME 07, RespiCon, 2nd Control
AEA09-FF-07-RES-L1	Fortification Sample, ME 07, RespiCon, 1st Low Level
AEA09-FF-07-RES-L2	Fortification Sample, ME 07, RespiCon, 2nd Low Level
AEA09-FF-07-RES-L3	Fortification Sample, ME 07, RespiCon, 3rd Low Level
AEA09-FF-07-RES-H1	Fortification Sample, ME 07, RespiCon, 1st High Level
AEA09-FF-07-RES-H2	Fortification Sample, ME 07, RespiCon, 2nd High Level
AEA09-FF-07-RES-H3	Fortification Sample, ME 07, RespiCon, 3rd High Level
AEA09-FF-07-HW-C1	Fortification Sample, ME 07, Hand Wash, 1st Control
AEA09-FF-07-HW-C2	Fortification Sample, ME 07, Hand Wash, 2nd Control
AEA09-FF-07-HW-L1	Fortification Sample, ME 07, Hand Wash, 1st Low Level
AEA09-FF-07-HW-L2	Fortification Sample, ME 07, Hand Wash, 2nd Low Level
AEA09-FF-07-HW-L3	Fortification Sample, ME 07, Hand Wash, 3rd Low Level
AEA09-FF-07-HW-H1	Fortification Sample, ME 07, Hand Wash, 1st High Level
AEA09-FF-07-HW-H2	Fortification Sample, ME 07, Hand Wash, 2nd High Level
AEA09-FF-07-HW-H3	Fortification Sample, ME 07, Hand Wash, 3rd High Level
AEA09-FF-07-FW-C1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Control
AEA09-FF-07-FW-C2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Control
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Low Level
AEA09-FF-07-FW-L3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd Low Level
AEA09-FF-07-FW-H1	Fortification Sample, ME 07, Face and Neck Wipe, 1st High Level

Sample ID Number	Description
AEA09-FF-07-FW-H2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd High Level
AEA09-FF-07-FW-H3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd High Level
AEA09-FF-07-ID-C1	Fortification Sample, ME 07, Inner Dosimeter, 1st Control
AEA09-FF-07-ID-C2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Control
AEA09-FF-07-ID-L1	Fortification Sample, ME 07, Inner Dosimeter, 1st Low Level
AEA09-FF-07-ID-L2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Low Level
AEA09-FF-07-ID-L3	Fortification Sample, ME 07, Inner Dosimeter, 3rd Low Level
AEA09-FF-07-ID-H1	Fortification Sample, ME 07, Inner Dosimeter, 1st High Level
AEA09-FF-07-ID-H2	Fortification Sample, ME 07, Inner Dosimeter, 2nd High Level
AEA09-FF-07-ID-H3	Fortification Sample, ME 07, Inner Dosimeter, 3rd High Level
AEA09-FF-07-OD-C1	Fortification Sample, ME 07, Outer Dosimeter, 1st Control
AEA09-FF-07-OD-C2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Control
AEA09-FF-07-OD-L1	Fortification Sample, ME 07, Outer Dosimeter, 1st Low Level
AEA09-FF-07-OD-L2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Low Level
AEA09-FF-07-OD-L3	Fortification Sample, ME 07, Outer Dosimeter, 3rd Low Level
AEA09-FF-07-OD-H1	Fortification Sample, ME 07, Outer Dosimeter, 1st High Level
AEA09-FF-07-OD-H2	Fortification Sample, ME 07, Outer Dosimeter, 2nd High Level
AEA09-FF-07-OD-H3	Fortification Sample, ME 07, Outer Dosimeter, 3rd High Level
AEA09-FF-08-PH-C1	Fortification Sample, ME 08, Painter's Hat, 1st Control
AEA09-FF-08-PH-C2	Fortification Sample, ME 08, Painter's Hat, 2nd Control
AEA09-FF-08-PH-L1	Fortification Sample, ME 08, Painter's Hat, 1st Low Level
AEA09-FF-08-PH-L2	Fortification Sample, ME 08, Painter's Hat, 2nd Low Level
AEA09-FF-08-PH-L3	Fortification Sample, ME 08, Painter's Hat, 3rd Low Level
AEA09-FF-08-PH-H1	Fortification Sample, ME 08, Painter's Hat, 1st High Level
AEA09-FF-08-PH-H2	Fortification Sample, ME 08, Painter's Hat, 2nd High Level
AEA09-FF-08-PH-H3	Fortification Sample, ME 08, Painter's Hat, 3rd High Level
AEA09-FF-08-AR-C1	Fortification Sample, ME 08, Air Sampling Tube, 1st Control
AEA09-FF-08-AR-C2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Control
AEA09-FF-08-AR-L1	Fortification Sample, ME 08, Air Sampling Tube, 1st Low Level
AEA09-FF-08-AR-L2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Low Level
AEA09-FF-08-AR-L3	Fortification Sample, ME 08, Air Sampling Tube, 3rd Low Level
AEA09-FF-08-AR-H1	Fortification Sample, ME 08, Air Sampling Tube, 1st High Level
AEA09-FF-08-AR-H2	Fortification Sample, ME 08, Air Sampling Tube, 2nd High Level
AEA09-FF-08-AR-H3	Fortification Sample, ME 08, Air Sampling Tube, 3rd High Level
AEA09-FF-08-RES-C1	Fortification Sample, ME 08, RespiCon, 1st Control
AEA09-FF-08-RES-C2	Fortification Sample, ME 08, RespiCon, 2nd Control
AEA09-FF-08-RES-L1	Fortification Sample, ME 08, RespiCon, 1st Low Level
AEA09-FF-08-RES-L2	Fortification Sample, ME 08, RespiCon, 2nd Low Level
AEA09-FF-08-RES-L3	Fortification Sample, ME 08, RespiCon, 3rd Low Level
AEA09-FF-08-RES-H1	Fortification Sample, ME 08, RespiCon, 1st High Level
AEA09-FF-08-RES-H2	Fortification Sample, ME 08, RespiCon, 2nd High Level
AEA09-FF-08-RES-H3	Fortification Sample, ME 08, RespiCon, 3rd High Level
AEA09-FF-08-HW-C1	Fortification Sample, ME 08, Hand Wash, 1st Control
AEA09-FF-08-HW-C2	Fortification Sample, ME 08, Hand Wash, 2nd Control

Sample ID Number	Description
AEA09-FF-08-HW-L1	Fortification Sample, ME 08, Hand Wash, 1st Low Level
AEA09-FF-08-HW-L2	Fortification Sample, ME 08, Hand Wash, 2nd Low Level
AEA09-FF-08-HW-L3	Fortification Sample, ME 08, Hand Wash, 3rd Low Level
AEA09-FF-08-HW-H1	Fortification Sample, ME 08, Hand Wash, 1st High Level
AEA09-FF-08-HW-H2	Fortification Sample, ME 08, Hand Wash, 2nd High Level
AEA09-FF-08-HW-H3	Fortification Sample, ME 08, Hand Wash, 3rd High Level
AEA09-FF-08-FW-C1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Control
AEA09-FF-08-FW-C2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Control
AEA09-FF-08-FW-L1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Low Level
AEA09-FF-08-FW-L2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Low Level
AEA09-FF-08-FW-L3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd Low Level
AEA09-FF-08-FW-H1	Fortification Sample, ME 08, Face and Neck Wipe, 1st High Level
AEA09-FF-08-FW-H2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd High Level
AEA09-FF-08-FW-H3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd High Level
AEA09-FF-08-ID-C1	Fortification Sample, ME 08, Inner Dosimeter, 1st Control
AEA09-FF-08-ID-C2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Control
AEA09-FF-08-ID-L1	Fortification Sample, ME 08, Inner Dosimeter, 1st Low Level
AEA09-FF-08-ID-L2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Low Level
AEA09-FF-08-ID-L3	Fortification Sample, ME 08, Inner Dosimeter, 3rd Low Level
AEA09-FF-08-ID-H1	Fortification Sample, ME 08, Inner Dosimeter, 1st High Level
AEA09-FF-08-ID-H2	Fortification Sample, ME 08, Inner Dosimeter, 2nd High Level
AEA09-FF-08-ID-H3	Fortification Sample, ME 08, Inner Dosimeter, 3rd High Level
AEA09-FF-08-OD-C1	Fortification Sample, ME 08, Outer Dosimeter, 1st Control
AEA09-FF-08-OD-C2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Control
AEA09-FF-08-OD-L1	Fortification Sample, ME 08, Outer Dosimeter, 1st Low Level
AEA09-FF-08-OD-L2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Low Level
AEA09-FF-08-OD-L3	Fortification Sample, ME 08, Outer Dosimeter, 3rd Low Level
AEA09-FF-08-OD-H1	Fortification Sample, ME 08, Outer Dosimeter, 1st High Level
AEA09-FF-08-OD-H2	Fortification Sample, ME 08, Outer Dosimeter, 2nd High Level
AEA09-FF-08-OD-H3	Fortification Sample, ME 08, Outer Dosimeter, 3rd High Level
AEA09-FF-09-PH-C1	Fortification Sample, ME 09, Painter's Hat, 1st Control
AEA09-FF-09-PH-C2	Fortification Sample, ME 09, Painter's Hat, 2nd Control
AEA09-FF-09-PH-L1	Fortification Sample, ME 09, Painter's Hat, 1st Low Level
AEA09-FF-09-PH-L2	Fortification Sample, ME 09, Painter's Hat, 2nd Low Level
AEA09-FF-09-PH-L3	Fortification Sample, ME 09, Painter's Hat, 3rd Low Level
AEA09-FF-09-PH-H1	Fortification Sample, ME 09, Painter's Hat, 1st High Level
AEA09-FF-09-PH-H2	Fortification Sample, ME 09, Painter's Hat, 2nd High Level
AEA09-FF-09-PH-H3	Fortification Sample, ME 09, Painter's Hat, 3rd High Level
AEA09-FF-09-AR-C1	Fortification Sample, ME 09, Air Sampling Tube, 1st Control
AEA09-FF-09-AR-C2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Control

Sample ID Number	Description
AEA09-FF-09-AR-L1	Fortification Sample, ME 09, Air Sampling Tube, 1st Low Level
AEA09-FF-09-AR-L2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Low Level
AEA09-FF-09-AR-L3	Fortification Sample, ME 09, Air Sampling Tube, 3rd Low Level
AEA09-FF-09-AR-H1	Fortification Sample, ME 09, Air Sampling Tube, 1st High Level
AEA09-FF-09-AR-H2	Fortification Sample, ME 09, Air Sampling Tube, 2nd High Level
AEA09-FF-09-AR-H3	Fortification Sample, ME 09, Air Sampling Tube, 3rd High Level
AEA09-FF-09-RES-C1	Fortification Sample, ME 09, RespiCon, 1st Control
AEA09-FF-09-RES-C2	Fortification Sample, ME 09, RespiCon, 2nd Control
AEA09-FF-09-RES-L1	Fortification Sample, ME 09, RespiCon, 1st Low Level
AEA09-FF-09-RES-L2	Fortification Sample, ME 09, RespiCon, 2nd Low Level
AEA09-FF-09-RES-L3	Fortification Sample, ME 09, RespiCon, 3rd Low Level
AEA09-FF-09-RES-H1	Fortification Sample, ME 09, RespiCon, 1st High Level
AEA09-FF-09-RES-H2	Fortification Sample, ME 09, RespiCon, 2nd High Level
AEA09-FF-09-RES-H3	Fortification Sample, ME 09, RespiCon, 3rd High Level
AEA09-FF-09-HW-C1	Fortification Sample, ME 09, Hand Wash, 1st Control
AEA09-FF-09-HW-C2	Fortification Sample, ME 09, Hand Wash, 2nd Control
AEA09-FF-09-HW-L1	Fortification Sample, ME 09, Hand Wash, 1st Low Level
AEA09-FF-09-HW-L2	Fortification Sample, ME 09, Hand Wash, 2nd Low Level
AEA09-FF-09-HW-L3	Fortification Sample, ME 09, Hand Wash, 3rd Low Level
AEA09-FF-09-HW-H1	Fortification Sample, ME 09, Hand Wash, 1st High Level
AEA09-FF-09-HW-H2	Fortification Sample, ME 09, Hand Wash, 2nd High Level
AEA09-FF-09-HW-H3	Fortification Sample, ME 09, Hand Wash, 3rd High Level
AEA09-FF-09-FW-C1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Control
AEA09-FF-09-FW-C2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Control
AEA09-FF-09-FW-L1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Low Level
AEA09-FF-09-FW-L2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Low Level
AEA09-FF-09-FW-L3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd Low Level
AEA09-FF-09-FW-H1	Fortification Sample, ME 09, Face and Neck Wipe, 1st High Level
AEA09-FF-09-FW-H2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd High Level
AEA09-FF-09-FW-H3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd High Level
AEA09-FF-09-ID-C1	Fortification Sample, ME 09, Inner Dosimeter, 1st Control
AEA09-FF-09-ID-C2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Control
AEA09-FF-09-ID-L1	Fortification Sample, ME 09, Inner Dosimeter, 1st Low Level
AEA09-FF-09-ID-L2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Low Level
AEA09-FF-09-ID-L3	Fortification Sample, ME 09, Inner Dosimeter, 3rd Low Level
AEA09-FF-09-ID-H1	Fortification Sample, ME 09, Inner Dosimeter, 1st High Level
AEA09-FF-09-ID-H2	Fortification Sample, ME 09, Inner Dosimeter, 2nd High Level
AEA09-FF-09-ID-H3	Fortification Sample, ME 09, Inner Dosimeter, 3rd High Level
AEA09-FF-09-OD-C1	Fortification Sample, ME 09, Outer Dosimeter, 1st Control
AEA09-FF-09-OD-C2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Control

Sample ID Number	Description
AEA09-FF-09-OD-L1	Fortification Sample, ME 09, Outer Dosimeter, 1st Low Level
AEA09-FF-09-OD-L2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Low Level
AEA09-FF-09-OD-L3	Fortification Sample, ME 09, Outer Dosimeter, 3rd Low Level
AEA09-FF-09-OD-H1	Fortification Sample, ME 09, Outer Dosimeter, 1st High Level
AEA09-FF-09-OD-H2	Fortification Sample, ME 09, Outer Dosimeter, 2nd High Level
AEA09-FF-09-OD-H3	Fortification Sample, ME 09, Outer Dosimeter, 3rd High Level
AEA09-FF-10-PH-C1	Fortification Sample, ME 10, Painter's Hat, 1st Control
AEA09-FF-10-PH-C2	Fortification Sample, ME 10, Painter's Hat, 2nd Control
AEA09-FF-10-PH-L1	Fortification Sample, ME 10, Painter's Hat, 1st Low Level
AEA09-FF-10-PH-L2	Fortification Sample, ME 10, Painter's Hat, 2nd Low Level
AEA09-FF-10-PH-L3	Fortification Sample, ME 10, Painter's Hat, 3rd Low Level
AEA09-FF-10-PH-H1	Fortification Sample, ME 10, Painter's Hat, 1st High Level
AEA09-FF-10-PH-H2	Fortification Sample, ME 10, Painter's Hat, 2nd High Level
AEA09-FF-10-PH-H3	Fortification Sample, ME 10, Painter's Hat, 3rd High Level
AEA09-FF-10-AR-C1	Fortification Sample, ME 10, Air Sampling Tube, 1st Control
AEA09-FF-10-AR-C2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Control
AEA09-FF-10-AR-L1	Fortification Sample, ME 10, Air Sampling Tube, 1st Low Level
AEA09-FF-10-AR-L2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Low Level
AEA09-FF-10-AR-L3	Fortification Sample, ME 10, Air Sampling Tube, 3rd Low Level
AEA09-FF-10-AR-H1	Fortification Sample, ME 10, Air Sampling Tube, 1st High Level
AEA09-FF-10-AR-H2	Fortification Sample, ME 10, Air Sampling Tube, 2nd High Level
AEA09-FF-10-AR-H3	Fortification Sample, ME 10, Air Sampling Tube, 3rd High Level
AEA09-FF-10-RES-C1	Fortification Sample, ME 10, RespiCon, 1st Control
AEA09-FF-10-RES-C2	Fortification Sample, ME 10, RespiCon, 2nd Control
AEA09-FF-10-RES-L1	Fortification Sample, ME 10, RespiCon, 1st Low Level
AEA09-FF-10-RES-L2	Fortification Sample, ME 10, RespiCon, 2nd Low Level
AEA09-FF-10-RES-L3	Fortification Sample, ME 10, RespiCon, 3rd Low Level
AEA09-FF-10-RES-H1	Fortification Sample, ME 10, RespiCon, 1st High Level
AEA09-FF-10-RES-H2	Fortification Sample, ME 10, RespiCon, 2nd High Level
AEA09-FF-10-RES-H3	Fortification Sample, ME 10, RespiCon, 3rd High Level
AEA09-FF-10-HW-C1	Fortification Sample, ME 10, Hand Wash, 1st Control
AEA09-FF-10-HW-C2	Fortification Sample, ME 10, Hand Wash, 2nd Control
AEA09-FF-10-HW-L1	Fortification Sample, ME 10, Hand Wash, 1st Low Level
AEA09-FF-10-HW-L2	Fortification Sample, ME 10, Hand Wash, 2nd Low Level
AEA09-FF-10-HW-L3	Fortification Sample, ME 10, Hand Wash, 3rd Low Level
AEA09-FF-10-HW-H1	Fortification Sample, ME 10, Hand Wash, 1st High Level
AEA09-FF-10-HW-H2	Fortification Sample, ME 10, Hand Wash, 2nd High Level
AEA09-FF-10-HW-H3	Fortification Sample, ME 10, Hand Wash, 3rd High Level
AEA09-FF-10-FW-C1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Control
AEA09-FF-10-FW-C2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Control
AEA09-FF-10-FW-L1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Low Level
AEA09-FF-10-FW-L2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Low Level
AEA09-FF-10-FW-L3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-10-FW-H1	Fortification Sample, ME 10, Face and Neck Wipe, 1st High Level
AEA09-FF-10-FW-H2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd High Level
AEA09-FF-10-FW-H3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd High Level
AEA09-FF-10-ID-C1	Fortification Sample, ME 10, Inner Dosimeter, 1st Control
AEA09-FF-10-ID-C2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Control
AEA09-FF-10-ID-L1	Fortification Sample, ME 10, Inner Dosimeter, 1st Low Level
AEA09-FF-10-ID-L2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Low Level
AEA09-FF-10-ID-L3	Fortification Sample, ME 10, Inner Dosimeter, 3rd Low Level
AEA09-FF-10-ID-H1	Fortification Sample, ME 10, Inner Dosimeter, 1st High Level
AEA09-FF-10-ID-H2	Fortification Sample, ME 10, Inner Dosimeter, 2nd High Level
AEA09-FF-10-ID-H3	Fortification Sample, ME 10, Inner Dosimeter, 3rd High Level
AEA09-FF-10-OD-C1	Fortification Sample, ME 10, Outer Dosimeter, 1st Control
AEA09-FF-10-OD-C2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Control
AEA09-FF-10-OD-L1	Fortification Sample, ME 10, Outer Dosimeter, 1st Low Level
AEA09-FF-10-OD-L2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Low Level
AEA09-FF-10-OD-L3	Fortification Sample, ME 10, Outer Dosimeter, 3rd Low Level
AEA09-FF-10-OD-H1	Fortification Sample, ME 10, Outer Dosimeter, 1st High Level
AEA09-FF-10-OD-H2	Fortification Sample, ME 10, Outer Dosimeter, 2nd High Level
AEA09-FF-10-OD-H3	Fortification Sample, ME 10, Outer Dosimeter, 3rd High Level
AEA09-FF-11-PH-C1	Fortification Sample, ME 11, Painter's Hat, 1st Control
AEA09-FF-11-PH-C2	Fortification Sample, ME 11, Painter's Hat, 2nd Control
AEA09-FF-11-PH-L1	Fortification Sample, ME 11, Painter's Hat, 1st Low Level
AEA09-FF-11-PH-L2	Fortification Sample, ME 11, Painter's Hat, 2nd Low Level
AEA09-FF-11-PH-L3	Fortification Sample, ME 11, Painter's Hat, 3rd Low Level
AEA09-FF-11-PH-H1	Fortification Sample, ME 11, Painter's Hat, 1st High Level
AEA09-FF-11-PH-H2	Fortification Sample, ME 11, Painter's Hat, 2nd High Level
AEA09-FF-11-PH-H3	Fortification Sample, ME 11, Painter's Hat, 3rd High Level
AEA09-FF-11-AR-C1	Fortification Sample, ME 11, Air Sampling Tube, 1st Control
AEA09-FF-11-AR-C2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Control
AEA09-FF-11-AR-L1	Fortification Sample, ME 11, Air Sampling Tube, 1st Low Level
AEA09-FF-11-AR-L2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Low Level
AEA09-FF-11-AR-L3	Fortification Sample, ME 11, Air Sampling Tube, 3rd Low Level
AEA09-FF-11-AR-H1	Fortification Sample, ME 11, Air Sampling Tube, 1st High Level
AEA09-FF-11-AR-H2	Fortification Sample, ME 11, Air Sampling Tube, 2nd High Level
AEA09-FF-11-AR-H3	Fortification Sample, ME 11, Air Sampling Tube, 3rd High Level
AEA09-FF-11-RES-C1	Fortification Sample, ME 11, RespiCon, 1st Control
AEA09-FF-11-RES-C2	Fortification Sample, ME 11, RespiCon, 2nd Control
AEA09-FF-11-RES-L1	Fortification Sample, ME 11, RespiCon, 1st Low Level
AEA09-FF-11-RES-L2	Fortification Sample, ME 11, RespiCon, 2nd Low Level
AEA09-FF-11-RES-L3	Fortification Sample, ME 11, RespiCon, 3rd Low Level
AEA09-FF-11-RES-H1	Fortification Sample, ME 11, RespiCon, 1st High Level
AEA09-FF-11-RES-H2	Fortification Sample, ME 11, RespiCon, 2nd High Level
AEA09-FF-11-RES-H3	Fortification Sample, ME 11, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-11-HW-C1	Fortification Sample, ME 11, Hand Wash, 1st Control
AEA09-FF-11-HW-C2	Fortification Sample, ME 11, Hand Wash, 2nd Control
AEA09-FF-11-HW-L1	Fortification Sample, ME 11, Hand Wash, 1st Low Level
AEA09-FF-11-HW-L2	Fortification Sample, ME 11, Hand Wash, 2nd Low Level
AEA09-FF-11-HW-L3	Fortification Sample, ME 11, Hand Wash, 3rd Low Level
AEA09-FF-11-HW-H1	Fortification Sample, ME 11, Hand Wash, 1st High Level
AEA09-FF-11-HW-H2	Fortification Sample, ME 11, Hand Wash, 2nd High Level
AEA09-FF-11-HW-H3	Fortification Sample, ME 11, Hand Wash, 3rd High Level
AEA09-FF-11-FW-C1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Control
AEA09-FF-11-FW-C2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Control
AEA09-FF-11-FW-L1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Low Level
AEA09-FF-11-FW-L2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Low Level
AEA09-FF-11-FW-L3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd Low Level
AEA09-FF-11-FW-H1	Fortification Sample, ME 11, Face and Neck Wipe, 1st High Level
AEA09-FF-11-FW-H2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd High Level
AEA09-FF-11-FW-H3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd High Level
AEA09-FF-11-ID-C1	Fortification Sample, ME 11, Inner Dosimeter, 1st Control
AEA09-FF-11-ID-C2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Control
AEA09-FF-11-ID-L1	Fortification Sample, ME 11, Inner Dosimeter, 1st Low Level
AEA09-FF-11-ID-L2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Low Level
AEA09-FF-11-ID-L3	Fortification Sample, ME 11, Inner Dosimeter, 3rd Low Level
AEA09-FF-11-ID-H1	Fortification Sample, ME 11, Inner Dosimeter, 1st High Level
AEA09-FF-11-ID-H2	Fortification Sample, ME 11, Inner Dosimeter, 2nd High Level
AEA09-FF-11-ID-H3	Fortification Sample, ME 11, Inner Dosimeter, 3rd High Level
AEA09-FF-11-OD-C1	Fortification Sample, ME 11, Outer Dosimeter, 1st Control
AEA09-FF-11-OD-C2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Control
AEA09-FF-11-OD-L1	Fortification Sample, ME 11, Outer Dosimeter, 1st Low Level
AEA09-FF-11-OD-L2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Low Level
AEA09-FF-11-OD-L3	Fortification Sample, ME 11, Outer Dosimeter, 3rd Low Level
AEA09-FF-11-OD-H1	Fortification Sample, ME 11, Outer Dosimeter, 1st High Level
AEA09-FF-11-OD-H2	Fortification Sample, ME 11, Outer Dosimeter, 2nd High Level
AEA09-FF-11-OD-H3	Fortification Sample, ME 11, Outer Dosimeter, 3rd High Level
AEA09-FF-12-PH-C1	Fortification Sample, ME 12, Painter's Hat, 1st Control
AEA09-FF-12-PH-C2	Fortification Sample, ME 12, Painter's Hat, 2nd Control
AEA09-FF-12-PH-L1	Fortification Sample, ME 12, Painter's Hat, 1st Low Level
AEA09-FF-12-PH-L2	Fortification Sample, ME 12, Painter's Hat, 2nd Low Level
AEA09-FF-12-PH-L3	Fortification Sample, ME 12, Painter's Hat, 3rd Low Level
AEA09-FF-12-PH-H1	Fortification Sample, ME 12, Painter's Hat, 1st High Level
AEA09-FF-12-PH-H2	Fortification Sample, ME 12, Painter's Hat, 2nd High Level
AEA09-FF-12-PH-H3	Fortification Sample, ME 12, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-AR-C1	Fortification Sample, ME 12, Air Sampling Tube, 1st Control
AEA09-FF-12-AR-C2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Control
AEA09-FF-12-AR-L1	Fortification Sample, ME 12, Air Sampling Tube, 1st Low Level
AEA09-FF-12-AR-L2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Low Level
AEA09-FF-12-AR-L3	Fortification Sample, ME 12, Air Sampling Tube, 3rd Low Level
AEA09-FF-12-AR-H1	Fortification Sample, ME 12, Air Sampling Tube, 1st High Level
AEA09-FF-12-AR-H2	Fortification Sample, ME 12, Air Sampling Tube, 2nd High Level
AEA09-FF-12-AR-H3	Fortification Sample, ME 12, Air Sampling Tube, 3rd High Level
AEA09-FF-12-RES-C1	Fortification Sample, ME 12, RespiCon, 1st Control
AEA09-FF-12-RES-C2	Fortification Sample, ME 12, RespiCon, 2nd Control
AEA09-FF-12-RES-L1	Fortification Sample, ME 12, RespiCon, 1st Low Level
AEA09-FF-12-RES-L2	Fortification Sample, ME 12, RespiCon, 2nd Low Level
AEA09-FF-12-RES-L3	Fortification Sample, ME 12, RespiCon, 3rd Low Level
AEA09-FF-12-RES-H1	Fortification Sample, ME 12, RespiCon, 1st High Level
AEA09-FF-12-RES-H2	Fortification Sample, ME 12, RespiCon, 2nd High Level
AEA09-FF-12-RES-H3	Fortification Sample, ME 12, RespiCon, 3rd High Level
AEA09-FF-12-HW-C1	Fortification Sample, ME 12, Hand Wash, 1st Control
AEA09-FF-12-HW-C2	Fortification Sample, ME 12, Hand Wash, 2nd Control
AEA09-FF-12-HW-L1	Fortification Sample, ME 12, Hand Wash, 1st Low Level
AEA09-FF-12-HW-L2	Fortification Sample, ME 12, Hand Wash, 2nd Low Level
AEA09-FF-12-HW-L3	Fortification Sample, ME 12, Hand Wash, 3rd Low Level
AEA09-FF-12-HW-H1	Fortification Sample, ME 12, Hand Wash, 1st High Level
AEA09-FF-12-HW-H2	Fortification Sample, ME 12, Hand Wash, 2nd High Level
AEA09-FF-12-HW-H3	Fortification Sample, ME 12, Hand Wash, 3rd High Level
AEA09-FF-12-FW-C1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Control
AEA09-FF-12-FW-C2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Control
AEA09-FF-12-FW-L1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Low Level
AEA09-FF-12-FW-L2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Low Level
AEA09-FF-12-FW-L3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd Low Level
AEA09-FF-12-FW-H1	Fortification Sample, ME 12, Face and Neck Wipe, 1st High Level
AEA09-FF-12-FW-H2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd High Level
AEA09-FF-12-FW-H3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd High Level
AEA09-FF-12-ID-C1	Fortification Sample, ME 12, Inner Dosimeter, 1st Control
AEA09-FF-12-ID-C2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Control
AEA09-FF-12-ID-L1	Fortification Sample, ME 12, Inner Dosimeter, 1st Low Level
AEA09-FF-12-ID-L2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Low Level
AEA09-FF-12-ID-L3	Fortification Sample, ME 12, Inner Dosimeter, 3rd Low Level
AEA09-FF-12-ID-H1	Fortification Sample, ME 12, Inner Dosimeter, 1st High Level
AEA09-FF-12-ID-H2	Fortification Sample, ME 12, Inner Dosimeter, 2nd High Level
AEA09-FF-12-ID-H3	Fortification Sample, ME 12, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-OD-C1	Fortification Sample, ME 12, Outer Dosimeter, 1st Control
AEA09-FF-12-OD-C2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Control
AEA09-FF-12-OD-L1	Fortification Sample, ME 12, Outer Dosimeter, 1st Low Level
AEA09-FF-12-OD-L2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Low Level
AEA09-FF-12-OD-L3	Fortification Sample, ME 12, Outer Dosimeter, 3rd Low Level
AEA09-FF-12-OD-H1	Fortification Sample, ME 12, Outer Dosimeter, 1st High Level
AEA09-FF-12-OD-H2	Fortification Sample, ME 12, Outer Dosimeter, 2nd High Level
AEA09-FF-12-OD-H3	Fortification Sample, ME 12, Outer Dosimeter, 3rd High Level
AEA09-FF-13-PH-C1	Fortification Sample, ME 13, Painter's Hat, 1st Control
AEA09-FF-13-PH-C2	Fortification Sample, ME 13, Painter's Hat, 2nd Control
AEA09-FF-13-PH-L1	Fortification Sample, ME 13, Painter's Hat, 1st Low Level
AEA09-FF-13-PH-L2	Fortification Sample, ME 13, Painter's Hat, 2nd Low Level
AEA09-FF-13-PH-L3	Fortification Sample, ME 13, Painter's Hat, 3rd Low Level
AEA09-FF-13-PH-H1	Fortification Sample, ME 13, Painter's Hat, 1st High Level
AEA09-FF-13-PH-H2	Fortification Sample, ME 13, Painter's Hat, 2nd High Level
AEA09-FF-13-PH-H3	Fortification Sample, ME 13, Painter's Hat, 3rd High Level
AEA09-FF-13-AR-C1	Fortification Sample, ME 13, Air Sampling Tube, 1st Control
AEA09-FF-13-AR-C2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Control
AEA09-FF-13-AR-L1	Fortification Sample, ME 13, Air Sampling Tube, 1st Low Level
AEA09-FF-13-AR-L2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Low Level
AEA09-FF-13-AR-L3	Fortification Sample, ME 13, Air Sampling Tube, 3rd Low Level
AEA09-FF-13-AR-H1	Fortification Sample, ME 13, Air Sampling Tube, 1st High Level
AEA09-FF-13-AR-H2	Fortification Sample, ME 13, Air Sampling Tube, 2nd High Level
AEA09-FF-13-AR-H3	Fortification Sample, ME 13, Air Sampling Tube, 3rd High Level
AEA09-FF-13-RES-C1	Fortification Sample, ME 13, RespiCon, 1st Control
AEA09-FF-13-RES-C2	Fortification Sample, ME 13, RespiCon, 2nd Control
AEA09-FF-13-RES-L1	Fortification Sample, ME 13, RespiCon, 1st Low Level
AEA09-FF-13-RES-L2	Fortification Sample, ME 13, RespiCon, 2nd Low Level
AEA09-FF-13-RES-L3	Fortification Sample, ME 13, RespiCon, 3rd Low Level
AEA09-FF-13-RES-H1	Fortification Sample, ME 13, RespiCon, 1st High Level
AEA09-FF-13-RES-H2	Fortification Sample, ME 13, RespiCon, 2nd High Level
AEA09-FF-13-RES-H3	Fortification Sample, ME 13, RespiCon, 3rd High Level
AEA09-FF-13-HW-C1	Fortification Sample, ME 13, Hand Wash, 1st Control
AEA09-FF-13-HW-C2	Fortification Sample, ME 13, Hand Wash, 2nd Control
AEA09-FF-13-HW-L1	Fortification Sample, ME 13, Hand Wash, 1st Low Level
AEA09-FF-13-HW-L2	Fortification Sample, ME 13, Hand Wash, 2nd Low Level
AEA09-FF-13-HW-L3	Fortification Sample, ME 13, Hand Wash, 3rd Low Level
AEA09-FF-13-HW-H1	Fortification Sample, ME 13, Hand Wash, 1st High Level
AEA09-FF-13-HW-H2	Fortification Sample, ME 13, Hand Wash, 2nd High Level
AEA09-FF-13-HW-H3	Fortification Sample, ME 13, Hand Wash, 3rd High Level
AEA09-FF-13-FW-C1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Control
AEA09-FF-13-FW-C2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Control
AEA09-FF-13-FW-L1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Low Level
AEA09-FF-13-FW-L2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Low Level
AEA09-FF-13-FW-L3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-13-FW-H1	Fortification Sample, ME 13, Face and Neck Wipe, 1st High Level
AEA09-FF-13-FW-H2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd High Level
AEA09-FF-13-FW-H3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd High Level
AEA09-FF-13-ID-C1	Fortification Sample, ME 13, Inner Dosimeter, 1st Control
AEA09-FF-13-ID-C2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Control
AEA09-FF-13-ID-L1	Fortification Sample, ME 13, Inner Dosimeter, 1st Low Level
AEA09-FF-13-ID-L2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Low Level
AEA09-FF-13-ID-L3	Fortification Sample, ME 13, Inner Dosimeter, 3rd Low Level
AEA09-FF-13-ID-H1	Fortification Sample, ME 13, Inner Dosimeter, 1st High Level
AEA09-FF-13-ID-H2	Fortification Sample, ME 13, Inner Dosimeter, 2nd High Level
AEA09-FF-13-ID-H3	Fortification Sample, ME 13, Inner Dosimeter, 3rd High Level
AEA09-FF-13-OD-C1	Fortification Sample, ME 13, Outer Dosimeter, 1st Control
AEA09-FF-13-OD-C2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Control
AEA09-FF-13-OD-L1	Fortification Sample, ME 13, Outer Dosimeter, 1st Low Level
AEA09-FF-13-OD-L2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Low Level
AEA09-FF-13-OD-L3	Fortification Sample, ME 13, Outer Dosimeter, 3rd Low Level
AEA09-FF-13-OD-H1	Fortification Sample, ME 13, Outer Dosimeter, 1st High Level
AEA09-FF-13-OD-H2	Fortification Sample, ME 13, Outer Dosimeter, 2nd High Level
AEA09-FF-13-OD-H3	Fortification Sample, ME 13, Outer Dosimeter, 3rd High Level
AEA09-FF-14-PH-C1	Fortification Sample, ME 14, Painter's Hat, 1st Control
AEA09-FF-14-PH-C2	Fortification Sample, ME 14, Painter's Hat, 2nd Control
AEA09-FF-14-PH-L1	Fortification Sample, ME 14, Painter's Hat, 1st Low Level
AEA09-FF-14-PH-L2	Fortification Sample, ME 14, Painter's Hat, 2nd Low Level
AEA09-FF-14-PH-L3	Fortification Sample, ME 14, Painter's Hat, 3rd Low Level
AEA09-FF-14-PH-H1	Fortification Sample, ME 14, Painter's Hat, 1st High Level
AEA09-FF-14-PH-H2	Fortification Sample, ME 14, Painter's Hat, 2nd High Level
AEA09-FF-14-PH-H3	Fortification Sample, ME 14, Painter's Hat, 3rd High Level
AEA09-FF-14-AR-C1	Fortification Sample, ME 14, Air Sampling Tube, 1st Control
AEA09-FF-14-AR-C2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Control
AEA09-FF-14-AR-L1	Fortification Sample, ME 14, Air Sampling Tube, 1st Low Level
AEA09-FF-14-AR-L2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Low Level
AEA09-FF-14-AR-L3	Fortification Sample, ME 14, Air Sampling Tube, 3rd Low Level
AEA09-FF-14-AR-H1	Fortification Sample, ME 14, Air Sampling Tube, 1st High Level
AEA09-FF-14-AR-H2	Fortification Sample, ME 14, Air Sampling Tube, 2nd High Level
AEA09-FF-14-AR-H3	Fortification Sample, ME 14, Air Sampling Tube, 3rd High Level
AEA09-FF-14-RES-C1	Fortification Sample, ME 14, RespiCon, 1st Control
AEA09-FF-14-RES-C2	Fortification Sample, ME 14, RespiCon, 2nd Control
AEA09-FF-14-RES-L1	Fortification Sample, ME 14, RespiCon, 1st Low Level
AEA09-FF-14-RES-L2	Fortification Sample, ME 14, RespiCon, 2nd Low Level
AEA09-FF-14-RES-L3	Fortification Sample, ME 14, RespiCon, 3rd Low Level
AEA09-FF-14-RES-H1	Fortification Sample, ME 14, RespiCon, 1st High Level
AEA09-FF-14-RES-H2	Fortification Sample, ME 14, RespiCon, 2nd High Level
AEA09-FF-14-RES-H3	Fortification Sample, ME 14, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-14-HW-C1	Fortification Sample, ME 14, Hand Wash, 1st Control
AEA09-FF-14-HW-C2	Fortification Sample, ME 14, Hand Wash, 2nd Control
AEA09-FF-14-HW-L1	Fortification Sample, ME 14, Hand Wash, 1st Low Level
AEA09-FF-14-HW-L2	Fortification Sample, ME 14, Hand Wash, 2nd Low Level
AEA09-FF-14-HW-L3	Fortification Sample, ME 14, Hand Wash, 3rd Low Level
AEA09-FF-14-HW-H1	Fortification Sample, ME 14, Hand Wash, 1st High Level
AEA09-FF-14-HW-H2	Fortification Sample, ME 14, Hand Wash, 2nd High Level
AEA09-FF-14-HW-H3	Fortification Sample, ME 14, Hand Wash, 3rd High Level
AEA09-FF-14-FW-C1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Control
AEA09-FF-14-FW-C2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Control
AEA09-FF-14-FW-L1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Low Level
AEA09-FF-14-FW-L2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Low Level
AEA09-FF-14-FW-L3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd Low Level
AEA09-FF-14-FW-H1	Fortification Sample, ME 14, Face and Neck Wipe, 1st High Level
AEA09-FF-14-FW-H2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd High Level
AEA09-FF-14-FW-H3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd High Level
AEA09-FF-14-ID-C1	Fortification Sample, ME 14, Inner Dosimeter, 1st Control
AEA09-FF-14-ID-C2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Control
AEA09-FF-14-ID-L1	Fortification Sample, ME 14, Inner Dosimeter, 1st Low Level
AEA09-FF-14-ID-L2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Low Level
AEA09-FF-14-ID-L3	Fortification Sample, ME 14, Inner Dosimeter, 3rd Low Level
AEA09-FF-14-ID-H1	Fortification Sample, ME 14, Inner Dosimeter, 1st High Level
AEA09-FF-14-ID-H2	Fortification Sample, ME 14, Inner Dosimeter, 2nd High Level
AEA09-FF-14-ID-H3	Fortification Sample, ME 14, Inner Dosimeter, 3rd High Level
AEA09-FF-14-OD-C1	Fortification Sample, ME 14, Outer Dosimeter, 1st Control
AEA09-FF-14-OD-C2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Control
AEA09-FF-14-OD-L1	Fortification Sample, ME 14, Outer Dosimeter, 1st Low Level
AEA09-FF-14-OD-L2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Low Level
AEA09-FF-14-OD-L3	Fortification Sample, ME 14, Outer Dosimeter, 3rd Low Level
AEA09-FF-14-OD-H1	Fortification Sample, ME 14, Outer Dosimeter, 1st High Level
AEA09-FF-14-OD-H2	Fortification Sample, ME 14, Outer Dosimeter, 2nd High Level
AEA09-FF-14-OD-H3	Fortification Sample, ME 14, Outer Dosimeter, 3rd High Level
AEA09-FF-15-PH-C1	Fortification Sample, ME 15, Painter's Hat, 1st Control
AEA09-FF-15-PH-C2	Fortification Sample, ME 15, Painter's Hat, 2nd Control
AEA09-FF-15-PH-L1	Fortification Sample, ME 15, Painter's Hat, 1st Low Level
AEA09-FF-15-PH-L2	Fortification Sample, ME 15, Painter's Hat, 2nd Low Level
AEA09-FF-15-PH-L3	Fortification Sample, ME 15, Painter's Hat, 3rd Low Level
AEA09-FF-15-PH-H1	Fortification Sample, ME 15, Painter's Hat, 1st High Level
AEA09-FF-15-PH-H2	Fortification Sample, ME 15, Painter's Hat, 2nd High Level
AEA09-FF-15-PH-H3	Fortification Sample, ME 15, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-AR-C1	Fortification Sample, ME 15, Air Sampling Tube, 1st Control
AEA09-FF-15-AR-C2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Control
AEA09-FF-15-AR-L1	Fortification Sample, ME 15, Air Sampling Tube, 1st Low Level
AEA09-FF-15-AR-L2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Low Level
AEA09-FF-15-AR-L3	Fortification Sample, ME 15, Air Sampling Tube, 3rd Low Level
AEA09-FF-15-AR-H1	Fortification Sample, ME 15, Air Sampling Tube, 1st High Level
AEA09-FF-15-AR-H2	Fortification Sample, ME 15, Air Sampling Tube, 2nd High Level
AEA09-FF-15-AR-H3	Fortification Sample, ME 15, Air Sampling Tube, 3rd High Level
AEA09-FF-15-RES-C1	Fortification Sample, ME 15, RespiCon, 1st Control
AEA09-FF-15-RES-C2	Fortification Sample, ME 15, RespiCon, 2nd Control
AEA09-FF-15-RES-L1	Fortification Sample, ME 15, RespiCon, 1st Low Level
AEA09-FF-15-RES-L2	Fortification Sample, ME 15, RespiCon, 2nd Low Level
AEA09-FF-15-RES-L3	Fortification Sample, ME 15, RespiCon, 3rd Low Level
AEA09-FF-15-RES-H1	Fortification Sample, ME 15, RespiCon, 1st High Level
AEA09-FF-15-RES-H2	Fortification Sample, ME 15, RespiCon, 2nd High Level
AEA09-FF-15-RES-H3	Fortification Sample, ME 15, RespiCon, 3rd High Level
AEA09-FF-15-HW-C1	Fortification Sample, ME 15, Hand Wash, 1st Control
AEA09-FF-15-HW-C2	Fortification Sample, ME 15, Hand Wash, 2nd Control
AEA09-FF-15-HW-L1	Fortification Sample, ME 15, Hand Wash, 1st Low Level
AEA09-FF-15-HW-L2	Fortification Sample, ME 15, Hand Wash, 2nd Low Level
AEA09-FF-15-HW-L3	Fortification Sample, ME 15, Hand Wash, 3rd Low Level
AEA09-FF-15-HW-H1	Fortification Sample, ME 15, Hand Wash, 1st High Level
AEA09-FF-15-HW-H2	Fortification Sample, ME 15, Hand Wash, 2nd High Level
AEA09-FF-15-HW-H3	Fortification Sample, ME 15, Hand Wash, 3rd High Level
AEA09-FF-15-FW-C1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Control
AEA09-FF-15-FW-C2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Control
AEA09-FF-15-FW-L1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Low Level
AEA09-FF-15-FW-L2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Low Level
AEA09-FF-15-FW-L3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd Low Level
AEA09-FF-15-FW-H1	Fortification Sample, ME 15, Face and Neck Wipe, 1st High Level
AEA09-FF-15-FW-H2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd High Level
AEA09-FF-15-FW-H3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd High Level
AEA09-FF-15-ID-C1	Fortification Sample, ME 15, Inner Dosimeter, 1st Control
AEA09-FF-15-ID-C2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Control
AEA09-FF-15-ID-L1	Fortification Sample, ME 15, Inner Dosimeter, 1st Low Level
AEA09-FF-15-ID-L2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Low Level
AEA09-FF-15-ID-L3	Fortification Sample, ME 15, Inner Dosimeter, 3rd Low Level
AEA09-FF-15-ID-H1	Fortification Sample, ME 15, Inner Dosimeter, 1st High Level
AEA09-FF-15-ID-H2	Fortification Sample, ME 15, Inner Dosimeter, 2nd High Level
AEA09-FF-15-ID-H3	Fortification Sample, ME 15, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-OD-C1	Fortification Sample, ME 15, Outer Dosimeter, 1st Control
AEA09-FF-15-OD-C2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Control
AEA09-FF-15-OD-L1	Fortification Sample, ME 15, Outer Dosimeter, 1st Low Level
AEA09-FF-15-OD-L2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Low Level
AEA09-FF-15-OD-L3	Fortification Sample, ME 15, Outer Dosimeter, 3rd Low Level
AEA09-FF-15-OD-H1	Fortification Sample, ME 15, Outer Dosimeter, 1st High Level
AEA09-FF-15-OD-H2	Fortification Sample, ME 15, Outer Dosimeter, 2nd High Level
AEA09-FF-15-OD-H3	Fortification Sample, ME 15, Outer Dosimeter, 3rd High Level
AEA09-FF-16-PH-C1	Fortification Sample, ME 16, Painter's Hat, 1st Control
AEA09-FF-16-PH-C2	Fortification Sample, ME 16, Painter's Hat, 2nd Control
AEA09-FF-16-PH-L1	Fortification Sample, ME 16, Painter's Hat, 1st Low Level
AEA09-FF-16-PH-L2	Fortification Sample, ME 16, Painter's Hat, 2nd Low Level
AEA09-FF-16-PH-L3	Fortification Sample, ME 16, Painter's Hat, 3rd Low Level
AEA09-FF-16-PH-H1	Fortification Sample, ME 16, Painter's Hat, 1st High Level
AEA09-FF-16-PH-H2	Fortification Sample, ME 16, Painter's Hat, 2nd High Level
AEA09-FF-16-PH-H3	Fortification Sample, ME 16, Painter's Hat, 3rd High Level
AEA09-FF-16-AR-C1	Fortification Sample, ME 16, Air Sampling Tube, 1st Control
AEA09-FF-16-AR-C2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Control
AEA09-FF-16-AR-L1	Fortification Sample, ME 16, Air Sampling Tube, 1st Low Level
AEA09-FF-16-AR-L2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Low Level
AEA09-FF-16-AR-L3	Fortification Sample, ME 16, Air Sampling Tube, 3rd Low Level
AEA09-FF-16-AR-H1	Fortification Sample, ME 16, Air Sampling Tube, 1st High Level
AEA09-FF-16-AR-H2	Fortification Sample, ME 16, Air Sampling Tube, 2nd High Level
AEA09-FF-16-AR-H3	Fortification Sample, ME 16, Air Sampling Tube, 3rd High Level
AEA09-FF-16-RES-C1	Fortification Sample, ME 16, RespiCon, 1st Control
AEA09-FF-16-RES-C2	Fortification Sample, ME 16, RespiCon, 2nd Control
AEA09-FF-16-RES-L1	Fortification Sample, ME 16, RespiCon, 1st Low Level
AEA09-FF-16-RES-L2	Fortification Sample, ME 16, RespiCon, 2nd Low Level
AEA09-FF-16-RES-L3	Fortification Sample, ME 16, RespiCon, 3rd Low Level
AEA09-FF-16-RES-H1	Fortification Sample, ME 16, RespiCon, 1st High Level
AEA09-FF-16-RES-H2	Fortification Sample, ME 16, RespiCon, 2nd High Level
AEA09-FF-16-RES-H3	Fortification Sample, ME 16, RespiCon, 3rd High Level
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-HW-C2	Fortification Sample, ME 16, Hand Wash, 2nd Control
AEA09-FF-16-HW-L1	Fortification Sample, ME 16, Hand Wash, 1st Low Level
AEA09-FF-16-HW-L2	Fortification Sample, ME 16, Hand Wash, 2nd Low Level
AEA09-FF-16-HW-L3	Fortification Sample, ME 16, Hand Wash, 3rd Low Level
AEA09-FF-16-HW-H1	Fortification Sample, ME 16, Hand Wash, 1st High Level
AEA09-FF-16-HW-H2	Fortification Sample, ME 16, Hand Wash, 2nd High Level
AEA09-FF-16-HW-H3	Fortification Sample, ME 16, Hand Wash, 3rd High Level
AEA09-FF-16-FW-C1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Control
AEA09-FF-16-FW-C2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Control
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-FW-L1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Low Level
AEA09-FF-16-FW-L2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Low Level

Sample ID Number	Description
AEA09-FF-16-FW-L3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd Low Level
AEA09-FF-16-FW-H1	Fortification Sample, ME 16, Face and Neck Wipe, 1st High Level
AEA09-FF-16-FW-H2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd High Level
AEA09-FF-16-FW-H3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd High Level
AEA09-FF-16-ID-C1	Fortification Sample, ME 16, Inner Dosimeter, 1st Control
AEA09-FF-16-ID-C2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Control
AEA09-FF-16-ID-L1	Fortification Sample, ME 16, Inner Dosimeter, 1st Low Level
AEA09-FF-16-ID-L2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Low Level
AEA09-FF-16-ID-L3	Fortification Sample, ME 16, Inner Dosimeter, 3rd Low Level
AEA09-FF-16-ID-H1	Fortification Sample, ME 16, Inner Dosimeter, 1st High Level
AEA09-FF-16-ID-H2	Fortification Sample, ME 16, Inner Dosimeter, 2nd High Level
AEA09-FF-16-ID-H3	Fortification Sample, ME 16, Inner Dosimeter, 3rd High Level
AEA09-FF-16-OD-C1	Fortification Sample, ME 16, Outer Dosimeter, 1st Control
AEA09-FF-16-OD-C2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Control
AEA09-FF-16-OD-L1	Fortification Sample, ME 16, Outer Dosimeter, 1st Low Level
AEA09-FF-16-OD-L2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Low Level
AEA09-FF-16-OD-L3	Fortification Sample, ME 16, Outer Dosimeter, 3rd Low Level
AEA09-FF-16-OD-H1	Fortification Sample, ME 16, Outer Dosimeter, 1st High Level
AEA09-FF-16-OD-H2	Fortification Sample, ME 16, Outer Dosimeter, 2nd High Level
AEA09-FF-16-OD-H3	Fortification Sample, ME 16, Outer Dosimeter, 3rd High Level
AEA09-FF-17-PH-C1	Fortification Sample, ME 17, Painter's Hat, 1st Control
AEA09-FF-17-PH-C2	Fortification Sample, ME 17, Painter's Hat, 2nd Control
AEA09-FF-17-PH-L1	Fortification Sample, ME 17, Painter's Hat, 1st Low Level
AEA09-FF-17-PH-L2	Fortification Sample, ME 17, Painter's Hat, 2nd Low Level
AEA09-FF-17-PH-L3	Fortification Sample, ME 17, Painter's Hat, 3rd Low Level
AEA09-FF-17-PH-H1	Fortification Sample, ME 17, Painter's Hat, 1st High Level
AEA09-FF-17-PH-H2	Fortification Sample, ME 17, Painter's Hat, 2nd High Level
AEA09-FF-17-PH-H3	Fortification Sample, ME 17, Painter's Hat, 3rd High Level
AEA09-FF-17-AR-C1	Fortification Sample, ME 17, Air Sampling Tube, 1st Control
AEA09-FF-17-AR-C2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Control
AEA09-FF-17-AR-L1	Fortification Sample, ME 17, Air Sampling Tube, 1st Low Level
AEA09-FF-17-AR-L2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Low Level
AEA09-FF-17-AR-L3	Fortification Sample, ME 17, Air Sampling Tube, 3rd Low Level
AEA09-FF-17-AR-H1	Fortification Sample, ME 17, Air Sampling Tube, 1st High Level
AEA09-FF-17-AR-H2	Fortification Sample, ME 17, Air Sampling Tube, 2nd High Level
AEA09-FF-17-AR-H3	Fortification Sample, ME 17, Air Sampling Tube, 3rd High Level
AEA09-FF-17-RES-C1	Fortification Sample, ME 17, RespiCon, 1st Control
AEA09-FF-17-RES-C2	Fortification Sample, ME 17, RespiCon, 2nd Control
AEA09-FF-17-RES-L1	Fortification Sample, ME 17, RespiCon, 1st Low Level
AEA09-FF-17-RES-L2	Fortification Sample, ME 17, RespiCon, 2nd Low Level
AEA09-FF-17-RES-L3	Fortification Sample, ME 17, RespiCon, 3rd Low Level

Sample ID Number	Description
AEA09-FF-17-RES-H1	Fortification Sample, ME 17, RespiCon, 1st High Level
AEA09-FF-17-RES-H2	Fortification Sample, ME 17, RespiCon, 2nd High Level
AEA09-FF-17-RES-H3	Fortification Sample, ME 17, RespiCon, 3rd High Level
AEA09-FF-17-HW-C1	Fortification Sample, ME 17, Hand Wash, 1st Control
AEA09-FF-17-HW-C2	Fortification Sample, ME 17, Hand Wash, 2nd Control
AEA09-FF-17-HW-L1	Fortification Sample, ME 17, Hand Wash, 1st Low Level
AEA09-FF-17-HW-L2	Fortification Sample, ME 17, Hand Wash, 2nd Low Level
AEA09-FF-17-HW-L3	Fortification Sample, ME 17, Hand Wash, 3rd Low Level
AEA09-FF-17-HW-H1	Fortification Sample, ME 17, Hand Wash, 1st High Level
AEA09-FF-17-HW-H2	Fortification Sample, ME 17, Hand Wash, 2nd High Level
AEA09-FF-17-HW-H3	Fortification Sample, ME 17, Hand Wash, 3rd High Level
AEA09-FF-17-FW-C1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Control
AEA09-FF-17-FW-C2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Control
AEA09-FF-17-FW-L1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Low Level
AEA09-FF-17-FW-L2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Low Level
AEA09-FF-17-FW-L3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd Low Level
AEA09-FF-17-FW-H1	Fortification Sample, ME 17, Face and Neck Wipe, 1st High Level
AEA09-FF-17-FW-H2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd High Level
AEA09-FF-17-FW-H3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd High Level
AEA09-FF-17-ID-C1	Fortification Sample, ME 17, Inner Dosimeter, 1st Control
AEA09-FF-17-ID-C2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Control
AEA09-FF-17-ID-L1	Fortification Sample, ME 17, Inner Dosimeter, 1st Low Level
AEA09-FF-17-ID-L2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Low Level
AEA09-FF-17-ID-L3	Fortification Sample, ME 17, Inner Dosimeter, 3rd Low Level
AEA09-FF-17-ID-H1	Fortification Sample, ME 17, Inner Dosimeter, 1st High Level
AEA09-FF-17-ID-H2	Fortification Sample, ME 17, Inner Dosimeter, 2nd High Level
AEA09-FF-17-ID-H3	Fortification Sample, ME 17, Inner Dosimeter, 3rd High Level
AEA09-FF-17-OD-C1	Fortification Sample, ME 17, Outer Dosimeter, 1st Control
AEA09-FF-17-OD-C2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Control
AEA09-FF-17-OD-L1	Fortification Sample, ME 17, Outer Dosimeter, 1st Low Level
AEA09-FF-17-OD-L2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Low Level
AEA09-FF-17-OD-L3	Fortification Sample, ME 17, Outer Dosimeter, 3rd Low Level
AEA09-FF-17-OD-H1	Fortification Sample, ME 17, Outer Dosimeter, 1st High Level
AEA09-FF-17-OD-H2	Fortification Sample, ME 17, Outer Dosimeter, 2nd High Level
AEA09-FF-17-OD-H3	Fortification Sample, ME 17, Outer Dosimeter, 3rd High Level
AEA09-FF-18-PH-C1	Fortification Sample, ME 18, Painter's Hat, 1st Control
AEA09-FF-18-PH-C2	Fortification Sample, ME 18, Painter's Hat, 2nd Control
AEA09-FF-18-PH-L1	Fortification Sample, ME 18, Painter's Hat, 1st Low Level
AEA09-FF-18-PH-L2	Fortification Sample, ME 18, Painter's Hat, 2nd Low Level
AEA09-FF-18-PH-L3	Fortification Sample, ME 18, Painter's Hat, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-PH-H1	Fortification Sample, ME 18, Painter's Hat, 1st High Level
AEA09-FF-18-PH-H2	Fortification Sample, ME 18, Painter's Hat, 2nd High Level
AEA09-FF-18-PH-H3	Fortification Sample, ME 18, Painter's Hat, 3rd High Level
AEA09-FF-18-AR-C1	Fortification Sample, ME 18, Air Sampling Tube, 1st Control
AEA09-FF-18-AR-C2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Control
AEA09-FF-18-AR-L1	Fortification Sample, ME 18, Air Sampling Tube, 1st Low Level
AEA09-FF-18-AR-L2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Low Level
AEA09-FF-18-AR-L3	Fortification Sample, ME 18, Air Sampling Tube, 3rd Low Level
AEA09-FF-18-AR-H1	Fortification Sample, ME 18, Air Sampling Tube, 1st High Level
AEA09-FF-18-AR-H2	Fortification Sample, ME 18, Air Sampling Tube, 2nd High Level
AEA09-FF-18-AR-H3	Fortification Sample, ME 18, Air Sampling Tube, 3rd High Level
AEA09-FF-18-RES-C1	Fortification Sample, ME 18, RespiCon, 1st Control
AEA09-FF-18-RES-C2	Fortification Sample, ME 18, RespiCon, 2nd Control
AEA09-FF-18-RES-L1	Fortification Sample, ME 18, RespiCon, 1st Low Level
AEA09-FF-18-RES-L2	Fortification Sample, ME 18, RespiCon, 2nd Low Level
AEA09-FF-18-RES-L3	Fortification Sample, ME 18, RespiCon, 3rd Low Level
AEA09-FF-18-RES-H1	Fortification Sample, ME 18, RespiCon, 1st High Level
AEA09-FF-18-RES-H2	Fortification Sample, ME 18, RespiCon, 2nd High Level
AEA09-FF-18-RES-H3	Fortification Sample, ME 18, RespiCon, 3rd High Level
AEA09-FF-18-HW-C1	Fortification Sample, ME 18, Hand Wash, 1st Control
AEA09-FF-18-HW-C2	Fortification Sample, ME 18, Hand Wash, 2nd Control
AEA09-FF-18-HW-L1	Fortification Sample, ME 18, Hand Wash, 1st Low Level
AEA09-FF-18-HW-L2	Fortification Sample, ME 18, Hand Wash, 2nd Low Level
AEA09-FF-18-HW-L3	Fortification Sample, ME 18, Hand Wash, 3rd Low Level
AEA09-FF-18-HW-H1	Fortification Sample, ME 18, Hand Wash, 1st High Level
AEA09-FF-18-HW-H2	Fortification Sample, ME 18, Hand Wash, 2nd High Level
AEA09-FF-18-HW-H3	Fortification Sample, ME 18, Hand Wash, 3rd High Level
AEA09-FF-18-FW-C1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Control
AEA09-FF-18-FW-C2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Control
AEA09-FF-18-FW-L1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Low Level
AEA09-FF-18-FW-L2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Low Level
AEA09-FF-18-FW-L3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd Low Level
AEA09-FF-18-FW-H1	Fortification Sample, ME 18, Face and Neck Wipe, 1st High Level
AEA09-FF-18-FW-H2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd High Level
AEA09-FF-18-FW-H3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd High Level
AEA09-FF-18-ID-C1	Fortification Sample, ME 18, Inner Dosimeter, 1st Control
AEA09-FF-18-ID-C2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Control
AEA09-FF-18-ID-L1	Fortification Sample, ME 18, Inner Dosimeter, 1st Low Level
AEA09-FF-18-ID-L2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Low Level
AEA09-FF-18-ID-L3	Fortification Sample, ME 18, Inner Dosimeter, 3rd Low Level

Sample ID Number	**Description**
AEA09-FF-18-ID-H1	Fortification Sample, ME 18, Inner Dosimeter, 1st High Level
AEA09-FF-18-ID-H2	Fortification Sample, ME 18, Inner Dosimeter, 2nd High Level
AEA09-FF-18-ID-H3	Fortification Sample, ME 18, Inner Dosimeter, 3rd High Level
AEA09-FF-18-OD-C1	Fortification Sample, ME 18, Outer Dosimeter, 1st Control
AEA09-FF-18-OD-C2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Control
AEA09-FF-18-OD-L1	Fortification Sample, ME 18, Outer Dosimeter, 1st Low Level
AEA09-FF-18-OD-L2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Low Level
AEA09-FF-18-OD-L3	Fortification Sample, ME 18, Outer Dosimeter, 3rd Low Level
AEA09-FF-18-OD-H1	Fortification Sample, ME 18, Outer Dosimeter, 1st High Level
AEA09-FF-18-OD-H2	Fortification Sample, ME 18, Outer Dosimeter, 2nd High Level
AEA09-FF-18-OD-H3	Fortification Sample, ME 18, Outer Dosimeter, 3rd High Level

PROTOCOL AMENDMENT NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: April 26, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section B. Analytical Method (Protocol page 41), the fourth paragraph reads:

   "GPL Analytical Method GPL-MTH-079…"

   will now read:

   "GPL Analytical Method GPL-MTH-081…"

2. In Section B. Analytical Method (Protocol page 41), the sixth paragraph reads:

   "All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile/ 50% water, to quantitate."

   will now read:

   "All subject samples, except hand wipes/washes and air sampling tubes, will be extracted using methanol/water/formic acid (70:30:0.016, v/v/v) [MWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Air sampling tubes will be extracted using acetonitrile/water/formic acid (70:30:0.016, v/v/v) [AWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using MWF, to quantitate."

3. In Section 10. Monitoring Event Procedures (Protocol page 29), the additional information is added for pre-washing of outer dosimeters (due to potential background BIT residues in the matrix):

   "All outer dosimeter pants and shirts will be pre-washed to remove potential background BIT residues before use. Outer dosimeters will be washed in a commercial or residential washing machine on a cold wash cycle with no detergent

added. Pants and shirts are hung to dry, folded into new large plastic bags labeled with the date of the pre-washing, then considered ready for use."

Justification:

The above changes:

1. Correct a typo
2. Clarifies the analytical method summary.
3. Adds information on how to pre-wash cotton outer dosimeters.

Effect on the Study:

No adverse impact on the study.

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR: Robert J. Testman 05/02/16

Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE: Hasmukh Shah 4/29/16

Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL AMENDMENT NO.: 2
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: June 10, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section 11.B. Transportation (Protocol page 39), the paragraph reads:

   "Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain of-custody record will be available for each sample." will now read:

   "Samples will be transported from the exposure site to the analytical laboratory by study personnel shortly after collection. A chain of-custody record will be available for each sample."

Justification:

Since the exposure site is in very close proximity to the analytical laboratory the samples can be placed directly into the analytical laboratory freezer and dry ice transport is not necessary.

Effect on the Study:

No adverse impact on the study.

PREPARED BY:

FIELD COORDINATOR:

06/10/16
Megan T. Boatwright, B.S. Date
Golden Pacific Laboratories, LLC

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR:

06/10/16
Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE:

Hasmukh Shah 06/10/16
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL DEVIATION NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

List of Deviations, Dates, Reasons for Deviation, and Effect on Study

1. Date of Deviation: N/A

Description of Deviation: For the inner dosimeter (ID) garments worn by the subjects painting in ME01, ME02, ME04, ME06, ME07, ME10, ME12, ME13, ME16 and ME17, BIT background contamination was observed at higher levels than total residues found in outer dosimeters. Summary ID residues will be reported using an EPA reviewed penetration factor applied to outer dosimeter samples for these subjects (Section 12B).

Reason for Deviation: The analytically determined residues in ID samples for these subjects were higher than OD samples. A subsequent investigation demonstrated that some inner dosimeter lots were received contaminated with BIT from the manufacturer.

Effect on the Study: The eight subject inner dosimeters from non-contaminated lots will be used to calculate a penetration factor which will be applied to calculate summary statistics for the study. Estimates based on using a penetration factor will allow for representative data on dermal exposure.

2. Date of Deviation: May 5, 2016

Description of Deviation: The Protocol states: IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle (Section 9.A.ii). The advertisement was unable to be placed in the California Advocate.

Reason for Deviation: Staff at the California Advocate indicated that the advertisement would be placed in the next available issue, May 20, 2016. However, no copies of the paper could be found and phone calls to confirm placement were not returned.

Effect on the Study: No adverse impact on the study. Recruitment proceeded through the Fresno Bee and Vide en Valle newspapers which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled in the study.

3. Date of Deviation: June 8, 2016 – June 10, 2016

Description of Deviation: The additional BIT added to the test substance was dissolved in diethylene glycol instead of dipropylene glycol (Section 7A).

Reason for Deviation: Analytical coordinator oversight.

Effect on the Study: No adverse impact on the study. The solvent used is very similar chemically to that called for in the protocol. All paints were assayed in triplicate prior to use to ensure acceptable BIT concentration.

4. Date of Deviation: June 7, 2016 – April 27, 2017

Description of Deviation: The BIT internal standard was used after its September 21, 2015 retest date (Section 12Aii).

Reason for Deviation: The BIT internal standard was custom synthesized and was not retested prior to use.

Effect on the Study: No adverse impact on the study. The BIT internal standard is used consistently in both calibration standards and samples to normalize the peak area ratio of the reference substance. A currently retested internal standard substance is not required as exact purity has no effect on analytical results.

5. Date of Deviation: May 3, 2016 – June 14, 2016

Description of Deviation: The test substance containers were temporarily stored at ambient temperature at GPL with a data logger to monitor storage conditions until transfer to field contractor personnel. Upon downloading the data logger data, it was discovered that the device did not record any temperature data (Section 7A).

Reason for Deviation: Device malfunction.

Effect on the Study: No adverse impact on the study. Temperature min/max is recorded weekly at a nearby GPL room temperature location and the temperature range was 21 °C – 25 °C.

6. Date of Deviation: December 12, 2016 – April 26, 2017

Description of Deviation: Select inner dosimeter (8 sets), outer dosimeters (7 sets), painter's hats (6 sets), air sampling tube (1 set), and background wall wipe (1 set) samples were analyzed after being stored frozen for 6 months, later than the experimentally confirmed stability interval (Section 12C).

Reason for Deviation: Personnel oversight.

Effect on the Study: No adverse impact on the study. All samples, including those analyzed after the storage interval, were analyzed with field fortified samples which did not show low analyte recovery. This demonstrates that samples were stable after being stored frozen beyond 6-months.

7. **Date of Deviation: June 13, 2016 – July 1, 2016**

Description of Deviation: Study samples were generated in this study using ID suffixes not listed in Section 11A or Appendix I. These samples were generally background air sampling tubes, background wall wipes, and sweat wipes. (Section 11A).

Reason for Deviation: Example sample ID information for these matrices was inadvertently not included in the protocol when it was written.

Effect on the Study: No adverse impact on the study. The background wall wipes, air sampling tubes, and sweat wipes are all referenced in the protocol, however the ID suffixes designating sample identification was not listed in page 39 of the protocol or the study sample list.

PREPARED BY: _____ DATE: 10/27/17

STUDY DIRECTOR: _____ 10/27/17
Robert J. Testman, M.B.A Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESNTATIVE: _____ 10/27/17
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL DEVIATION NO.: 2
GPL Study # 120463
AEATF Study No.: AEA09

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

List of Deviations, Dates, Reasons for Deviation, and Effect on Study

Date of Deviation: April 26, 2016

Description of Deviation: The method reference in Section B. Analytical Method was 'GPL-MTH-081' when it should have been 'GPL-MTH-081, Revision 2'.

Additionally, in Section 20. References, the method reference was:

'Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079…'

The method reference should have been:

'GPL Analytical Method GPL-MTH-081, Revision 2…'

Reason for Deviation: The method reference in Section B. was amended, however the Revision 2 portion was inadvertently omitted. In Section 20, the reference was incorrect and not amended.

Effect on the Study: No negative effect on the study as the correct analytical method was used throughout the study.

STUDY DIRECTOR: 01/29/18
Robert J. Testman, M.B.A Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESNTATIVE: 01/29/18
Has Shah, Ph.D. Date
Sponsor Representative

APPENDIX B.

IRB APPROVED SCRIPT (ENGLISH)

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

APPENDIX C.

IRB APPROVED SCRIPT (SPANISH)

Guión de invitación a participar para el sujeto

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

Queremos determinar la cantidad de productos químicos que se encuentra en el aire que respira o que puede entrar en contacto con la piel cuando aplica productos de pintura con una brocha y un rodillo. Mediremos la cantidad de compuestos de pintura que quede en la ropa que vista y en las manos, cara y cuello. Además, mediremos la cantidad presente en el aire que respira en el momento que pinte habitaciones.

El producto de prueba será la PINTURA DE LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

Debe haber pintado con una brocha y un rodillo en los últimos cinco años, pero no haber trabajado como pintor profesional en los últimos diez años.

Su participación en el estudio durará alrededor de medio día. Le proporcionaremos una ropa especial que deberá usar durante la prueba. Le colocaremos una pequeña bomba de aire para tomar muestras del aire que respira. Luego, se le pedirá que pinte paredes, molduras y zócalos con los productos de prueba. Deberá usar una brocha y un rodillo para aplicar dos galones de pintura. Cuando termine, deberá cambiarse para volver a ponerse su ropa y devolver la ropa especial al equipo de investigación.

¿Le gustaría saber más sobre este proyecto?

(If no, thank them for their time.)

(If yes, instruct them as follows)

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del día del estudio. Para reunir los requisitos para participar, debe mostrar una identificación con foto para comprobar su edad. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni amamantando.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está ubicada en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con el investigador principal, Robert Testman. Si prefiere, podemos realizar la entrevista en español. La entrevista se programará para la fecha y hora que le resulte más conveniente, incluso durante un fin de semana. Le explicaremos el estudio en detalle, entre otras cosas, qué puede esperar y qué se espera de usted. Responderemos todas sus preguntas. La primera visita durará alrededor de una hora. Deberá traer un documento de identificación con foto emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

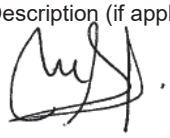
(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Phone Screen - MA1601861-0
Description (if applicable): Subject Invitation to Participate Script



_____ _MMB_ 3/14/2016 8:00 AM (PST)
MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX D.

IRB APPROVED ADVERTISMENT (ENGLISH)

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

APPENDIX E.

IRB APPROVED ADVERTISMENT (SPANISH)

SE BUSCAN PINTORES AFICIONADOS

Se buscan voluntarios que deseen participar en un estudio de investigación que evalúa la exposición a componentes de la pintura al pintar en el interior con una brocha y un rodillo. Los voluntarios recibirán una compensación de hasta $120 por las molestias de participar. No se aceptan pintores profesionales.

Comuníquese con Robert Testman (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091 para obtener más información.

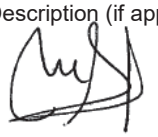
Estudio patrocinado por *Antimicrobial Exposure Assessment Task Force* (AEATF, Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos); administrado por *American Chemistry Council* (ACC, Consejo Estadounidense de Química) y dirigido por Golden Pacific Laboratories (GPL) de Fresno, CA. 559-275-9091

Versión: 04/11/2013

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Ad-Print - MA1601862-0
Description (if applicable): N/A



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX F.

IRB APPROVED INFORMED CONSENT FORMS (ENGLISH AND SPANISH)

INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection
To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

    When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____

Subject's Signature

_____

Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]

This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____

Spanish Speaking Researcher's Signature

_____

Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____

Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA09) Estudio para medir la potencial exposición dérmica y por inhalación durante la aplicación con brocha y rodillo de una pintura de látex que contiene un producto pesticida antimicrobiano en superficies interiores

Investigador principal: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Coordinadores de campo:

Megan T. Boatwright (inglés)
Coordinadora de campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Natan R. Chavez (inglés y español)
Asociado de investigaciones en el campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
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Thomas F. Moate, M.S. (inglés)
Asociado de investigaciones en el campo
Gerente general
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Instalaciones en el campo: (Lugar de la entrevista para el consentimiento informado del sujeto)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Lugar de los procedimientos del estudio)
Un edificio comercial vacante en Fresno County, CA

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono las 24 horas: 949-939-3585 (Robert Testman)

Le estamos pidiendo que considere participar en un estudio de investigación porque tiene experiencia pintando con brocha y rodillo. Su participación es voluntaria. Este formulario de consentimiento informado explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar y comentarlo con sus amigos o familia antes de decidir si desea participar en el estudio. Si tiene alguna pregunta o si no entiende algo de este formulario, pida a uno de nosotros que se lo expliquemos. Si prefiere hablar en español, por favor indíquelo así. Le podemos explicar el estudio en inglés o en español.

Schulman Institutional Review Board, Inc. (Schulman), un comité institucional de revisión, ha aprobado la información que contiene este documento de consentimiento y ha autorizado al médico del estudio para que efectúe el estudio. Un comité institucional de revisión (Institutional Review Board o IRB, por sus siglas en inglés) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado que usted participe en el estudio. Es a usted a quien corresponde examinar la información de este documento de consentimiento y, seguidamente, decidir si desea participar en el estudio.

Finalidad de este estudio

Golden Pacific Laboratories está llevando a cabo esta investigación. Nos gustaría saber cuánta sustancia química puede caer en su piel cuando aplica una pintura de látex para interiores con una brocha y un rodillo. Mediremos la cantidad de la sustancia química que le cae en la ropa que usa y en sus manos, cara y cuello. Le pediremos que pinte superficies interiores como paredes, cielorraso y molduras. También nos gustaría saber la cantidad de la sustancia química que se encuentra en el aire que usted respira durante el estudio. Esta información se proporcionará a la Agencia de Protección Ambiental de EE. UU. o EPA por sus siglas en inglés. La EPA usará esta información para evaluar los niveles de exposición a las sustancias químicas de la pintura de este estudio y de otras pinturas similares a ella.

Un grupo de compañías que fabrica productos para reducir la cantidad de microorganismos paga este estudio. Este grupo de compañías se llama Grupo Operativo de Evaluación de la Exposición a Agentes Antimicrobianos II (Antimicrobial Exposure Assessment Task Force II). La EPA ha registrado estos productos como pesticidas.

Robert Testman, Thomas Moate, Megan Boatwright y Natan Chavez trabajan en Golden Pacific Laboratories. Robert Testman está a cargo del estudio. Thomas Moate, Megan Boatwright y Natan Chavez también están capacitados para explicar el estudio y contestar cualquier pregunta que pudiera tener. Natan Chavez habla español. Él será el principal investigador de habla hispana.

Producto de prueba
El producto de prueba es una pintura de látex para interiores de Sherwin-Williams. Esta es una pintura de uso común. Este producto se usa para pintar paredes y molduras en casas y empresas. El producto de prueba contiene una sustancia química conocida como BIT que ayuda a evitar el crecimiento bacteriano. Hemos añadido una cantidad adicional de BIT a la pintura para este estudio, pero no más que la necesaria para evaluar su exposición a este producto. Se le entregará una copia de la etiqueta del producto. También le daremos la hoja de datos de seguridad del material, o "MSDS" por sus siglas en inglés, de este producto, si lo desea.

Selección de sujetos
Para participar en el estudio debe estar sano y tener 18 años de edad o más. Debe poder leer y hablar inglés o español. Necesitará comprobar su edad con un documento de identidad con fotografía expedido por el gobierno, como una licencia para conducir o un pasaporte. Debe tener experiencia pintando con brocha y rodillo, pero no ser pintor profesional. Debe querer participar en este estudio. Debe estar dispuesto a firmar este consentimiento, el formulario Declaración de derechos de los sujetos participantes en experimentos y una ficha de calificación. Le pediremos que proporcione cierta información personal adicional y que siga las instrucciones de los investigadores.

No podrá participar en esta investigación si es empleado o cónyuge de un empleado de Golden Pacific Laboratories, de cualquiera de las compañías que pagan esta investigación, del Consejo Americano de Química (American Chemistry Council) o de un fabricante de pinturas; si está embarazada o lactando; si ha tenido reacciones alérgicas al jabón, alcohol isopropílico, productos de pintura o productos químicos (incluido el BIT); si tiene psoriasis, eccema, llagas o cortaduras abiertas en la piel; si tiene problemas cardiacos o respiratorios; o si tiene otros problemas médicos que dificultaran su participación.

En este estudio participarán entre dieciocho y veinticuatro personas. Inscribiremos a unas pocas personas más que las que necesitamos en caso de que alguien no pueda participar el día de la prueba.

Haremos el estudio en un edificio vacante aquí en Fresno County. Puede participar en el estudio solamente una vez. Si en un día usted es el suplente y no se lo selecciona, es posible que pueda participar en el estudio otro día.

Inscripción en el estudio
Hoy se va a reunir con el investigador principal, Robert Testman, con los coordinadores de campo, Megan Boatwright o Thomas Moate; o si lo prefiere, con un investigador que habla español. Ellos le darán más información sobre lo que debe esperar durante el estudio y lo que se espera de usted. También contestarán cualquier pregunta que tenga sobre el estudio. Usted puede decidir hoy si desea participar en el estudio o puede llevarse a casa este formulario para conversarlo con su familia y amigos antes de tomar su decisión.

Le preguntaremos sobre su experiencia como pintor y sobre su salud general. Le preguntaremos su nombre y edad, y si tiene alguna afección en la piel de sus manos. Si decidimos que es apto, y si usted decide que quiere participar en el estudio, le pediremos que firme este consentimiento informado y el formulario Declaración de derechos de los sujetos participantes en experimentos. Luego le preguntaremos su estatura y peso y la talla de su ropa.

Si lo inscribimos en el estudio, le pediremos que venga al sitio del estudio cierto día y a cierta hora. Lo llamaremos un día antes para recordarle y asegurarnos de que aún desea participar en el estudio. También le pediremos que se asegure de tomar una ducha o darse un baño antes de ir al sitio del estudio.

Procedimiento del estudio

Si se lo selecciona, hará la prueba en cuartos pequeños construidos dentro de un edificio vacante ubicado en Fresno County. La prueba durará 3 o 4 horas en un día. Después de que llegue se pondrá ropa especial para la prueba y se le colocarán dos bombas pequeñas para tomar muestras del aire que respira. Luego le pediremos que pinte las paredes, los cielorrasos, los zócalos, la moldura de la ventana y la moldura de la puerta con una brocha y un rodillo de pintura. Le proporcionaremos todo el equipo que usará, como una brocha, un rodillo, una bandeja para el rodillo, trapos para pintura, etc. Usted pintará como lo hace normalmente cuando pinta una habitación en su propia casa. Se le pedirá que use aproximadamente dos galones de pintura en varios cuartos. Puede descansar entre cuartos si lo necesita. El tiempo real que pasará pintando puede ser de varias horas. Después recogeremos la ropa especial que usó, usted se pondrá su propia ropa, recibirá su pago y se irá.

Esto es exactamente lo que sucederá.

1. El día del estudio usted irá al sitio del estudio a la hora que se le dijo, y se reunirá con el equipo de estudio.

2. Robert Testman y el equipo de investigación revisarán con usted y con los otros participantes lo que sucederá, y usted tendrá otra oportunidad de hacer preguntas. Le recordaremos que en cualquier momento, antes o después de que comience el estudio, puede cambiar de parecer con respecto a su participación en el estudio. Todo lo que necesita hacer es decirnos que cambió de parecer. No sufrirá sanciones de ningún tipo si decide abandonar el estudio.

3. Dado que es importante que usted NO participe en este estudio si está embarazada, el día de la prueba cada voluntaria pasará a un área privada y recibirá un kit de prueba de embarazo como los que puede comprar en la farmacia. Una investigadora le explicará cómo usarlo y contestará sus preguntas. Después de hacerse la prueba le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no se le preguntará la razón y no se registrarán los resultados de la prueba. Se le pagarán $100 por venir al sitio de la prueba y entonces podrá irse. Si desea permanecer en el estudio, una investigadora capacitada verificará los resultados con usted. Nadie aparte de usted verá los resultados pero nosotros haremos una nota indicando que la prueba se hizo.

4. Antes de que comience la prueba se lavará las manos y la cara con jabón Ivory y agua, y se las secará con toallas de papel. Revisaremos sus manos para asegurarnos de que no tiene cortaduras, raspaduras ni ninguna afección que pudiera aumentar el riesgo de que sufra problemas en la piel durante la prueba.

5. Una persona de su mismo sexo lo llevará a un área limpia y privada para que se cambie y se prepare para el estudio. Le pediremos que se quite su ropa excepto la ropa interior. Luego se pondrá calzoncillos largos de algodón (*long johns*), una camiseta de algodón de mangas largas y pantalones largos de algodón. Nosotros le proporcionaremos toda esta ropa. Es posible que tengamos que recortar el reborde de las mangas o de las piernas de los calzoncillos largos para que no sobresalgan. Colocará su propia ropa y sus objetos de valor en un área de almacenamiento bajo llave, y usted conservará la llave. Usará su propio calzado, pero si quiere le daremos cubiertas para evitar que le caiga pintura en los zapatos.

6. Le daremos una gorra de pintor y gafas de seguridad para que las use mientras pinta. Debe usar estos artículos mientras pinta con la brocha o el rodillo.

7. Le instalaremos en el cinturón, alrededor de su cintura, dos pequeñas bombas para muestreo de aire. Si no lleva cinturón le proporcionaremos uno para que lo use. Le colocaremos un pequeño tubo en el cuello de la camisa y lo conectaremos en una de las bombas. Instalaremos un pequeño tomador de muestras de aire en la otra bomba y lo colocaremos frente a usted con una pequeña correa alrededor de su pecho. Ambas bombas tomarán muestras del aire que respira mientras pinta. Cada bomba es del tamaño aproximado de un radio portátil. El tubo es del tamaño de un lápiz, y el tomador de muestras de aire es aproximadamente del tamaño de una bola de tenis.

8. Le mostraremos el equipo que usará para pintar, incluido el pequeño cubo que contiene la pintura, la brocha, el rodillo, la bandeja para el rodillo, el mango de extensión y los trapos para pintura. También contaremos con ribeteadores de pintura y pequeños vasos de pintura por si desea usarlos. Le preguntaremos si tiene alguna pregunta.

9. Lo llevaremos a uno de los cuartos pequeños en donde comenzará a trabajar. Encenderemos las bombas de aire que le colocamos y le pediremos que se ponga la gorra y las gafas de seguridad. Le entregaremos una lata de pintura cerrada que contiene pintura. Quitará la tapa de la lata de pintura con un abridor. Usará una brocha con la lata de pintura para pintar las molduras de una o más paredes. Verterá algo de pintura de la lata en la bandeja para el rodillo y pintará con el rodillo el cielorraso y las paredes. Cuando se termine la pintura de la lata, le daremos una lata nueva hasta que haya usado la cantidad asignada. Uno de nosotros lo observará mientras trabaja, anotando el tiempo que trabaja y la cantidad de superficie que pinta. También podemos tomar fotografías o grabar videos para mostrar lo que sucedió en el estudio, pero en el informe final, tales fotografías no mostrarán rostros, tatuajes ni otras características identificadoras. **Si no desea que se le tomen fotografías, no debe participar en este estudio.**

10. Le pediremos que aplique aproximadamente dos galones de pintura. Trabajará en tantos cuartos como sea necesario para usar la cantidad asignada de pintura. Puede tomar un breve descanso en cualquier momento que desee, tal como lo haría en el trabajo. No podrá fumar ni comer durante la prueba, pero puede consumir una bebida fría durante su descanso. Si necesita usar el baño, uno de los investigadores le limpiará sus manos antes de que vaya, para recoger cualquier pintura que pueda tener en ellas.

11. Cuando termine de pintar, un investigador de su mismo sexo lo llevará al área donde se cambia la ropa y le tomará muestras:

    a. El investigador le quitará la gorra de pintor, las bombas tomadoras de muestras de aire y el equipo.

    b. El investigador frotará sus manos con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua, se las enjuagará con la misma solución y guardará la solución del enjuague.

    c. El investigador le limpiará la cara y el cuello con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua para recoger cualquier pintura que pudiera tener en la piel.

    d. El investigador lo ayudará a quitarse los zapatos (y los calcetines si lo desea).

    e. El investigador lo ayudará a quitarse la camiseta y los pantalones y los guardará para analizarlos.

    f. El investigador lo ayudará a quitarse los calzoncillos largos y los guardará para analizarlos.

Cuando hayamos tomado todas estas muestras, se vestirá otra vez con su propia ropa. Revisaremos sus manos antes de que se vaya para ver si las tiene enrojecidas o muestra otros signos de irritación. Le pagaremos $100 en efectivo y podrá irse.

Riesgos
Si participa el este estudio estaría expuesto a varias clases de riesgos:

1. El riesgo de una reacción a la pintura de látex o al ingrediente de pesticida (BIT) de la pintura. El contacto directo con la pintura puede causar enrojecimiento de los ojos, dolor e inflamación o irritación de la piel, de manera temporal, y la respiración del vapor puede causar tos e irritar su garganta. Usará gafas de seguridad para evitar que le caiga pintura en los ojos, y camiseta de manga larga y pantalones para evitar que le caiga pintura en la piel. También podría tener una reacción alérgica a la pintura. Pudiera sentirse mareado o tener dolor de cabeza. Si anteriormente ha tenido una reacción a un producto de pintura, asegúrese de decírnoslo. Si nota enrojecimiento o comezón, se siente mareado o piensa que le cayó pintura en los ojos, deje de pintar inmediatamente y dígaselo al investigador.

2. Riesgo de molestia Las bombas de aire instaladas en su cinturón y las mangueras de aire usadas para muestrear el aire que respira pueden causarle incomodidad. También pudiera resultarle incómodo usar dos capas de ropa.

3. Riesgo de lesiones Se le pedirá que use equipo para pintura y unas escaleras para pintar los cuartos. Si perdiera el equilibrio y cayera pudiera resultar herido. Si piensa que necesita ayuda para evitar lesionarse, o pudiera haberse lesionado, dígaselo a un miembro del equipo de investigación.

4. Riesgo de escozor causado por el lavado con alcohol y las toallitas El alcohol isopropílico diluido usado para frotar y enjuagar sus manos y limpiar su cara y cuello puede causarle escozor si tiene alguna cortadura o abrasiones en las manos o en la cara.

5. Riesgo de calor Como usará una capa adicional de ropa, pudiera tener demasiado calor. Supervisaremos la temperatura y la humedad durante la prueba, y detendremos el estudio si aumenta demasiado la temperatura para su seguridad. Si siente desvanecerse o demasiado calor, o está sudando mucho, deje de pintar inmediatamente y notifíquelo a un miembro del equipo de investigación.

6. Riesgo de sentir vergüenza Es posible que sienta vergüenza que un investigador esté presente mientras se cambia de ropa. Esto es necesario para asegurarnos de que la ropa le queda adecuadamente y que no se ensucie cuando termine la prueba. El investigador que lo ayudará será de su mismo sexo y será la única persona presente con usted. Usted usará su propia ropa interior en todo momento.

7. Si es mujer, le podría sorprender enterarse el día de la investigación que está embarazada. Solamente usted sabrá si los resultados de la prueba muestran que está embarazada, y no se registrarán estos resultados.

Riesgos desconocidos o imprevisibles
La participación en este estudio pudiera conllevar otros riesgos que desconocemos o que no podemos predecir. Si nos enteramos de algo nuevo que pudiera influenciar su decisión de participar, se lo notificaremos inmediatamente.

Lesiones relacionadas con la investigación
Si se lesiona o enferma mientras participa en el estudio, se le proporcionará atención en una instalación médica cercana. Si es necesario lo llevaremos ahí. AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no pague su propio seguro o el seguro de un tercero en el cual tenga cobertura. El investigador principal, en consulta con el profesional médico del sitio, decidirán si usted sufre una lesión o enfermedad que se debe a su participación en el estudio. Si dentro del período de 24 horas de su participación en el estudio experimenta una reacción en la piel u otro efecto adverso que usted cree que se relaciona con su participación en el estudio, debe buscar tratamiento médico y llamar al investigador principal, Robert Testman, a Golden Pacific Laboratories (559 275-9091) tan pronto como sea posible. Ningún expediente médico formará parte del estudio.

Al firmar este formulario no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio será porque usted quiere hacerlo. No recibirá un beneficio directo si decide participar y no sufrirá daños si decide no participar. Es su decisión.

Beneficios
Su participación en este estudio no le producirá beneficios directos. Lo que aprendamos de este estudio nos ayudará a asegurarnos de que los productos de pintura como la pintura de látex de Sherwin-Williams se puede usar con seguridad. Usted se pudiera beneficiar si pide sus resultados de este estudio, pues se puede enterar de cuánta pintura le cayó en el cuerpo en comparación con otros trabajadores que hicieron la misma tarea. Las personas que pagan el estudio también se beneficiarán del mismo, ya que ellos necesitan hacer este estudio para mantener en el mercado sus productos antibacterianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede formularlas en cualquier momento, antes durante o después del estudio. Simplemente hágalas a Robert Testman o a cualquier otro miembro del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico. Schulman IRB está a cargo de proteger sus derechos. Puede encontrar más información sobre sus derechos y el papel de los investigadores en el sitio web de Schulman IRB, www.sairb.com.

Costos y pagos
No le costará nada participar en este estudio. Al final de la entrevista para el consentimiento informado se le pagarán $20 en efectivo por su tiempo y las inconveniencias de venir a nuestra oficina. Si se lo selecciona para el estudio y va al sitio del estudio asignado, se le pagarán $100 en efectivo cuando termine el día, independientemente de si participa o no.

Confidencialidad
Le daremos un número de ID especial para este estudio y registraremos e informaremos todos los datos usando este número. Solo conservaremos un registro que relacione su nombre con este número de ID, y lo guardaremos separado de otros datos, en un gabinete bajo llave. No lo identificaremos por su nombre ni de ninguna otra manera en los informes del estudio. Ninguna fotografía suya que se use en un informe de este estudio mostrará su cara ni ninguna otra característica que lo identifique (como tatuajes).

Restringiremos el acceso a los expedientes de este estudio a solo unas pocas personas. Pero las personas que pagan el estudio, las agencias gubernamentales que revisarán los informes, y SAIRB, Inc., que vigila su seguridad, pueden revisar los expedientes del estudio. Debido a esto no podemos garantizar completamente la confidencialidad. Puede obtener una copia de sus propios expedientes con el investigador principal si la solicita.

Derecho a retirarse del estudio
Puede retirarse de este estudio en cualquier momento, por cualquier motivo. Simplemente notifíquelo a cualquier miembro del equipo de investigación. Si decide no participar en este estudio o retirarse del mismo, no se lo penalizará de ninguna manera ni perderá ningún beneficio.

Retiro del estudio
Robert Testman, el investigador principal a cargo de este estudio, puede retirarlo del estudio aunque usted desee permanecer en él. Lo pudiera retirar si, por ejemplo:

- Piensa que si usted permanece en el estudio correría riesgos.
- Usted no sigue las indicaciones de los investigadores.
- El estudio se detiene porque aumenta mucho la temperatura para continuar de forma segura, o por otra razón.

Si se lo retira del estudio o si se detiene todo el estudio, se le pagará de todas maneras por su tiempo e inconveniencias.

FORMULARIO DECLARACIÓN DE DERECHOS DE LOS SUJETOS PARTICIPANTES EN EXPERIMENTOS

Los siguientes son los derechos de cualquier persona a la que se pide que participe en un estudio de investigación. Como sujeto de un experimento, tengo los siguientes derechos:

1. Que se me diga el propósito del estudio.
2. Que se me diga lo que me sucederá y si cualquiera de los procedimientos, pesticidas o dispositivos es diferente del que se utilizaría en la práctica normal.
3. Que se me informe acerca de los riesgos, efectos secundarios o malestares frecuentes e/o importantes, o de las cosas que me sucederán durante el estudio.
4. Que se me informe si puedo esperar algún beneficio de mi participación y, de ser así, cuál podría ser el beneficio.
5. Que se me digan las alternativas a participar en el estudio.
6. Que se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el curso del estudio.
7. Que se me diga qué tipo de tratamiento médico está disponible en caso de que surjan complicaciones.
8. Rehusarme absolutamente a participar o cambiar de parecer acerca de mi participación después de que el estudio haya comenzado. Esta decisión no afectará mi estado con mi empleador.
9. Recibir una copia del formulario de consentimiento firmado y fechado; y
10. No ser presionado cuando esté considerando si deseo participar en el estudio;

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico.

Si tiene otras preguntas, debe formularlas al investigador principal o a los investigadores del estudio.

Contactos telefónicos:

Investigador principal: Robert Testman (559) 275-9091 o (949) 939-3585

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de Derechos de los Sujetos, y todas mis preguntas han sido contestadas en un idioma que entiendo bien. Acepto voluntariamente participar en este estudio como sujeto de investigación. Al firmar este formulario no renuncio a ninguno de mis derechos legales. Recibiré mi propia copia de este formulario con todas las firmas.

Fecha y hora: _____ _____
Firma del sujeto

_____
Nombre del sujeto (en letra de imprenta)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

SchulmanIRB

CERTIFICATION OF TRANSLATION

Protocol Number: AEA09
IRB Number: 201307318
PI: Robert J. Testman, M.B.A.
Material Type (if applicable): Informed Consent
Description (if applicable):
This is to certify that this Spanish translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Diane Barrett

Translated from English source document approved 03/04/2016

Diane Barrett 03/10/2016

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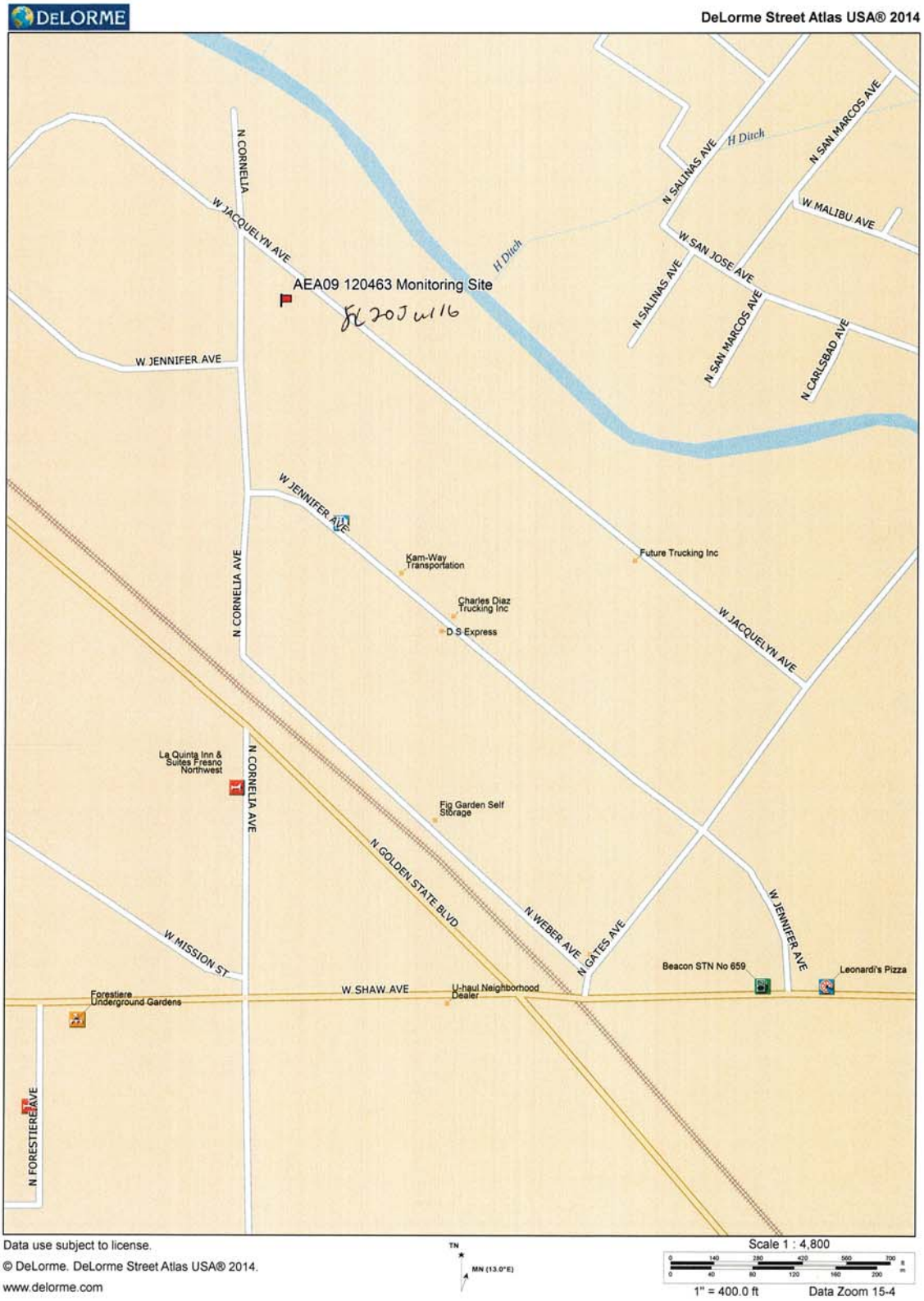
Schulman Associates, IRB, Inc. (ATA Member No. 252187)

APPENDIX G.

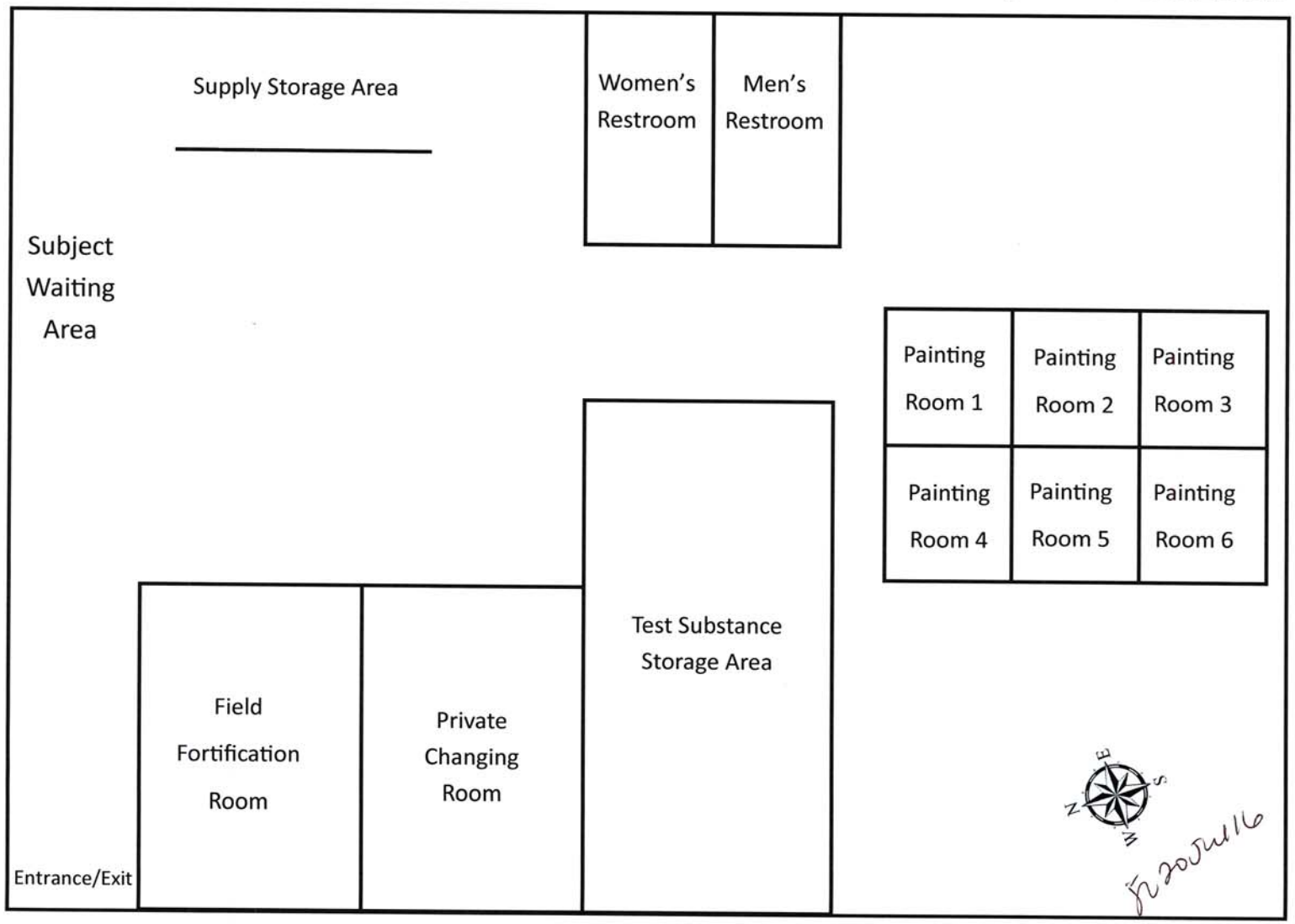
PICTURES AND MAPS OF THE TEST SITE LOCATION

DeLORME
DeLorme Street Atlas USA® 2014
Arnold Ranch
41
San Joaquin River
Sierra Sky Park
Pinedale
Herndon
99
AEA09 120463 Monitoring Site
Fr 20Jul16
Clovis
168
Fresno Yosemite Intl
180
W WHITESBRIDGE AVE
N MARKS AVE
Fresno Chandler Executive
VENTURA ST
E VENTURA AVE
E KINGS CANYON RD
Fresno
Calwa
Malaga
Turner Field
Data use subject to license.
© DeLorme. DeLorme Street Atlas USA® 2014.
www.delorme.com
TN
MN (13.0°E)
Scale 1 : 125,000
1" = 1.97 mi
Data Zoom 10-6


DeLorme
DeLorme Street Atlas USA® 2014
AEA09 120463 Monitoring Site
FL 20J w116
N CORNELIA
W JACQUELYN AVE
H Ditch
N SALINAS AVE
N SAN MARCOS AVE
W MALIBU AVE
W SAN JOSE AVE
N CARLSBAD AVE
W JENNIFER AVE
N CORNELIA AVE
Kam-Way Transportation
Future Trucking Inc
Charles Diaz Trucking Inc
D S Express
La Quinta Inn & Suites Fresno Northwest
Fig Garden Self Storage
N GOLDEN STATE BLVD
N WEBER AVE
N GATES AVE
W MISSION ST
W SHAW AVE
U-haul Neighborhood Dealer
Beacon STN No 659
Leonardi's Pizza
Forestiere Underground Gardens
N FORESTIERE AVE
Data use subject to license.
© DeLorme. DeLorme Street Atlas USA® 2014.
www.delorme.com
TN
MN (13.0°E)
Scale 1 : 4,800
1" = 400.0 ft
Data Zoom 15-4

Monitoring Site (overhead view)

AEATF Study # AEA09 GPL Study # 120463

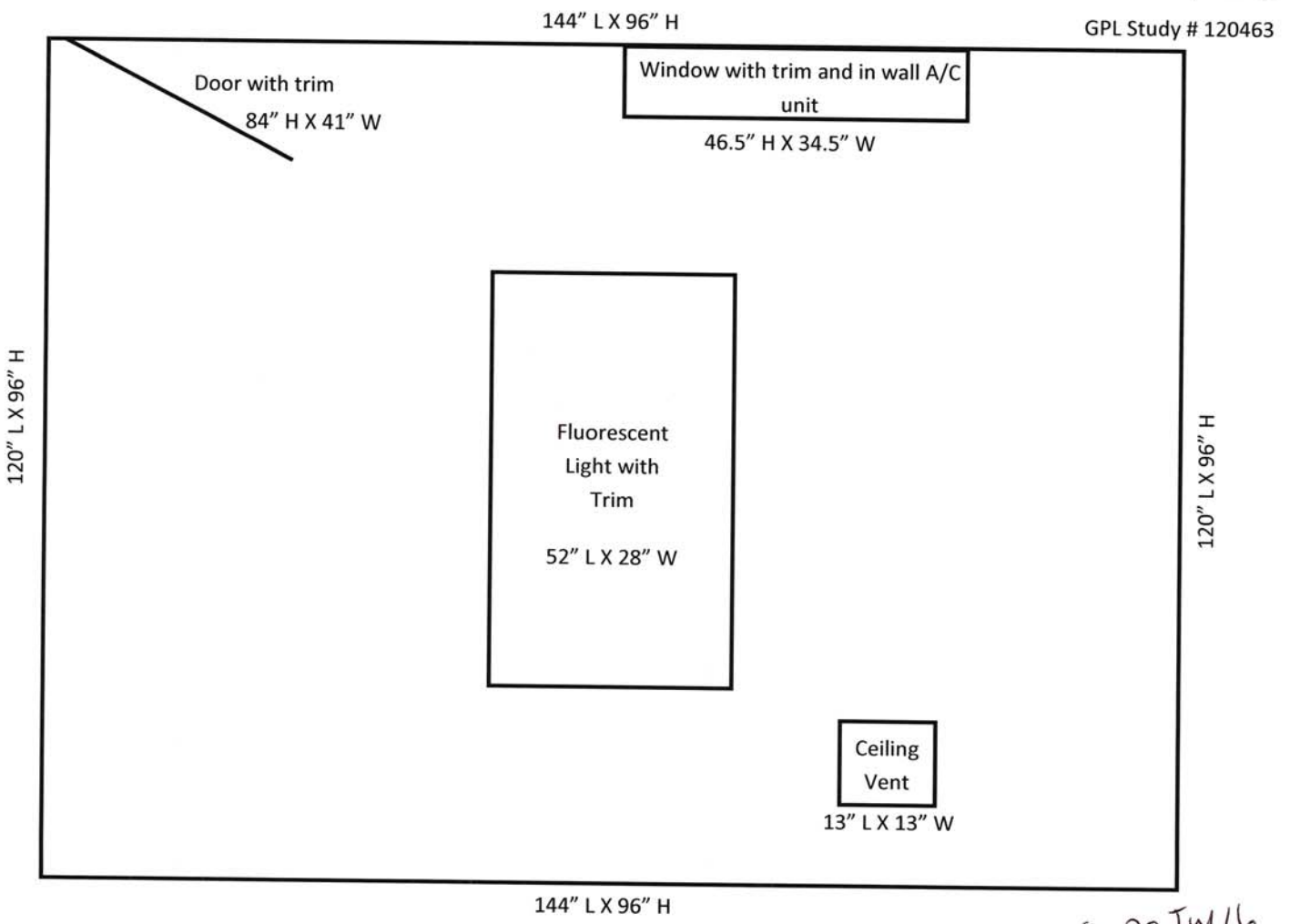


Page 1 of 1

Painting Room Dimensions (overhead view)

AEATF Study # AEA09

GPL Study # 120463



SL 20 Jul 16

APPENDIX H.

MONITORING EVENT OBSERVATIONS

ME #: 01
Date: 13 Jun 16

Time	Observations/Comments
0948	• ME01 received last minute instructions from Study Director and research staff. • Outside of room one (R1).
0954	• ME01 opened first gallon of paint and poured into paint tray. • Inside R1.
0956	• Began painting with roller on south side of Wall D. • Rolls length of wall in an up and down fashion. • Rolling approximately 10-15 times between re-dipping roller in paint tray. • Covering approximately 2 ft. wide strip between dippings. • Rolls from bottom trim to ceiling without cutting edges. • Some paint visible on ceiling and baseboards/window trim.
1002	• Pours more paint into tray from gallon #1.
1004	• Approximately halfway done with Wall D. • Approximately 10 penny sized drops of paint on floor from moving tray across floor.
1006	• Done with rolling on Wall D. • Some spots left unpainted (trim and surrounding areas). • Pauses rolling briefly to pour more into tray.
1007	• Begins rolling on Wall C. • In general, paint coverage is fairly light. • ME01 does not use extender pole but instead stands on tips of toes and squats to cover full height of wall.
1011	• Paint splatter visible on hands, from rolling. • Pauses to pour more paint into tray. • Paint can approximately half empty.
1014	• Done with Wall C (rolling only).
1016	• Pauses to move to next wall. • Stated he felt fine. • Sweat wipe #1 performed by nurse.
1017	• Resumes painting (rolling), on Wall B.
1019	• Pours more paint from gallon #1 to paint tray. • Resumes painting.
1021	• Approximately halfway done with Wall B (rolling only). • Large paint spots on knuckles, from rubbing against wall. • Gallon #1 empty. Set aside.
1025	• Observer adjusted cuffs of inner dosimeter (sticking out from OD, so were rolled back).
1027	• Resumed painting. • Moved to Wall A.
1028	• Stopped to wipe up paint that sloshed out of tray while moving. • Used 2 painters rags to wipe up.
1029	• Returned to rolling. • Putting paint on slightly thicker than before.

Continued on following page

ME #: 01 ***(Continued)***
Date: 13 Jun 16

Time	Observations/Comments
1030	• ME01 wiped sweat from nose with back of forearm. • ME01 asked to pause for sweat wipe #2 by nurse.
1034	• Sweat wipe performed. • ME01 sat in chair outside of R1, drank Gatorade with assistance from nurse. • Stated he felt fine. • ME01 picked at paint on hands, before being asked to stop.
1037	• Back in R1. • Used rag to wipe sloshed paint off of floor prior to moving tray.
1039	• Opened gallon #2. • Poured into tray. • Uses brush to start painting corner of room between Wall A and D. • Dipping brush into tray of paint on floor. • Brushing with left hand, holding paint cup with right hand to catch excess paint off brush.
1043	• Moves to painting window trim, following same method as corner.
1047	• Paused briefly to pour more paint to tray from gallon #2.
1048	• Painting top approximately ⅔ of baseboards, not reaching all the way to floor.
1049	• Moved to door frame. • More paint spots dripping to floor now that brush is being used. • ME01 brushes back and forth, covering approximately 5 ft. between re-dipping in painters cup. • ME01 works quickly, so some paint is visible on non-target areas (i.e. window, door).
1052	• ME01 done with door sill and small area of wall between door and Wall C. • Moves to Wall C baseboard.
1056	• Moves to Wall B baseboard. • Accidentally lets brush touch floor while painting. • Uses rag to wipe off of floor.
1057	• Resumes baseboards on Wall B and Wall A.
1059	• Attaches pole extender to roller, after finishing baseboards. • Begins rolling ceiling, south end first. • Similar procedure as walls (rolling). • Moves roller back and forth in 5 ft. long sections (swaths). • Covers approximately 2-3 ft. wide area length of ceiling between re-dipping.
1107	• ME01 about half way done rolling ceiling. • Gallon #2 less than half full. • Large amount of visible paint on fingers of ME01. • Paint is not visible on outer dosimeter (same color), however small splatters visible on Respicon harness. • None visible on face of ME01.

Continued on following page

ME #: 01 ***(Continued)***
Date: 13 Jun 16

Time	Observations/Comments
1113	• Done rolling ceiling. • ME01 uses brush to paint corners of walls that were missed.
1117	• Uses stepstool to brush paint edges between walls and ceiling, starting on Wall A. • Steps onto first step of stepstool and reaches to edge. • Paints as far as he can reach, then steps down, moves stepstool, and resumes painting with brush at new spot.
1120	• Done with top edge on Wall A. • Moves across room to C and continues same procedure.
1123	• Same procedure on Wall D.
1126	• Same procedure on Wall B.
1128	• Done with all surfaces in Room 1. • Carries roller on extender pole to room #2 (R2). • Observer pushes cart with the other tools/equipment. • ME01 stated he felt fine, did not want break. • Removes extender pole. • Pours remainder of gallon #2 into tray.
1129	• Starts rolling in room 2. • Follows same procedures as R1. • Starts on Wall A.
1134	• Approximately half done rolling Wall A. • Front of hands almost entirely covered in paint.
1137	• ME01 stops rolling. • Done with Wall A. • Opens gallon #3. • Pours approximately ⅓ into paint tray.
1138	• Resumes rolling. • Now on Wall B. • Same procedures.
1145	• ME01 pauses rolling briefly to pour remaining paint in brush cup into tray, per observer's request.
1146	• Back rolling, approximately halfway done with Wall B.
1148	• Done with Wall B rolling. • Moves on to Wall C. • Lots of visible paint splatter on floor.
1152	• Out of paint. • Approximately ⅔ done with Wall C. • ME01 puts roller back into paint tray. • Walks back to sampling room. • Lots of visible paint drops/splatters on front of lower legs and arms. • Observer assisted in removing booties off of ME01. • ME01 was careful to preserve paint on hands, i.e. held hands out away from body and tries not to touch anything.

Continued on following page

ME #: 01 ***(Continued)***
Date: 13 Jun 16

Time	Observations/Comments
1154	• Pumps turned off. • ME01 stated he felt fine, did not want water/Gatorade.
1220	• ME01 had small flecks left in cuticles of hands. • Per worker sampler, inner dosimeter was visibly clean and dry.
Summary	Pump Start Time: 0950 Pump Stop Time: 1154
	In general, a fairly light coat applied. Only top ⅔ of baseboards painted, avoiding part touching floor.

ME #: 02
Date: 15 Jun 16

Time	Observations/Comments
0900	• Pump turned on. • ME02 received last minute instructions from researchers. • Walked in to R1.
0902	• ME02 used paint key to open gallon #1 of paint. • Poured paint into paint cup. • Requested ladder.
0903	• Used brush to start painting top edge (between wall and ceiling) on Wall D. • Brushing in 3-4 ft. strokes covering ceiling and wall with a paintbrush wide band. • ME02 steps down from ladder and moves to next section.
0905	• Done with section of Wall D from window to corner. • Moves to Wall A.
0909	• Done with Wall A. • Moves to Wall B. • ME02 requests rag to clean drips of edge of paint cup. • Holds on top of ladder in left hand while painting with right hand.
0915	• ME02 done with Wall B. • Pours more paint into cup from gallon #1. • Returns to painting following same procedures. • Now on Wall C. • ME02 typically stands on third step from ground, painting at an arm's length away from wall.
0921	• Starts on remaining portion of Wall D. • ME02 paints top approximately 3 ft. of corner between Wall C and Wall D while on ladder. • In general, ME02 applies paint thickly but not to a point of over application.
0926	• ME02 paints top edge of door trim and window trim, while on ladder.
0931	• ME02 done painting top edges of room. • Holds paint cup in hand. • Paints remaining parts of window trim and door trim. • Uses up remaining paint in cup on corner between Wall D and A, puts paint rag back on cart.
0936	• ME02 done with brushing. • Pours paint into paint tray. • Begins rolling on Wall A. • Note: Using roller with extender pole. • Rolls left to right and diagonally along wall covering about 5 $ft.^2$ before re-applying paint on to roller. • Also applying on ceiling in approximately 2 ft. bands.
0944	• Face sweat wipe performed by nurse. • ME02 accidentally wipe forehead and touched hat before sweat wipe could be performed. • ME02 drank water.
0946	• ME02 resumed rolling on Wall A. • Approximately half done with rolling.

Continued on following page

ME #: 02 ***(Continued)***
Date: 15 Jun 16

Time	Observations/Comments
0955	• ME02 requested break. • Sat outside of room in front of AC (air conditioner). • Drank Gatorade. • A lot of visible paint on hands.
1003	• ME02 returned to R1 (room 1). • Opened gallon #2. • Stirred with stir stick and poured into paint tray.
1004	• Returned to painting on Wall D where she left off. • Paints all the way to baseboards, some visible paint on baseboards. • Same procedures, painting wall by moving roller up.
1014	• Done rolling on Wall D. • Puts roller back into paint tray. • Pours paint from gallon #2 into paint cup. • Sits down on cushion to paint baseboards (Wall D).
1016	• Used rag to wipe paint off of floor that was accidentally applied.
1017	• Done brushing what she can reach from the sitting position. • Stands up and bends over to paint remaining baseboards on Wall D. • Paints area between door and corner of Wall C that cannot be reached with roller also.
1021	• Done with small section between the door and Wall C. • Moved to corner between Wall A and B.
1023	• Felt dizzy. • Sat down in chair outside of R1. • Accidentally rubs hand and face while sitting in chair.
1025	• Returns to R1. • Finishes brushing corner then begins rolling on Wall B. • Following same procedure as before.
1031	• Pours more paint into tray. • Note: ME02 rests left hand on left knee while reapplying paint to roller.
1038	• Finishing up Wall B. • Requested to end study. • Walked back to room to collect samples. • Note: finished Wall B prior to ending.
1039	• Pump turned off. • ME02 stated she felt fine. • Inner dosimeter visibly clean and dry.
Summary	Pump Start Time: 0900 Pump Stop Time: 1039

ME #: 03
Date: 15 Jun 16

Time	Observations/Comments
1017	• Pump On.
1020	• ME03 into room #4. • ME03 opened paint can #1 with paint key.
1023	• Worker ME03 poured paint from paint can #1 into brush bucket; filled all the way full. • Worker ME03 took brush out of packaging.
1024	• ME03 started painting window trim. • On lateral trim used long up and down strokes. • On vertical trim used short strokes. • Filled the brush up with paint each time, lots of extra paint on brush. • Standing while painting trim.
1027	• Still painting window trim. • Standing approximately 16 in. from wall.
1028	• Starting to wipe paint off brush after dipping into paint; seems to be ME03's typical practice.
1032	• ME03 done painting window trim. • ME03 put kneepad on ground and started painting Wall B trim starting by door. • ME03 kneeling on pad and using left arm to stabilize, left hand is on the ground. • Starting with long strokes on baseboard, then using short strokes to smooth out paint.
1033	• Subject used rag to wipe paint from ground, kept using brush to paint baseboard.
1035	• ME03 used rag to clean paint from ground.
1036	• ME03 has used approximately ¼ of the paint cup's paint. • Subject is kneeling approximately 12 in from baseboard.
1037	• ME03 used rag to wipe paint from ground.
1040	• ME03 done paint Wall B baseboard. • Moved to Wall C baseboard.
1041	• ME03 wiped paint with rag from floor. • Subject stays kneeling while painting baseboards.
1048	• ME03 wiped paint from floor with rag. • ME03 done painting baseboard of Wall C, moved to baseboard of Wall D, using same procedure as before.
1050	• ME03 used rag to wipe paint from floor.
1051	• ME03 used rag to wipe paint from floor – continued painting.
1052	• ME03 used rag to wipe paint from floor. • Subject ME03 stopped using kneepad and is either in a crouching position of kneeling on one knee directly on the floor.
1055	• Subject's shirt became untucked in the back; observer re-tucked the OD shirt while wearing disposable latex gloves. • Subject continued painting.
1056	• ME03 wiped paint off the floor using a rag – continued painting.
1059	• ME03 wiped paint off the floor using a rag – continued painting.

Continued on following page

ME #: 03 *(Continued)*
Date: 15 Jun 16

Time	Observations/Comments
1101	• ME03 done painting baseboard on Wall D. • Started painting Wall A baseboard.
1104	• ME03's cuffs fell down. • Observer put gloves on and rolled them back up.
1108	• ME03 used rag to wipe paint from floor – continued painting.
1112	• ME03 used rag to wipe paint from floor – continued painting.
1116	• ME03 changed to sitting on the floor.
1117	• ME03 wiped paint from floor with rag. • ME03 done painting Wall A. • Started painting door trim. • Using wide strokes 10-14 in. then going back with small strokes 4-6 in. to smooth out paint.
1120	• ME03 stood up to paint the higher area of the door trim. • Kept paint cup on the ground.
1122	• ME03 done painting left side of door trim. • Starts painting top door trim.
1123	• ME03 done painting top of door trim. • Starts painting right side.
1124	• ME03 done paint right side of door trim.
1125	• ME03 pours the remaining paint from paint cup (approximately half) into roller tray. • Picked up roller tray and roller and placed on the ground by Wall B.
1126	• Spilled some paint from roller tray. • Used rag to wipe it off floor.
1127	• Started rolling Wall B. • Using longer strokes approximately 3-4 ft. when roller is full of paint then shorter, faster strokes as roller dries.
1131	• Added more paint from Can #1 to roller tray – continued rolling.
1132	• Used brush to smooth out an area that the roller left a drip.
1136	• ME03 added more paint to roller tray.
1138	• ME03 done painting Wall B. • Started rolling Wall C.
1141	• ME03 OD shirt back became untucked. • Observer put gloves on and re-tucked the OD shirt.
1142	• ME03 added more paint to roller tray – continued painting.
1144	• Worker ME03 moved roller tray closer to Wall C.
1145	• ME03 wiped up paint from floor with rag – continued painting. • ME03 added more paint to roller tray – continued painting. • Worker would occasionally rest his hand on his knee while rolling the lower portion of wall. • Some paint splatter visible when removing roller from roller tray.
1147	• ME03 added remaining contents from Can #1 into roller tray – continued painting.

Continued on following page

ME #: 03 ***(Continued)***
Date: 15 Jun 16

Time	Observations/Comments
1148	• Worker ME03 cleaned up paint from floor using rag – continued painting.
1150	• ME03 done rolling Wall C. • Started rolling Wall D.
1151	• ME03 took a drink of Gatorade from Nurse.
1152	• ME03 opened can #2, poured paint from can #2 into roller tray.
1155	• ME03 moved roller tray closer to where he was painting. • Added paint to roller tray – continued painting.
1158	• ME03 done rolling Wall D. • Starts rolling Wall A.
1201	• ME03 added more paint from can #2 to roller tray.
1203	• ME03 shirt (OD) became untucked. • Observer put on gloves and re-tucked in shirt.
1205	• ME03 moved roller tray closer to where he was painting.
1206	• ME03 poured more paint into roller tray.
1207	• ME03 done rolling Wall A. • Starts rolling the approximately 4 in. gap between door and wall.
1208	• Done painting small gap by door.
1209	• ME03 pours more paint from can #2 into roller tray. • ME03 attaches extension rod to roller frame – starts painting ceiling.
1212	• ME03 adds more paint from can #2 into roller tray.
1215	• ME03 cleaned up paint that fell on the floor with a rag.
1216	• ME03 added more paint from can #2 into roller tray. • While rolling ceiling subject would hold roller with one hand on bottom of extension and the other hand in the middle of the extension.
1220	• ME03 added the last of the paint from can #2 to the roller tray.
1222	• ME03 done painting ceiling. • Poured the remaining paint from roller tray into paint cup. • Started painting edge of Wall C/D.
1223	• Done painting edge of Wall C/D. • Started painting edge of Wall B/C.
1224	• ME03 stood on stool to paint ceiling/Wall B and C corner.
1226	• ME03 opened can #3 and poured into paint cup.
1227	• ME03 done painting ceiling/Wall B edge. • Moved to ceiling/Wall A edge. • While painting ceiling ME03 would stand on second step of stool and hold paint cup in one hand and brush in the other.
1230	• ME03 done painting Wall A/ceiling. • Started painting Wall D/ceiling and Wall D/A edge. • ME03 would move stool approximately 3 ft. at a time and could paint approximately a 4 ft. area at trim before having to move stool.

Continued on following page

ME #: 03 ***(Continued)***
Date: 15 Jun 16

Time	Observations/Comments
1231	• ME03 done painting Wall D/ceiling. • Started painting Wall C/ceiling.
1232	• ME03 done painting Wall C/ceiling. • Started touching up Wall A.
1233	• Pump off 12:33. • Note: ME03 stated he felt fine; dosimeter was dry with small areas of paint.
Summary	Pump Start Time: 1017 Pump Stop Time: 1233

ME #: 04
Date: 17 Jun 16

Time	Observations/Comments
0841	• Pump On.
0842	• ME04 opened can #1 with can opener, stirred paint with stir stick.
0843	• Poured approximately ⅓ of paint from can #1 into roller tray, dipped roller in tray and started painting Wall A. • ME04 rolls the top ⅓ of the wall using strokes that cover the whole top half of the wall. • Will roll approximately a 2'-3' section of the top ⅓ of the wall before refilling roller with paint.
0849	• Worker ME04 done painting top ⅓ of Wall A. • Starts painting middle ⅓ of Wall A. • While rolling ME04 will switch hands back and forth.
0852	• ME04 done painting middle ⅓ of Wall A. • Starts painting bottom ⅓ of Wall A.
0854	• ME04 done painting bottom ⅓ of Wall A. • Starts painting top half of Wall B. • ME04 can reach the top of the walls with the roller without an extension pole or ladder. • When rolling the top of walls ME04 stands approximately 6 to 12 in. from wall.
0857	• ME04 done painting top half of Wall B. • Starts painting bottom half of Wall B.
0858	• ME04 added more paint from can #1 to roller tray, approximately ⅓ of can #1. • When rolling bottom portion of wall ME04 will start standing straight up, then move into a crouching then kneeling position.
0901	• ME04 done painting bottom of Wall B. • Starts painting top half of Wall C.
0904	• ME04 done painting top half of Wall C. • Starts painting bottom half of Wall C.
0907	• ME04 done painting bottom half of Wall C. • ME04 said his safety glasses were fogging up. • Nurse came in to clean safety glasses.
0909	• ME04 starts painting above door on Wall D. • ME04 accidentally got paint on door, used rag to wipe it off.
0910	• ME04 done painting above door. • Starts painting left of window on Wall D.
0912	• ME04 done painting left of window. • Starts painting above and below window.
0913	• ME04 done painting above and below window. • Starts painting to the right of window on Wall D.
0914	• ME04 added the remaining paint from can #1 to roller tray.

Continued on following page

ME #: 04 ***(Continued)***
Date: 17 Jun 16

Time	Observations/Comments
0915	• ME04 done painting Wall D. • Put on extension pole. • Starts painting ceiling. • ME04 will roll an approximately 18 in. section the entire length of the ceiling at a time. • He will add more paint to the roller 2-3 times per 18 in. section.
0918	• ME04's roller was sliding off so he hit the end of the roller with the edging tool.
0920	• ME04's glasses were fogging up again so the nurse wiped them off and performed a sweat wipe. • ME04 also requested and took a drink of Gatorade being held up by the nurse.
0922	• ME04 continued painting ceiling.
0928	• ME04 opened paint can #2 with can opener and stirred with stir stick. • Poured approximately ¼ of can #2 into roller tray.
0930	• ME04's glasses fogged up. • Nurse wiped them off.
0931	• ME04 done painting ceiling. • Pours approximately ¼ of can #2 into paint cup. • Starts painting left of door Wall D with brush. • Using long up and down strokes.
0933	• Done painting left of door. • Starts painting baseboard on Wall C.
0935	• Done painting baseboard on Wall C. • Starts painting baseboard on Wall B. • While painting baseboards ME04 is in a crouched position holding paint cup in left hand, brush in right.
0936	• ME04 starts painting baseboard on Wall A. • While painting baseboard, ME04 uses long strokes left and right approximately 24 in..
0937	• ME04 starts painting baseboard on Wall D.
0940	• ME04's glasses were fogging up. • Nurse wiped them.
0941	• ME04 starts painting door trim.
0943	• Observer tightened Respicon harness as it was starting to fall forward.
0944	• ME04 done painting door trim; starts painting window trim. • When ME04 painting window trim and door trim he starts with small strokes then smooths with longer strokes, 12-18 in.
0946	• ME04 quickly painted corners of walls. • Took less than 1 minute to paint all four corners.
0947	• ME04 used stepstool to paint to of wall/ceiling corners. • Started with Wall B.
0949	• ME04 started painting Wall A top corner.
0950	• ME04 starts painting Wall D top corner. • ME04 would paint approximately a 3-4 ft. section of the corner before having to move stepstool.

Continued on following page

ME #: 04 ***(Continued)***
Date: 17 Jun 16

Time	Observations/Comments
0951	• ME04 starts painting top corner of Wall C.
0952	• ME04 done painting room #1. • Requested sweat wipe, drink, and glasses cleaned, all performed by nurse.
0955	• ME04 moved to room #2, poured the remaining paint from paint cup into roller tray and poured approximately ¼ of can #2 into roller tray.
0956	• ME04 started rolling top half of Wall A.
1000	• ME04 starts painting bottom half of Wall A.
1002	• ME04 starts painting top half of Wall B.
1005	• ME04 starts painting bottom half of Wall B.
1006	• ME04 poured approximately ¼ of can #2 into roller tray. • Continued rolling.
1008	• ME04 used his fingers to push the roller back onto the roller frame.
1009	• ME04 started painting top half of Wall C.
1010	• Nurse wiped ME04 glasses.
1012	• ME04 poured the remaining paint from can #2 into roller tray.
1013	• ME04 started painting bottom half of Wall C.
1016	• ME04 starts painting between door and window on Wall D.
1017	• ME04 starts painting under window on Wall D.
1018	• ME04 paints between window and Wall A on Wall D.
1019	• ME04 paints above window on Wall D.
1020	• ME04 paints above door on Wall D.
1021	• ME04 pours remaining paint from roller tray into paint cup. • Starts painting between door and Wall C on Wall D with paint brush.
1022	• ME04 starts painting door trim.
1024	• ME04 starts painting window trim.
1026	• ME04 starts painting corner of Wall A and Wall D.
1027	• ME04 out of paint. • Waiting for sampling room to be cleaned. • Standing in room #2.
1031	• Pump off. • Note: OD has some paint, ID clean.
Summary	Pump Start Time: 0841 Pump Stop Time: 1031

ME #: 05
Date: 17 Jun 16

Time	Observations/Comments
1128	• Pump turned on. • ME05 walked to room #4 (R4).
1129	• Opened gallon #1 with key. • Poured directly into paint cup. • Paint cup all the way full. • Poured from paint cup into paint tray.
1130	• Started painting with roller on Wall B. • Started with paint tray in right hand, rolling with left hand. • Then moved rolling cart nearby and put paint tray on cart. • ME05 rolls up and down and side to side covering well (not too thick). • ME05 does not use extender pole or stepstool. • Stands fairly close to wall, but does not contact.
1138	• Done rolling majority of Wall B. • Uses brush and paint cup to paint window trim. • ME02 painted up to trim with roller so only front of trim is painted with brush.
1140	• Done with window trim. • Uses stepstool to roll top portion of Wall B. • Uses brush to paint edge between Wall B and ceiling.
1143	• ME05 steps down from stepstool. • Pours more paint from gallon #1, directly into paint tray.
1144	• Paints baseboard of Wall B with roller, covers only top half.
1146	• Moves to rolling on Wall C. • Covers approximately 10 $ft.^2$ between reapplying paint on roller.
1149	• Approximately 90% done with Wall C. • Pours paint from gallon #1 into paint cup. • Uses brush briefly to cover corner between Wall C and Wall D. • Back to rolling.
1152	• Finishes Wall C. • Starts rolling on Wall D.
1157	• Approximately half done with Wall D. • A lot of visible paint on hands. • Some small specks visible on face. • Stops briefly to drink Gatorade. • Stated she felt fine.
1201	• Kneels on kneepad cushion while rolling bottom of Wall D.
1205	• Done rolling on Wall D, coverage was fairly light. • Uses brush to finish corner between Wall D and A, tops of baseboards.
1206	• Starts rolling on Wall D, uses cushion to kneel while painting bottom half. • Paints left to right (mostly), covering approximately 15 $ft.^2$ between reapplying.
1208	• Uses stepstool to reach top corner with brush.
1210	• Back to rolling on Wall A.

Continued on following page

ME #: 05 ***(Continued)***
Date: 17 Jun 16

Time	Observations/Comments
1212	• Uses stepstool and brush to paint top edge between Walls A and B and ceiling, also paints top half of corner between Wall A and B.
1214	• Uses roller to finish Wall B (above door) and between door and corner.
1215	• Uses brush to touch up around door trim and between door and wall.
1216	• Back rolling on Wall A. • Finishing bottom right quarter.
1220	• Starts painting ceiling with roller and extender pole. • Same procedure as walls. • Some visible drops while rolling overhead. • Landing on front of outer dosimeter and face.
1222	• Drank Gatorade.
1226	• Accidentally knocked hose off of Respicon while rolling. • Observer reattached. • Disconnected for <30 seconds.
1229	• ME05 out of paint from gallon #1. • Stands in front of Air conditioner to take break. • Does not want to sit.
1230	• Opens gallon #2. • Resumes painting ceiling. • ME05 has neck pain from painting ceiling, requests to stop. • Ceiling 80% done.
1233	• Moves cart to R5. • Uses brush to paint window trim and surrounding wall.
1235	• Starts painting with roller with extender pole on Wall B.
1237	• Stops rolling, grabs brush to paint corner between Wall B and C, and top edge of Wall C. • Pours paint from gallon #2 directly into paint cup. • Uses stir stick to catch drippings down side of gallon #2.
1240	• Back to rolling on Wall C. • Same procedures, fairly light coverage. • Note: A lot of visible paint on face.
1243	• Uses brush to finish corner between Wall C and D.
1245	• Removes extender pole. • Kneels on floor without kneepad cushion.
1247	• Pours more paint into tray from gallon #2. • Continues rolling, same procedures. • Finishing up Wall B and C.
1258	• Done with Wall B and C. • Uses stepstool and brush to get top edge of Wall D.
1300	• Back to rolling, on Wall D. • Fairly light coverage.

Continued on following page

ME #: 05 ***(Continued)***
Date: 17 Jun 16

Time	Observations/Comments
1304	• Kneeling with cushion to paint bottom half of Wall D.
1305	• Pours more paint into tray from gallon #2. • Continues rolling on Wall D. • Visible paint drops on brim of painters hat.
1308	• Uses brush to paint corner between Wall D and A.
1310	• Begins rolling on Wall A. • No change.
1321	• Uses stepstool and brush to paint top edges of Wall A.
1323	• Moves to Wall B. • Finishes top edge and door trim.
1326	• Moves around floor trim, painting top half.
1330	• Attaches extender pole, paints ceiling starting at northern end.
1333	• ME05 done with walls and trim in Room 5. • Note: Approximately 1000 mL left in paint tray when ME05 asked to stop.
1334	• Walks to sampling room. • Pump off.
1345	• Inner dosimeter visibly clean. • ME05 stated she felt fine.
Summary	Pump Start Time: 1128 Pump Stop Time: 1334

ME #: 06
Date: 20 Jun 16

Time	Observations/Comments
0925	• Pump on.
0927	• ME06 opens can 1 with can opener.
0928	• Puts extension pole on roller. • Pours approximately ⅓ of can #1 in roller tray.
0929	• Dips roller in roller tray. • Starts rolling Wall B. • When rolling ME06 uses extension pole and makes a single pass from top to bottom of wall, will paint approximately 18 in. until he needs to reapply paint to roller.
0932	• ME06 used his finger to remove a dried spot of paint from the wall.
0933	• ME06 done rolling Wall B. • Starts rolling Wall A.
0934	• ME06 added approximately ⅓ of can #1 to roller tray. • Continued painting.
0938	• ME06 done rolling Wall A. • Starts rolling Wall D.
0939	• ME06 used the stepstool to roll horizontally above the window.
0940	• ME06 added almost the rest of can #1 to the roller tray.
0941	• ME06 painted to the window on Wall D. • Started rolling ceiling.
0942	• While moving roller tray ME06 spilled some paint. • Used 2 rags to wipe it up – continued rolling ceiling.
0945	• ME06 stopped rolling ceiling. • Started rolling left of window, then moved back to ceiling.
0946	• Observer replaced roller handle as it had a large splinter in it.
0950	• ME06 dumped the remaining paint from can #1 into roller tray. • Started painting Wall C.
0952	• ME06 done painting Wall C. • Started rolling ceiling.
0955	• Nurse performed sweat wipe and wiped ME06s glasses.
0956	• ME06 continued rolling ceiling.
0959	• ME06 done rolling ceiling.
1000	• ME06 opened can #2 and poured approximately ¼ of can into roller tray.
1001	• ME06 finished rolling Wall D above door.
1003	• ME06 used stepstool to roll across top of walls and corner to get closer to edges.
1005	• ME06 poured paint from roller tray to paint cup and used brush and paint cup to paint wall and ceiling edges.
1008	• Nurse cleaned subject's glasses.
1009	• ME06 continues painting wall and ceiling edges. • Uses stepstool to reach corner.

Continued on following page

ME #: 06 ***(Continued)***
Date: 20 Jun 16

Time	Observations/Comments
1012	• ME06 switched to painting baseboards. • Subject on his hands and knees while painting baseboards. • Will hold brush in one hand and the other hand is on the ground.
1017	• ME06 poured the rest of the paint from the paint cup back into the paint can (can #2). • ME06 is now using the paint can to dip his brush into instead of the paint cup. • The paint can is near him on the ground as he switches back and forth from baseboard to wall edges.
1021	• ME06 started painting window trim then switched back to baseboard.
1025	• ME06 started painting window trim again.
1027	• ME06 started painting door trim.
1029	• ME06 used stepstool to paint corner above door.
1031	• ME06 started painting baseboards.
1033	• ME06 started painting corner of wall and ceiling using stepstool.
1035	• ME06 painting around light on ceiling.
1039	• ME06 done painting room #1. • Moved to room #2.
1040	• ME06 poured approximately ⅓ of can #2 into roller tray. • Attached roller handle to roller frame. • Started rolling Wall A.
1043	• ME06 switched to rolling Wall D. • Still has approximately 24 in. on Wall A not painted.
1044	• ME06 switched back to rolling Wall A. • Finished Wall A.
1045	• ME06 got on one knee and rolled under window on Wall D horizontally.
1047	• ME06 started rolling Wall B.
1051	• ME06 started rolling Wall C.
1054	• ME06 added the remaining paint from can #2 into roller tray.
1056	• ME06 started rolling Wall D.
1057	• ME06 switched to rolling part of ceiling.
1059	• ME06 out of paint in can #2.
1100	• Pump off. • Some paint on OD. • ID clean and dry.
Summary	Pump Start Time: 0925 Pump Stop Time: 1100

ME #: 07
Date: 20 Jun 16

Time	Observations/Comments
1011	• Pump turned on. • ME07 stood in Room 4 (R4). • Opened gallon #1. • Poured gallon #1 into paint tray, approximately ¼ poured. • Used brush to start painting window trim on Wall D.
1013	• Walking back and forth to paint in tray. • Pours some paint into paint cup from gallon #1. • Holds paint cup in left hand and returns to painting window trim.
1015	• ME07 is very careful while painting with brush, does not get paint on window area. • ME07 uses slow smooth strokes resulting in good coverage.
1019	• Done painting window trim and surrounding wall area. • Moves to painting door trim. • Same procedures. • Stands approximately 1 ft. away from trim while painting with brush.
1022	• ME07 opens door to paint inner edge of door trim.
1025	• Closes door to paint corner trim.
1026	• Accidentally gets some paint on door while brushing. • Uses rag to wipe off door. • Places rag in back pocket of outer dosimeter.
1027	• Back painting with brush. • Done with door trim. • Starts painting corner between door and Wall A.
1031	• Uses stepstool to reach top corner. • Also paints top edge between walls and ceiling as far as he can reach onto Wall A and B. • Approximately 2 ft. each way from corner.
1032	• Moves stepstool further down Wall B. • Continues painting top edge between wall and ceiling.
1035	• Done with top edge on Wall B, continues onto Wall C. • Paints top corner between Wall B and C while on stepstool.
1037	• Steps down from stepstool to paint bottom of corner. • Kneels on ground to paint very bottom and bottom baseboard along Wall B. • Paints carefully to paint all the way to the floor without painting floor.
1040	• Brush accidentally touches floor. • Uses rag from back pocket to wipe it off.
1042	• Done with baseboards on Wall B. • Moves back to stepstool. • Continues painting top edge of Wall C. • Stops briefly to pour more paint into cup from gallon #1. • Gallon #1 approximately half full.
1045	• Steps down from stepstool to paint bottom of corner. • Same procedures, kneeling on ground, then moves to painting baseboard.

Continued on following page

ME #: 07 *(Continued)*
Date: 20 Jun 16

Time	Observations/Comments
1047	• ME07 uses rag to wipe paint off of floor, puts back into back pocket.
1052	• Done with Wall C baseboards. • Moves to Wall D baseboards. • ME07 starts keeping rag in left hand and uses it when needed. • Some visible paint on hands on ME07, but in general has managed to stay relatively clean.
1059	• Done with baseboard on Wall D. • Moves to Wall A baseboard. • No change in procedure.
1103	• Done with Wall A baseboard. • Paints corner between Wall D and A as far as he can reach (height).
1104	• Returns to where he left off on top edge of Wall D.
1106	• Done with top edge on Wall D. • Same procedures on Wall A.
1108	• Done with Wall A top edge. Moves stepstool to middle of room to cut around light trim. • Visible paint on right elbow of outer dosimeter, presumably from leaning against corner.
1112	• ME07 still holding rag in left hand, using it to clean non-target areas.
1113	• Done with all trim/edges/baseboards in room 4 (R4). • Puts extender pole on roller. • Pours remaining paint in cup into paint tray. • Starts rolling on ceiling around light. • ME07 rolls slowly to ensure good coverage. • Covers roller in enough paint to cover one strip of ceiling (width of roller) before reapplying.
1118	• Paints small area on Wall B above door.
1119	• Returns to painting ceiling, on third strip of ceiling. • No change in procedure. • ME07 moves roller back and forth, straight, in approximately 5 ft. swaths the width of the roller.
1121	• Stops rolling to pour more paint into tray. • Gallon #1 approximately ¼ full after pouring.
1122	• Returns to rolling ceiling. • Same procedures.
1128	• ME07 pours more paint into tray from gallon #1, finishing last few strips on ceiling.

Continued on following page

ME #: 07 *(Continued)*
Date: 20 Jun 16

Time	Observations/Comments
1130	• Done with ceiling, moves to rolling on Wall B. • Similar procedures as ceiling. • Moves roller up and down in straight line. • Covers approximately 20 ft.^{2} before reapplying paint to roller. • ME07 applies the right amount of paint onto roller so it is not dripping but he does not have to push hard to roll onto wall. • ME07 pours remaining paint from gallon #1.
1135	• Done with Wall B. • Same procedures on Wall A. • ME07 works very cleanly, no visible splatter, hands relatively clean.
1139	• ME07 opens gallon #2 and pours approximately ⅕ into paint tray. • Returns to painting with roller on Wall A.
1140	• Done with Wall A, moves to Wall D. • No change.
1146	• Done with Wall D. • Pours more paint into tray from gallon #2 approximately half full. • Starts on Wall C.
1150	• Done with all surfaces in R1. • Walks to room 5 (R5) with roller in hand. • Drinks Gatorade.
1151	• Places roller down on cart. • Pours paint from gallon #2 into paint cup. • Starts painting window trim with brush. • No change in procedure.
1154	• Done with window trim. • Paints bottom corner between Wall B and C. • Then paints Wall B baseboards.
1200	• Done with Wall B baseboard, moves to door trim. • ME07 still holding rag in left hand, used when needed.
1203	• Paints small strip between door and Wall A while painting door trim.
1205	• Uses stepstool to brush top edge of Wall B. • Same procedures.
1210	• Done with Wall B top edge. • Moves to Wall C top edge.
1212	• Wall C top edge done. • Moves to Wall D. • Cuts edges on ceiling vent while doing Wall D top edge.
1213	• Steps down from stepstool to paint corner between Wall C and D. • No change in procedure.
1216	• Finishing Wall D top edge. • Moves to Wall A top edge and corner between Wall D and A.
1217	• Down from stepstool painting corner, kneeling.

Continued on following page

ME #: 07 ***(Continued)***
Date: 20 Jun 16

Time	Observations/Comments
1218	• Back on stepstool painting top edge of Wall A. • Knees visibly dirty from kneeling.
1220	• Done with all top edges and corners in R5. • Moves stepstool to center of room to paint edges around light. • Drips paint onto floor. • Wipes up with rag in left hand.
1224	• Moves to baseboard on Wall C. • Same procedures.
1228	• Moves to Wall D baseboards.
1235	• Moves to Wall A baseboards. • Still holding rag in left hand, using when needed.
1237	• Done with baseboards. • Pours remaining paint in cup into tray.
1238	• Puts rag into back right pocket. • Grabs roller with extender. • Starts rolling ceiling on northern end. • No change in procedures from R4.
1243	• Pours more paint into tray from gallon #2. • Gallon #2 ⅕ full.
1246	• Approximately ⅔ done with ceiling rolling. • Pours remainder of gallon #2 into tray.
1249	• Done with ceiling. • Moves to rolling on Wall B. • No change from R4. • Approximately 20 $ft.^2$ painted between applying paint to roller.
1253	• Done rolling Wall B. • Moves to Wall C.
1254	• Out of paint in tray. • Uses remainder of paint on roller on Wall C. • Approximately 50% done. • ME07 puts down roller on cart. • Walks back to sampling room. • Small visible flecks on face.
1255	• Pump turned off.
1313	• ME07 stated he felt fine. • Inner dosimeter clean and dry.
Summary	Pump Start Time: 1011 Pump Stop Time: 1255

ME #: 08
Date: 22 Jun 16

Time	Observations/Comments
0843	• Pump On. • ME08 opened can #1 with can opener. • Used stir stick to mix paint in can #1.
0844	• ME08 poured some paint in paint cup - filled paint cup approximately halfway full.
0845	• ME08 used paintbrush to paint baseboard left of door.
0846	• ME08 painted door trim with brush. • When painting trim ME08 used strokes approximately 18 in. long and went over the area multiple times to smooth the paint.
0848	• ME08 done painting door trim. • Started painting baseboard on Wall D. • When painting baseboard, ME08 is on his knees and switches between using his left and right hand to hold the paintbrush; the other hand is on the floor.
0852	• ME08 done painting baseboard on Wall D. • Started painting baseboard on Wall A.
0855	• ME08 done painting Wall A. • Started painting Wall C.
0858	• ME08 done painting Wall C baseboard. • Started painting Wall B baseboard.
0901	• ME08 done painting baseboard on Wall C. • Finishes painting door trim.
0903	• ME08 starts painting window trim. • When using the brush ME08 holds the brush on the metal plate close to the bristles the majority of the time; only when making large strokes around trim does he hold the handle.
0911	• ME08 done painting around window and window trim. • Starts painting wall around door trim, still using brush.
0913	• ME08 poured approximately ¼ of the paint from can #1 into the paint cup – continued painting around door trim.
0915	• ME08 done painting around door trim. • Starts painting Wall C/D corner.
0917	• ME08 poured the remaining paint from paint cup into the roller tray. • Poured approximately ¼ of the paint from can #1 into roller tray. • Attached roller frame to extension pole.
0918	• Started rolling Wall D.
0924	• Stopped rolling used brush and roller tray to paint corner of Wall D and Wall A.
0927	• Done painting Wall D/A corner. • Started painting Wall A/B corner.
0931	• ME08 poured approximately ¼ of paint from can #1 into roller tray. • Started rolling the remaining part of Wall D.
0933	• ME08 started rolling Wall A. • When rolling ME08 uses strokes approximately 2-3 ft. long and moves over approximately 18-24 in. before refilling roller with paint.
0934	• ME08 pushed roller cover back on roller frame.

Continued on following page

ME #: 08 *(Continued)*
Date: 22 Jun 16

Time	Observations/Comments
0938	• ME08 poured less than ¼ of the paint from can #1 into roller tray.
0940	• ME08 done rolling Wall A. • Starts rolling Wall B.
0943	• ME08 pushed roller cover back on roller frame.
0948	• ME08 poured the remaining paint from can #1 into roller tray.
0950	• ME08 done rolling. • Used brush to paint corner of Wall B/C.
0955	• ME08 pushed roller cover back onto roller frame.
0958	• Me08 done painting Wall C. • Started rolling ceiling.
1000	• ME08 used brush and roller tray to paint ceiling and Wall C corner. • When painting ceiling corner, ME08 used stepstool and would paint approximately 24 in. before moving stool.
1004	• ME08 opened can #2 using can opener, stirred with stir stick.
1006	• Poured a small amount (⅛?) of can #2 into paint cup; started painting Wall B/ceiling corner.
1010	• Nurse provided ME08 with a drink of water.
1011	• ME08 painted around fan in ceiling.
1013	• ME08 painted ceiling/Wall A corner.
1017	• ME08 poured a small amount of paint from can #2 into paint cup.
1018	• ME08 started painting ceiling/Wall D corner.
1021	• ME08 Done painting Wall D/ceiling corner. • Pours paint from paint cup into roller tray; pours a small amount of paint from can #2 into roller tray (can is now approximately ⅓ empty).
1022	• Started rolling ceiling.
1027	• ME08 pushed roller cover back onto roller frame.
1029	• ME08 poured approximately ¼ of can #2 into roller tray. • Continued rolling ceiling.
1040	• ME08 done painting Room #1; moved to room #2. • Nurse gave the subject a drink of water.
1042	• ME08 started painting the door trim with the brush and roller tray.
1048	• ME08 painting corner of Wall D and Wall C.
1052	• ME08 painting baseboard of Wall C.
1056	• ME08 done painting baseboard of Wall C. • Starts paint baseboard on Wall B. • ME08 painting corner of Wall B and C.
1100	• ME08 poured the paint from the roller tray into the paint cup. • Started painting above the door and Wall D/ceiling corner with brush and paint cup.
1103	• ME08 done painting above door. • Started painting Wall C/ceiling corner.
1106	• Some paint drips from brush when painting top corners of walls. • ME08 pours a small amount of paint from can #2 into paint cup.

Continued on following page

ME #: 08 ***(Continued)***
Date: 22 Jun 16

Time	Observations/Comments
1110	• ME08 done painting corner of Wall C/ceiling. • Pours approximately ¼ of can #2 into roller tray.
1111	• ME08 starts rolling Wall C.
1112	• ME08 pushed the roller cover back onto the roller frame.
1114	• ME08 pushed roller cover back onto roller frame.
1117	• ME08 poured the remaining paint from can #2 into roller tray.
1119	• ME08 done rolling Wall C, starts rolling Wall B.
1121	• ME08 pushed the roller cover back onto the roller frame.
1124	• ME08 pushed roller cover back on roller frame.
1126	• Same as above.
1127	• Same as above. • ME08 is pushing hard on the wall with the roller which is causing the roller cover to slide off of the roller frame.
1128	• ME08 done rolling Wall B, pours the paint from the roller tray into the paint cup.
1129	• ME08 uses the paint cup and brush to paint the baseboard on Wall B.
1131	• ME08 is done painting the baseboard on Wall B starts painting ceiling/Wall B corner.
1133	• ME08 done painting ceiling/Wall B corner. • Starts painting Wall A/B corner.
1135	• Pump off. • Note: Some paint on OD, ID some sweat, looks clean.
Summary	Pump Start Time: 0843 Pump Stop Time: 1135

ME #: 09
Date: 22 Jun 16

Time	Observations/Comments
0936	• ME09 stood in R1. • Receiving last minute instructions from research staff.
0938	• ME09 opens gallon #1 of paint. • Pours into paint tray.
0939	• Holds paint tray in left hand, brushes around window trim on Wall B. • No actually painting trim - using brush to paint wall surrounding trim that will not be covered by roller.
0942	• Starts painting surface of trim. • Places tray down on cart. • Uses rag to wipe drip of paint off of ground. • Places paint brush down into paint tray. Uses rag to wipe handle of paintbrush that fell into paint.
0945	• Approximately 50% done with window trim, puts down brush, applies paint to roller, starts rolling on Wall B. • Rolling section between window and Wall C, 3-7 ft. high.
0949	• ME09 holds tray between left hand and hip. • Coverage is fairly thick. • ME09 reapplies paint to roller several times to cover 10 ft.^{2}. • No visible dripping.
0957	• ME09 pours more paint into tray from gallon #1. Approximately half empty. • ME09 paints standing approximately 1 ft. away from wall, walking (shuffling) side to side, moving roller up and down in approximately 2 ft. swaths. • Paints over areas multiple times. • Now on Wall C.
1001	• ME09 stops rolling, uses brush to paint corner between Wall B and C. • 30% done with rolling on Wall C.
1003	• Done with what he can reach in corner. • Moves to corner between Wall C and D.
1005	• Decides to put tray on cart, and walk back and forth to reapply paint. • Note: only 3 ft. from cart to corner.
1007	• Done with what he can reach in corner. • Puts down brush. • Holds tray in left hand. • Rolls following same procedures at standing height.
1009	• Done with 3 ft. strip lengthwise across Wall C. • Moves to lower half of wall. • Doing a combination of bending over and squatting to reach to just above baseboards.

Continued on following page

ME #: 09 *(Continued)*
Date: 22 Jun 16

Time	Observations/Comments
1015	• Done with lower half of wall. • Coverage slightly lighter than middle section. • ME09 requests ladder. • Pours more paint from gallon #1 into paint cup this time. • Rolls top right corner of Wall C standing on ladder with roller. • Brushes top corner while standing on ladder.
1019	• ME09 done from ladder. • Attaches extender pole to roller.
1020	• Rolls top portion of Wall C. • Coverage similar to middle portion. • Stands approximately 2 ft. from wall moving roller up and down. • Extension pole almost parallel with wall.
1023	• ME09 disconnects roller from pole. • Pours more paint into tray from gallon #1. • Approximately ¼ left in gallon #1.
1024	• Moves ladder to corner between Wall B and C. • Stands sideways on ladder (second rung) to paint top of corner. • Holds paint cup in left hand while painting.
1026	• Moves ladder over to paint top edge of Wall C with brush. • Note: ME09 is fairly clean. Very small amount of visible spots of paint on hands approximately 1 hour into monitoring.
1029	• Done with top edge of Wall C. • Stands backwards on ladder to paint top edge of Wall D.
1030	• Down from ladder. • Reattaches pole to roller. • Starts rolling top approximately 2 ft. of Wall D. • Same procedures. • Thick coverage.
1033	• ME09 pours paint into tray from gallon #1. • Down to last little bit left in gallon, maybe only one more pour.
1034	• Continues painting top section of Wall D.
1036	• Done with top section of Wall D. • Moves to top section of Wall A.
1041	• Approximately 60% done with top section of Wall A. • Note: sections wall into thirds height wise. • Moves to middle third on Wall A.
1042	• Decides to remove extender pole from roller. • Back to rolling middle section. • Holding roller in hand, moves to Wall D middle section.

Continued on following page

ME #: 09 *(Continued)*
Date: 22 Jun 16

Time	Observations/Comments
1044	• Stops painting briefly to sip Gatorade. • Requests new roller. This is what he would normally do. • Takes break in chair outside of room 4 (R4).
1047	• Uses rag to remove roller from frame. • Places new roller onto frame. • Managed to keep hands clean by using rag.
1048	• Pours remaining paint into tray, from gallon #1. • Returns to Wall D and resumes rolling middle section. • No change in procedures.
1053	• Done with middle section of Wall D. • Returns to where he left off on middle section of Wall A.
1055	• ME09 opens gallon #2. • Pours small amount into tray.
1056	• Back painting on Wall A. • Now on lower section (third) of wall. • Same procedures, lighter coverage than elsewhere in room. • Still opting for leaving tray on cart.
1100	• Attaches pole extender. • 80% done with lower section of Wall A.
1101	• Applies paint to roller then starts rolling on lower section of Wall D.
1102	• Moves to ceiling above Wall D. • Paints between vent and Wall D on ceiling.
1103	• Removes extender pole. • Pours more paint from gallon #2. Approximately ¼ empty. • Reattaches pole.
1104	• Returns to painting ceiling surrounding vent.
1105	• Accidentally paints surface of vent. • Climbs on top of ladder to wipe off with rag. • Removes extender pole.
1106	• Back rolling on Wall D, lower section. • Using original procedures. • No extender pole. • Using a combination of squatting and bending to roll to just above baseboards.
1110	• Pours more from gallon #2 into tray. Approximately ⅔ full. • Done with Wall D rolling. • Returns to Wall A to finish remaining sections.
1113	• Attaches extender pole to reach remaining part of top section on Wall A.
1114	• Done with Wall A rolling. • Moves to top section of Wall B.

Continued on following page

ME #: 09 *(Continued)*
Date: 22 Jun 16

Time	Observations/Comments
1117	• Done with rolling on Wall B. • Pours more paint from gallon #2 into tray. • Starts rolling ceiling with extender pole. • Similar procedures as walls. • Moving roller back and forth in approximately 2-3 ft. swaths.
1122	• Pours more paint from gallon #2. Approximately half empty.
1124	• Done with 25% of ceiling. • ME09 states he would normally turn off light to paint around. • Light is left on due to no other light source.
1129	• ME09 stops painting to drink Gatorade.
1130	• Back rolling ceiling; approximately half done.
1132	• Pump ok. • No change in procedures. • Thick coverage. • Going over same swath multiple times.
1135	• Pours more paint from gallon #2. Approximately ⅓ full.
1142	• Done with ceiling. • Removes pole from roller. • Starts brushing top edge of Wall D. • Standing on 2nd rung of ladder.
1146	• Pours paint from tray into cup. • Still some remaining in tray.
1148	• Done with top edge of Wall D. • Down from ladder finishing corner between Wall D and A.
1149	• Back on ladder painting with brush on top edge of Wall A. • Continues this pattern, moving ladder a few feet at a time to paint top edge.
1152	• Down from ladder. • Painting area between door and Wall A. • Pours remaining paint from tray into cup.
1153	• Moves to painting baseboards on Wall C. • Squatting and brushing back and forth in approximately 1 ft. swaths. • Moving fast. • Some contact with floor.
1156	• Done with Wall C. • Moves to Wall B baseboards.
1157	• Paints door trim.
1158	• ME09 leans against ladder taking break. • Drinks Gatorade.
1159	• Back painting. • Now on Wall A. • Did not finish door trim.

Continued on following page

1200	• Moves to Wall D baseboards.
1202	• Pours more paint from gallon #2 into paint cup. • Very little remaining in gallon #2. • Finishes Wall D baseboard.
1203	• Moves ladder to corner between Wall B and C. • Paints top edge between Wall B and ceiling. • Same procedures as top edge from earlier.
1208	• Pours more paint from gallon #2. • Finishes top edges of room.
1210	• Paints remainder of window trim.
1212	• Done with window trim. • Moves to door trim.
1215	• Done with door trim. • Very little paint left in cup. • ME09 returns to changing room for final sampling.
1216	• Pump turned off. • Hands relatively clean. • Very little visible paint spots. • No visible spots on face. • Inner dosimeter visibly clean and damp from sweat. • Outer dosimeter had large paint spot on left upper left, presumably from leaning against wall.
Summary	Pump Start Time: 0936 Pump Stop Time: 1216

ME #: 10
Date: 24 Jun 16

Time	Observations/Comments
0904	• Pump turned on. • ME10 walks to R1.
0906	• ME10 opens gallon #1. • Pours approximately ⅓ into paint tray, and into paint cup.
0908	• Starts on baseboards of Wall B. • Squatting just above ground, moving brush back and forth in approximately 1 ft. swaths. • ME10 paints entire height of baseboards in one brush. • Large amount of contact with floor.
0910	• Moves to Wall A baseboard.
0911	• Moves to Wall D baseboards, kneeling on ground now.
0913	• ME10 uses trim guard to paint top edge of baseboards. • Holds trim guard against wall in left hand while brushing with right hand. • Repainting baseboard on Wall D.
0915	• Same procedure on Wall A.
0917	• Same procedure on Wall B. • Using trim guard to keep paint from going into crack between baseboard and wall. This is her normal practice.
0920	• Same procedures on Wall C baseboards.
0923	• Done with baseboards, moves to door trim. • Uses trim guard along door to keep from painting door.
0930	• Done with door trim. • Moves to window trim. • Not using trim guard. • Paints trim surface.
0932	• Uses trim guard to paint outside edges of trim. • ME10 has some visible paint on hands, mostly on front and sides.
0934	• ME10 done with trim. • ME10 applies paint to roller. • Stands on first step of stepstool. • Starts rolling on Wall B.
0937	• Paints all she can reach from stepstool on Wall B (approximately 9 $ft.^2$ in top left corner).
0938	• Paints similar area on Wall A while on stepstool (approximately 9 $ft.^2$ in top right corner).
0939	• ME10 moves stepstool along Wall B. • Paints top of wall from stepstool (approximately 9 $ft.^2$).
0940	• Steps down from stepstool. • Paints bottom left corner of Wall B.
0941	• Pours more paint from gallon #1. Approximately half empty.

Continued on following page

ME #: 10 *(Continued)*
Date: 24 Jun 16

Time	Observations/Comments
0942	• Back painting on Wall B. • Coverage is good. • ME10 applies enough paint to cover approximately 9 ft.^{2} (3 ft. × 3 ft.) without having too push hard. • Rolls on smoothly.
0944	• Continues pattern of moving stepstool along Wall B. • Painting top approximately ½ from first step of stepstool. • Paints lower half by bending over. • Does not use extender pole.
0947	• Done with Wall B. • Continues same procedure.
0949	• Pours more paint from gallon #1. • Returns to painting on Wall C.
0955	• Done with Wall C. • Moves to Wall B. • Note: ME10 stands approximately 1 ft. from wall when rolling.
0958	• ME10 pours more paint from gallon #1. Practically empty. • ME10 wants to get one more pour out of it.
1002	• Done with Wall D. • ME10 pours remaining paint into tray from gallon #1.
1003	• Sweat wipe performed by nurse. • ME10 drank Gatorade.
1005	• ME10 back rolling. • Now on Wall A.
1008	• ME10 accidentally scratches chin with tip of fingernail. • No visible paint on fingernail.
1012	• Done rolling on Wall A. • Grabs brush and cup. • Starts painting on corner between Wall D and A. • Stands on stepstool to paint top corner and top edge between ceiling.
1014	• ME10 opens gallon #2 with key. • Pours into paint cup. Approximately ⅛ empty.
1015	• Continues painting top edge along Wall A, moving stepstool as needed.
1016	• Done painting top edge on Wall A. • Paints corner between Wall A and B. • Gets down off stepstool to paint lower half.
1017	• Moves to painting top edge of Wall B.
1018	• Cuts around ceiling vent while next to it.
1020	• Done with Wall B top edge. • Paints corner between Wall B and C.

Continued on following page

ME #: 10 *(Continued)*
Date: 24 Jun 16

Time	Observations/Comments
1021	• Paints top edge of Wall C. • No change in procedure.
1023	• Done with Wall C. • Paints corner between Wall C and D. • Also paints area between door and Wall C that cannot be reached with roller.
1025	• Moves to top edge on Wall D. • Also paints top of door frame.
1029	• Done painting top edges of room. • ME10 pours remaining paint from cup into tray.
1030	• Sweat wipe #2 performed. • Drank Gatorade. • Did not want to take break.
1032	• Attaches pole to roller. • Starts painting ceiling. • Moves back and forth with roller (approximately 3 ft. swaths). • Coverage similar to walls.
1036	• Pours more paint from gallon #2 into tray. Approximately ⅓ empty.
1042	• Approximately half done with ceiling. • ME10's hat constantly sliding up; observer adjusts as needed.
1048	• Some small splatters visible on face.
1050	• ME10 pours more paint into tray from gallon #2. Approximately half empty.
1054	• Done with all surfaces in R1. • Drinks Gatorade. • Walks to R2 with roller and pole extender in hand.
1056	• Starts painting ceiling in R2. • Same procedures as R1.
1059	• Pours more paint into tray from gallon #2. Gallon #2 approximately ¼ full.
1100	• Returns to painting ceiling.
1104	• Approximately half done with ceiling. • ME10 has trouble seeing what has been painted. Sometimes goes back over what has already been done.
1109	• Big drop falls from roller and lands on right upper arm.
1110	• Pours more paint (remaining paint) from gallon #2.
1112	• Done with ceiling. • Starts painting on Wall B with roller and extender pole. • Stands approximately 3 ft. back from wall rolling in swaths approximately 5 ft. long. • Covering approximately 15 $ft.^2$ before reapplying.

Continued on following page

ME #: 10 ***(Continued)***
Date: 24 Jun 16

Time	Observations/Comments
1116	• Out of paint in tray and cup.
1117	• ME10 finishes paint on roller. • 90% done with wall. • Walks back to sampling room. • Pump turned off.
1140	• ME10 stated she felt fine. • Inner dosimeter visibly clean and dry.
Summary	Pump Start Time: 0904 Pump Stop Time: 1117

ME #: 11
Date: 24 Jun 16

Time	Observations/Comments
1055	• Pump on.
1058	• ME11 opened can #1 with can opener. • Used stir stick to stir paint in can #1.
1059	• ME11 poured approximately ¼ of can #1 into roller tray. • Put extension pole on roller frame.
1100	• ME11 started rolling ceiling. • When rolling ceiling, ME11 used approximately 24 in. long strokes and would paint an approximately 24 in. section before refilling roller.
1103	• ME11 added approximately ⅛ of can #1 into roller tray. • When rolling ceiling ME11 got some paint splatter on his face.
1111	• ME11 poured approximately ⅛ of can #1 into roller tray. • Started rolling Wall D. • When rolling walls ME11 used the extension pole and roller. • ME11 makes 2 ft.- 4 ft. long strokes up and down, sometimes at an angle. • Will go over the same spot multiple times to ensure an even coat.
1118	• ME11 done rolling Wall D. • Starts rolling Wall C.
1119	• ME11 poured approximately ⅛ of can #1 into roller tray.
1121	• ME11 used his hand to push roller back on roller frame.
1123	• ME11 done rolling Wall C. • Starts rolling Wall B.
1125	• ME11 poured almost the rest of can #1 paint into roller tray. • Continued painting Wall B.
1127	• ME11 went back to Wall C to touch up a place he missed. • Went back to Wall B.
1128	• ME11 done rolling Wall B. • Starts rolling Wall A.
1131	• ME11 poured the remaining paint from can #1 into roller tray.
1133	• ME11 finished rolling Wall A.
1134	• ME11 used foldable ladder to paint ceiling and Wall D corner with brush and roller tray.
1136	• ME11 done painting Wall D/ceiling corner. • Starts painting Wall C/ceiling corner.
1138	• ME11 starts painting Wall B/ceiling corner. • Switched to top of window trim.
1141	• ME11 started painting top of door trim.
1145	• ME11 requested sweat wipe and drink. • Nurse performed sweat wipe and gave subject a drink.
1147	• ME11 started painting Wall A/ceiling corner.
1149	• ME11 painted around trim on light on ceiling.
1150	• ME11 painted corner of Wall D/A.
1151	• ME11 painted baseboard on Wall D.
1153	• ME11 painted baseboard on Wall C.

Continued on following page

ME #: 11 *(Continued)*
Date: 24 Jun 16

Time	Observations/Comments
1154	• ME11 painted baseboard on Wall B.
1155	• ME11 poured approximately <⅛ of can #2 into roller tray. • Continued painting baseboard on Wall B.
1156	• ME11 painted trim around door. • When painting the corners and trim ME11 uses ~12 in. strokes and goes over the area multiple times to smooth paint.
1157	• ME11 started painting window trim.
1159	• ME11 finished painting door trim.
1200	• ME11 started painting Wall A baseboard.
1201	• When ME11 sat on floor to finish baseboard on Wall A the Respicon pump turned off. • Both the observer and the subject noticed right away. • The observer turned the pump back on. • Pump off for approximately 10 seconds. No painting done during this time.
1203	• ME11 done painting room #4. • Moves to room #5.
1204	• ME11 starts painting room #5. • Starts painting ceiling with roller and extension pole.
1208	• ME11 poured approximately ¼ of can #2 into roller tray.
1213	• ME11 done painting ceiling. • Starts rolling Wall D.
1215	• ME11 poured approximately ⅛ of can #2 into roller tray.
1218	• ME11 done rolling Wall D. • Starts rolling Wall A.
1221	• ME11 poured the remaining paint from can #2 into the roller tray.
1223	• ME11 done rolling Wall A. • Starts rolling Wall B.
1226	• ME11 done rolling Wall B. • Starts rolling Wall C.
1231	• ME11 done rolling walls.
1232	• ME11 uses ladder, brush, and roller tray to paint corner of Wall B and ceiling, and top of window trim.
1233	• ME11 painting the rest of the window trim.
1234	• ME11 painting the Wall C/ceiling corner. • Some paint dripped on the ground from brush.
1235	• ME11 painting Wall D/ceiling corner.
1237	• ME11 painting Wall A/ceiling corner.
1238	• ME11 painting above door trim.
1240	• ME11 painting both sides of door trim.
1242	• ME11 out of paint from can #2.

Continued on following page

ME #: 11 ***(Continued)***
Date: 24 Jun 16

Time	Observations/Comments
1243	• Pump off. • Note: Some paint on OD. ID clean.
Summary	Pump Start Time: 1055 Pump Stop Time: 1243

ME #: 12
Date: 27 Jun 16

Time	Observations/Comments
0940	• Pumps running.
0942	• Opened can 1; stirred and poured approximately 24 oz into paint cup. • Used long strokes to paint window frame. • ME12 held cup with left hand and brush with right hand.
0945	• Moved to paint door trim. • Leaned down to reach bottom of frame. • Brush was pressed firmly against wood while painting. • Painted frame and surrounding wall (brush width).
0947	• Used kneepad to kneel while painting trim at floor. • Paint cup approximately 12 in. under face while painting.
0949	• Stopped using kneepad. • Refilled cup.
0951	• Used very full brush of paint with 1 in. of coverage hitting floor. • Paint from brush drips on floor.
0953	• Used brush to cut corners of wall.
0955	• Stands 6-12 inches from wall while using brush. • Reached high to paint top of corners. • Drops of paint visible on hands.
0957	• Refilled cup. • Continued cutting corners and ceiling.
0959	• Used stepladder once and then stopped. • Reached high to finish cutting ceiling. • ME12 scrapes edge of cup with brush after dipping to refill. • Worked from Wall D, A, B, C.
1004	• Finished cutting. • Poured approximately 16 oz of paint into tray. • Commenced rolling Wall C. • Held roller at top with right hand and ⅓ from roller with left hand. • Used full strokes up and down entire wall, repeating areas if not fully covered.
1007	• Poured approximately 20 oz into tray. • Adjusted roller with hand. • Used firm pressure when rolling. • Moved steadily down wall, overlapping strokes slightly. • Used shorter strokes while finishing corner of wall. • Stood approximately 20-24 in. from wall while painting. • Refilled tray with remaining paint.
1011	• Started rolling Wall D. • Used brush to touch up top of door trim. • Roller is filled heavily and rolled on tray to remove small amount of paint. • Paint drops observed on nose and brim of hat. Also small drops on hairline.

Continued on following page

ME #: 12 ***(Continued)***
Date: 27 Jun 16

Time	Observations/Comments
1016	• Used can opener to open can 2. • Stirred with stick. • Wiped stick on side of can creating drips on can.
1017	• Poured approximately 16 oz paint in tray and commenced rolling Wall A. • Uses 8-10 strokes to cover approximately 2 ft. of wall and using up paint on roller.
1020	• Touched face with back of hand after sneezing. • Touched face again. • Presses roller on cart occasionally to secure roller.
1022	• Refilled tray. • Commenced rolling Wall B. • Paint dripped on floor.
1026	• Refilled tray.
1029	• Finished Wall B and started ceiling B.
1030	• ME12 reported sweat in eyes. • Nurse performed wipe of face and glasses. • ME12 picked up rag to wipe eyes but was stopped by observer.
1031	• Returned to rolling ceiling C. • ME12 rolled one swath along wall and then rolled back on ceiling towards center, holding roller 12-24 in. in front of body to right above head at end of 1-2 ft. stroke.
1034	• Refilled tray. • Rolled ceiling C toward center. Roller directly overhead.
1036	• Returned to ceiling B/D. • Drops of paint on face, hands, and chest. Also paint on roller handle.
1038	• Painted D/A ceiling and C/A ceiling. • Used approximately 2-3 ft. strokes on ceiling.
1042	• Finished ceiling.
1045	• Pumps turned off. • ME12 stated he is feeling fine. • Paint visible on outer clothing.
Summary	Pump Start Time: 0940 Pump Stop Time: 1045

ME #: 13
Date: 27 Jun 16

Time	Observations/Comments
1023	• Pump turned on.
1025	• ME13 opened gallon #1. • Used stir stick to stir gallon #1 prior to pouring into paint tray.
1026	• Attached extender pole to roller and moved paint tray to floor. • Began rolling on Wall C. • Paints entire length (height) of wall standing approximately 2 ft. from wall. • Coverage is good, covering approximately 10 ft.^{2} before reapplying to roller.
1031	• Done with Wall C. • Moves to rolling on Wall B. • ME13 pours more paint from gallon #1 – approximately half empty.
1040	• Done rolling on Wall B. • Pours more paint into paint tray. Approximately ¾ empty (gallon #1). • Starts rolling on Wall A. • No change in procedure. • ME13 rolls smoothly in approximately 5 ft. swaths. • ME13 works fast but clean.
1045	• Done rolling on Wall A. • Moves to rolling on Wall D. • Pours remainder of gallon #1 into paint tray.
1049	• ME13 has very little paint on hands; most came from pouring out of gallon #1.
1051	• Done rolling walls. • Moves to rolling ceiling.
1053	• Opens gallon #2. • Pours approximately ⅕ into tray. • Approximately ¼ done with ceiling.
1054	• Returns to rolling ceiling.
1057	• Small flecks of paint visible on chin and neck.
1100	• Pours more paint into tray from gallon #2. • Approximately 80% done with ceiling. • Gallon #2 approximately ⅓ empty.
1103	• Done rolling ceiling. • ME13 sits in chair in air conditioning. Sips Gatorade. • Sweat wipe performed by nurse.
1106	• ME13 pours paint from tray into cup.
1107	• Uses brush to start painting corner between Wall C and D.
1108	• Paints as high as she can reach on corner then starts painting baseboard on Wall C. • ME13 kneels on ground; moves quickly but is very clean. • Little to no contact with floor.
1111	• Done with Wall C baseboard. • Paints corner between Wall B and C, as high as she can reach (approximately 7 ft. high).
1112	• Moves to painting baseboard on Wall B.

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ME #: 13 *(Continued)*
Date: 27 Jun 16

Time	Observations/Comments
1115	• Paints small area between door and Wall A.
1117	• Moves to Wall A baseboards; no change in procedure. • More paint visible on hands since she started brushing, from contact with brush and paint cup.
1120	• Done with Wall A baseboard. • Paints bottom approximately 7 ft. of corner, then moves to baseboard on Wall D.
1123	• Done with all baseboards in R4.
1124	• Requests ladder. • Stands on third rung of ladder. • Paints top of corner between Wall A and D. • Paints top edge of Wall D.
1125	• Steps down from ladder and moves it approximately 3 ft. down wall to paint next section of top edge of Wall D.
1127	• Done with Wall D top edge. • Paints top corner between Wall C and D. • Moves to Wall C top edge.
1129	• Moves to Wall B. No change. • ME13 paints surface of window trim. • Paints top approximately half on ladder. • Paints bottom approximately half from ground.
1132	• Done painting window trim. • Pours more paint from gallon #2 into cup. • Gallon #2 approximately ⅓ full.
1133	• Back painting top edge on Wall B. • Also paints top of door trim (surface).
1136	• Paints remainder of door trim surface standing/kneeling on ground.
1137	• ME13 scratches cheek with tip of fingernail. No visible paint transfer.
1138	• Done with door trim. • Finishes top edge of Wall A. • Done with R4.
1140	• ME13 sits in chair in air conditioner. Sips Gatorade. • Sweat wipe performed by nurse.
1143	• ME13 walks to R5. • Pours remaining paint from cup into tray. • Pours more paint from gallon #2 into tray. • Begins rolling on Wall A. • Same procedures as R4.
1146	• Outer dosimeter from knees down is visibly dirty from kneeling on floor.
1148	• Done rolling on Wall A. • Moves to rolling on Wall D.
1150	• Pours remaining paint from gallon #2 into tray. • Continues rolling on Wall D.

Continued on following page

ME #: 13 ***(Continued)***
Date: 27 Jun 16

Time	Observations/Comments
1154	• Moves to Wall C rolling.
1156	• Done with approximately 60% of Wall C. • Out of paint. • ME13 walks back to sampling room.
1157	• Pump turned off.
1212	• ME13 stated she felt fine. • Inner dosimeter visibly clean and dry.
Summary	Pump Start Time: 1023 Pump Stop Time: 1157

ME #: 14
Date: 29 Jun 16

Time	Observations/Comments
0857	• Pump turned on. • ME14 walked into R1.
0858	• Opened gallon #1. • Poured into paint cup; approximately ⅙ empty.
0859	• Started painting baseboards on Wall D. • Kneeling on cushion.
0900	• Spilled approximately half of paint cup onto floor while sliding across. • Used rags to wipe it up.
0901	• Painted door trim. • ME14 works fast, not trying to avoid non-target areas (door, floor, etc.).
0902	• Moves to baseboards on Wall C.
0903	• Same procedures on Wall B. • Then moves to Wall A.
0905	• Done with baseboards. • Paints window trim.
0906	• Pours more paint into paint cup. • Gallon #1 approximately ⅓ empty. • Starts painting corner between Wall A and D.
0907	• Uses stepstool to paint top edges around room.
0909	• Continues to work around room, painting top edges and corners of room.
0913	• Done painting all trim, edges, and corners in R1.
0915	• ME14 pours more paint from gallon #1. • Sweat wipe performed by nurse. • Attaches extender pole to roller.
0916	• Starts rolling on Wall D. • ME14 puts a lot of paint on roller. • Covers approximately 10 $ft.^2$ before reapplying.
0919	• Done with Wall D. • Pours more paint into paint tray from gallon #1. • Very little left in gallon. • Starts rolling on Wall C. • ME14 works very fast; coverage is thick.
0924	• ME24 has allergies so she frequently itches nose with back of hand. • Asked to avoid if possible. • No visible paint transfer.
0925	• Done with Wall C. • Moves to rolling on Wall D. • Pours remaining paint out of gallon #1.
0927	• ME14 opens gallon #2. • Pours into paint tray.

Continued on following page

ME #: 14 ***(Continued)***
Date: 29 Jun 16

Time	Observations/Comments
0930	• ME14 pauses painting when done with Wall A for sweat wipe, performed by nurse.
0931	• Returns to rolling, now on Wall B. • Same procedures. • Pours more paint into tray from gallon #2, approximately half empty.
0936	• Pours more paint from gallon #2. • Gallon #2 empty. • Finishes Wall B.
0937	• Starts painting on ceiling. • Same procedures as walls. • Lots of paint on roller. • Drips common. • Visible on front of ME14 - upper dosimeter (outer) front torso and arms.
0941	• Pauses for sweat wipe by nurse. • Back to painting ceiling; approximately 75% done.
0944	• Done with all surfaces in R1. • Out of paint in tray. • Drips also visible on left thigh.
0945	• ME14 walks back to room for final sampling. • Pump turned off.
1010	• Inner dosimeter visibly clean and dry. • ME14 stated she felt fine.
Summary	Pump Start Time: 0857 Pump Stop Time: 0945

ME #: 15
Date: 29 Jun 16

Time	Observations/Comments
1041	• Used can opener to open can. • Stirred briskly; wiped stick on side of can. • Poured approximately 24 oz of paint in tray set on floor. • Moved tray back to cart. • Stood on stool to reach cut of Wall A. • Painted with a full brush; heavy drops or streams of paint fell from brush. • Used bottom step of stool as ME15 cut ceiling. • Moved stool and refreshed brush after making each approximately 20 in. swath.
1046	• Moved tray to floor, knelt on pad, and used brush and cutting tool to paint baseboard of Wall D. • Face approximately 8-10 in. from painted areas. • Painted approximately 12 in. swath back and forth. • ME15 was overloading brush causing thick drips. Observer recommended dabbing brush on ribbed tray to prevent this.
1047	• Very heavy drips from overloading brush was corrected.
1048	• Commenced rolling Wall D. • Paint tray on floor. • Held back of pole with right hand and left hand in center of pole. • Painted full up/down strokes, then short strokes to touch up.
1052	• Painted ceiling A/D with roller strokes approximately 4 ft. in front, overhead, and 2 ft. back of body.
1053	• Refilled tray. • Spilled approximately 4 oz. next to tray. • Attempted to use brush to wipe up. • Used rag to clean spill, rubbing until paint was absorbed.
1055	• Rolling Wall D. • Refilled with remainder of can 1. • Requested face wipe. • Paint visible (heavy) on hands. Small spot on neck and torso.
1058	• Resumed rolling D. • Stands approximately 3-4 ft. from wall.
1059	• On floor to cut baseboard C. • Uses brush to cover wood and approximately 6 in. of lower wall. • Uses cutting tool on floor below brush strokes. • Paint tray approximately 18 in. from body. • Fills brush with paint, then dabs on roller to clear some paint.
1102	• Cut corner of Wall B/C with brush. • Moved tray and roller to cart. • Stood on stool to cut ceiling of C. • Moved cart and stool every 2-3 ft.. • Brushes approximately 6 in. of wall and 4 in. of ceiling. • Surface is approximately 18 in. from face.

Continued on following page

ME #: 15 ***(Continued)***
Date: 29 Jun 16

Time	Observations/Comments
1105	• Cut window trim and surrounding wall with brush. • Approximately 12-in. strokes using brush and cutting tool. • Holds brush in right hand.
1108	• Requested wipe around mouth.
1110	• Cutting ceiling B. • Opened can 2. • Drips on can from stick. • Closed can. • Placed tray on floor.
1111	• Painted ceiling D with roller. • Moved roller from front extended, to back of body.
1113	• Rolling ceiling C using shorter strokes.
1114	• Rolled Wall C. • Made approximately 8 strokes before refilling roller. • Returned to ceiling C, then moved to Wall C.
1116	• Drips observed on rolled surfaces of Wall C (top). • Observer noted drips and instructed ME15 on clearing brush out of ribbed area of tray so ribs could be used to dab excess paint. • ME15 started dabbing excess on tray. • Rolls from one side of wall/ceiling with overlapping strokes.
1118	• Used rag to wipe approximately 2 oz. from tray spill on floor.
1119	• Used foot to push tray around floor (repeatedly).
1120	• Rolled Wall B, alternating with ceiling B. • Continued to overfill roller; drips on floor.
1122	• Refilled tray. • Set lid on can. • Used brush to cut baseboard B. • Held tool to bottom of board. • Kneeled on pad with one knee. • Knee closest to wall (approximately 10 in.) on floor. • Used hand to move tray while brushing.
1125	• Brushed door trim. • Opened door while painting trim.
1126	• Inner dosimeter visible at top of pants when reaching high. • Pants slid down approximately 2 in.. • Used hands to hike pants up. • Kneeled on ground with face very close to baseboard when finishing bottom of door trim.
1128	• Brushed baseboard A.

Continued on following page

ME #: 15 ***(Continued)***
Date: 29 Jun 16

Time	Observations/Comments
1129	• Poured last of can 2 into tray. • Rolled Wall B and ceiling B.
1131	• ME15 zipper is observed to be unzipped. • Painting is almost complete. • Inner dosimeter visible through opened zipper. • Clothes appear clean and dry.
1133	• Rolling Wall A.
1135	• Finished room.
1136	• Pump turned off. • ME15 said he felt fine.
Summary	Pump Start Time: 1039 Pump Stop Time: 1136

ME #: 16
Date: 01 Jul 16

Time	Observations/Comments
0758	• Pump on.
0800	• ME16 shook can #1 while closed. • Used can opener to open can #1. • Poured approximately half of can #1 into roller tray.
0801	• ME16 put roller tray on ground and put extension pole on roller frame.
0802	• Started rolling Wall B. • When ME16 rolls, he uses full wall strokes, up and down. • Paints one roller width before refilling roller.
0804	• ME16 put rag in pant pocket to have ready in case something spills.
0807	• ME16 poured ⅓ of can #1 into roller tray, and less than ¼ into paint cup. • Continued rolling Wall B.
0810	• ME16 done rolling Wall B. • Started rolling Wall C.
0815	• ME16 poured the remaining paint from can #1 into roller tray – approximately ¼ gallon.
0816	• ME16 done rolling Wall C. • Starts rolling ceiling. • When rolling ceiling, ME16 uses long strokes approximately half the width of the ceiling and adds approximately 1 roller width before filling roller again, but ME16 also goes back over where he painted last to smooth out paint.
0819	• ME16 shakes can #2 by hand with the lid still on.
0820	• ME16 opened can #2 with can opener and poured approximately ⅓ of can #2 into roller tray. • Continued rolling ceiling.
0823	• ME16 stopped painting ceiling. • Started rolling above door on Wall D.
0824	• ME16 started painting right of door on Wall D.
0827	• ME16 stopped rolling Wall D. • Started rolling the rest of the ceiling.
0828	• ME16 poured approximately ⅓ of can #2 into roller tray.
0829	• ME16 done rolling Wall D. • Starts rolling Wall A.
0830	• ME16 switched back to ceiling.
0831	• ME16 switched back to Wall A.
0833	• ME16 requested a drink of water. • Nurse supplied drink.
0835	• ME16 continued rolling Wall A.
0836	• ME16 switched to rolling ceiling.
0837	• ME16 switched to rolling Wall A.
0840	• ME16 poured the rest of the paint from can #2 into painters cup. • ME16 done rolling all walls in room #1.
0841	• ME16 used painters cup and brush to paint window trim on Wall D.

Continued on following page

ME #: 16 ***(Continued)***
Date: 01 Jul 16

Time	Observations/Comments
0842	• ME16 used stepladder to reach ceiling/Wall D corner.
0844	• ME16 painting Wall D/A corner. • Used stepstool to reach top of corner.
0845	• ME16 used stepstool to paint corner of Wall A/ceiling.
0847	• ME16 started to paint ceiling/Wall B corner; also painted around vent fan.
0848	• ME16 painted corner of Wall B/C.
0850	• ME16 painted corner of Wall C/ceiling. • When cutting, ME16 uses medium length strokes approximately 18 in. and paints approximately a 24-30 in. length before refilling brush. • ME16 holds paint cup in one hand and brush in the other.
0852	• ME16 painted space between the door and corner on Wall D. • ME16 used rag to wipe up paint on ground.
0854	• ME16 painted around light on ceiling.
0855	• ME16 out of paint.
0857	• Pump off. • Dosimeter was clean and dry.
Summary	Pump Start Time: 0758 Pump Stop Time: 0857

ME #: 17
Date: 01 Jul 16

Time	Observations/Comments
0905	• Pump turned on. • ME17 walks to R4.
0906	• ME17 opens gallon #1. • Moves paint tray to ground. • Pours approximately ⅔ from gallon #1 into paint tray.
0907	• Attaches extender pole to roller. • Starts rolling on Wall D. • Coverage is fairly light. • Rolls approximately 20 $ft.^2$ before reapplying paint to roller.
0911	• Done rolling on Wall D. • Areas near trim not finished. • ME17 rolls to approximately 2-3 in. from baseboard and ceiling. • Starts rolling on Wall C. • ME17 rolls in approximately 3-ft. swaths.
0914	• Done rolling on Wall C. • Moves to Wall B. • Same procedures.
0917	• Moves to Wall A. • Done with Wall B. • Pours remainder of gallon #1 into paint tray. • ME17 sloshed paint out of paint tray with roller. • Uses rag to wipe off of floor.
0918	• Resumes rolling on Wall A.
0921	• Done rolling on walls. • Coverage in general is fairly light. • Starts painting corner between Wall A and D with brush. • Bends over and dips brush into paint tray; dabs brush on edge of tray to remove excess paint. • Paints with fast approximately 1-ft. swaths back and forth.
0923	• Paints window trim. • Does not make huge effort to avoid non-target areas.
0925	• Paints baseboard. • Bends over at waist to paint. • Minimal contact with floor while brushing.
0926	• Paints door trim and area between door and Wall C.
0928	• Uses stepstool to paint top edge on Wall D.
0930	• Moves to top edge on Wall C. • Shirt came untucked on back side of ME17. • Re-tucked by researcher.

Continued on following page

ME #: 17 *(Continued)*
Date: 01 Jul 16

Time	Observations/Comments
0931	• Paints baseboards on Wall C. • Moves paint tray closer to Wall C. • Removes roller pole but leaves roller in tray. • Bends at waist and rests right elbow on knee while painting. • Less than 1 ft. away from wall while painting.
0933	• Moves to Wall B baseboard.
0935	• Approximately 60% done with baseboard. • Moves to top edge on Wall B.
0936	• Approximately 60% done with top edge on Wall B. • Uses rag to wipe sloshed paint off of floor. • Pours more paint, from gallon #2 now. • Approximately half empty after pouring.
0937	• Accidentally drops paint brush handle into tray. • Pulls out with fingers. • Uses rag to wipe handle clean. • Lots of visible paint on hands; most contact has come from cleaning up with rags.
0938	• Finishes baseboard on Wall B. • More contact with floor on this baseboard.
0939	• Finishes top edge of Wall B.
0941	• Paints top edge of Wall A. • Note: When brushing, covering more area than usual because did not roll all the way from ceiling to baseboard. • Having to paint approximately 2-3 in. of wall with brush.
0943	• Paints baseboard on Wall A, similarly to Wall B.
0945	• Done with all trim and edges on walls. • Researcher adjusts shirt and belt (re-tucks shirt). • ME17 drinks water.
0947	• ME17 starts rolling ceiling. • Similar procedure as walls. • Coverage fairly light.
0950	• Approximately ⅓ done with ceiling. • Small flecks of paint visible on face. • Rolling in approximately 3-ft. swaths back and forth. • Using extender pole and shuffling across floor to cover strip of ceiling. • Covering approximately 20 $ft.^2$ before reapplying.
0957	• Done with all surfaces in R4. • Picks up tray and places on cart. • Uses rag to wipe up sloshed paint on ground. • Walks to R5.

Continued on following page

ME #: 17 ***(Continued)***
Date: 01 Jul 16

Time	Observations/Comments
0958	• Starts rolling on Wall D. • Same procedures as R4.
1000	• Done with full lengths on Wall D. • Note: Did not paint small areas above and below window, and above door. • Pours remaining paint from gallon #2. • Starts rolling on Wall A.
1003	• Done with Wall A rolling. • Moves to Wall B. • Same procedures; fairly light coverage.
1005	• Rotates paint tray on floor for easier access. • Uses rags to wipe sloshed paint off of floor. • Finishes Wall B rolling.
1007	• Moves to rolling on Wall C.
1008	• No more paint in tray. • Rolls remaining paint in roller onto Wall C.
1009	• ME17 walks back to sampling room. • Pump turned off.
1033	• ME17 stated he felt fine. • Inner dosimeter visibly dry; small dirty spot along collar, presumably from sweat.
Summary	Pump Start Time: 0905 Pump Stop Time: 1009

ME #: 18
Date: 01 Jul 16

Time	Observations/Comments
1022	• Opened can with can opener and stirred can. • Poured approximately 24 oz. into paint cup. • Brushed paint on door trim. • Stood approximately 15 in. from door and reached to cover all trim using 10-12 in. strokes. • Brushed carefully to ensure neat, even coat. • Tapped brush on cup to remove excess. • Kneeled on ground when needed. • Held cup in left hand, brush in right.
1027	• Brushed window trim.
1030	• Small drip on floor. • Poured remaining paint from cup into tray. • Poured approximately 8 oz. from can into tray. • Moved tray to floor near Wall A. • Used brush to cut corner A/B. • Stood on stool to reach top. • Dipped brush into tray heavily and then scraped into cup. • Used cup to brush paint.
1034	• Cut around door.
1035	• Stood on stool. • Held tray in left hand and roller (no stick) in right. • Rolled above door 1-2 ft. strokes.
1037	• Filled cup with approximately 4 oz. paint from tray with brush. • Stood on stool to cut ceiling B, moving stool periodically. • Refilled again.
1039	• Safety glasses fell and caught. • Replaced by observer (same pair).
1041	• Cut corner B/C; knelt on floor. • Refilled again.
1043	• Cut ceiling C using stool. • Brushed with 12-24 in. strokes.
1044	• Cut corner C/D.
1046	• Glasses off and replaced again.
1047	• Refilled. • Cut ceiling D. • Used second step of stool when cutting. • Stool approximately 12 in. from wall and arm fully extended.
1050	• Stirred can and poured approximately 4 oz. in cup. • Cut corner D/A/

Continued on following page

ME #: 18 *(Continued)*
Date: 01 Jul 16

Time	Observations/Comments
1052	• Cut ceiling A. • A few drops of paint observed on right hand.
1055	• Poured approximately 12 oz. in tray.
1056	• Placed tray on floor B. • Rolled B. • Held stick in middle with left hand and 8 in. from back with right hand. • Stood approximately 3 ft. from wall. • Used ribs on tray to prime roller. • Rolled overlapping strokes in 3-ft. up/down motions. • Small drips occasionally when starting to roll. • Made careful light/moderate strokes with roller, looking often to check coverage.
1101	• Moved tray to cart. • Poured 12 oz in tray. • Wiped small drip off hand with rag. • Painted Wall C. • Knelt on floor while rolling lower wall.
1104	• Stirred; filled tray by holding can over tray on floor approximately 12 oz. • Rolled top half of each section, then bottom using 2-3 ft. strokes.
1108	• Rolled Wall D.
1111	• Requested water break by nurse. • Requested to leave room and take break. • Stood in unpainted A/C room. • ME18 stated he felt fine.
1114	• Returned to room and poured remainder of can 1 into tray. • Rolled remainder of Wall D. • Stood with tray near feet. • Small spill at tray. • Wiped with rag.
1120	• Rolled Wall A. • Used foot and roller to slide tray on floor. • Tightened handle to roller. • Knocked roller edge on tray to slide loose cover back on roller.
1124	• Opened can 2 and stirred. • Poured ¼ can into tray.
1126	• Power to lights out and restarted immediately. • Small drips on baseboard A.
1128	• Rolled ceiling A/B with fuller roller. • Paint dripped on ear – ¼ in. drop on lobe of ear near entrance to inner ear. • Nurse wiped off and also wiped forehead. • Drank water. • Painted ceiling B/A using 2-ft. strokes with roller mostly in front of body.
1135	• Power off and back on.

Continued on following page

ME #: 18 *(Continued)*
Date: 01 Jul 16

Time	Observations/Comments
1137	• Rolled ceiling D. • Small drops of paint on face.
1139	• ME18 uses 100% of paint in tray before refilling. • Refilled with only ¼ can. • ME18 leans directly over tray and can when pouring.
1140	• Rolled ceiling B/C.
1141	• Rolled ceiling C. • ME18 re-rolls over areas he believes need more coverage (were painted with a light touch and a dry roller).
1145	• Poured paint from tray into cup using brush to scrape paint.
1146	• Used moderately filled brush to paint baseboard (BB) C. • Painted approximately 12-in. strokes moving backward along floor.
1148	• Brushed BB D.
1150	• Brushed BB A. • ME18's body is approximately 10 in. from BB.
1153	• Brushed BB B.
1155	• Finished first room. • Moved to second room.
1156	• Drank water.
1157	• Poured paint from cup to tray. • Pour ¼ can into tray. • Assembled roller. • Rolled Wall C.
1204	• Refilled. • Approximately ⅛ can remaining.
1205	• Rolled Wall D.
1211	• Finished Wall D.
1212	• Pumps turned off. • ME18 had no visible paint on outer dosimeter. • ME18 stated he felt good.
Summary	Pump Start Time: 1019 Pump Stop Time: 1212

APPENDIX I.

SAMPLE TRACKING TABLE

Sample Tracking Table

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET45	AEA09-BRS-01-PH	Painters Hat	Subject	06/13/2016	06/13/2016	12/09/2016	179
463SET46	AEA09-BRS-01-PH-ID	Painters Hat	Subject	06/13/2016	06/13/2016	12/12/2016	182
463SET33	AEA09-BRS-01-AR	Air Sampling Tube	Subject	06/13/2016	06/13/2016	12/06/2016	176
463SET24	AEA09-BRS-01-RES-01	RespiCon	100 µm	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-BRS-01-RES-02	RespiCon	10 µm	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-BRS-01-RES-03	RespiCon	2.5 µm	06/13/2016	06/13/2016	11/14/2016	154
463SET06	AEA09-BRS-01-HW-01	Hand Wash	Final Rinse	06/13/2016	06/13/2016	10/19/2016	128
463SET15	AEA09-BRS-01-FW-01	Face/Neck Wipe	Final Wipe	06/13/2016	06/13/2016	10/21/2016	130
463SET46	AEA09-BRS-01-ID-UA	Inner Dosimeter	Upper Arm	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-BRS-01-ID-LA	Inner Dosimeter	Lower Arm	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-BRS-01-ID-FT	Inner Dosimeter	Front Torso	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-BRS-01-ID-RT	Inner Dosimeter	Rear Torso	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-BRS-01-ID-UL	Inner Dosimeter	Upper Leg	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-BRS-01-ID-LL	Inner Dosimeter	Lower Leg	06/13/2016	06/13/2016	12/12/2016	182
463SET44	AEA09-BRS-01-OD-UA	Outer Dosimeter	Upper Arm	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-BRS-01-OD-LA	Outer Dosimeter	Lower Arm	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-BRS-01-OD-FT	Outer Dosimeter	Front Torso	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-BRS-01-OD-RT	Outer Dosimeter	Rear Torso	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-BRS-01-OD-UL	Outer Dosimeter	Upper Leg	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-BRS-01-OD-LL	Outer Dosimeter	Lower Leg	06/13/2016	06/13/2016	12/09/2016	179
463SET15	AEA09-BRS-01-SW-01	Sweat Wipe	Final Wipe	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-BRS-01-SW-02	Sweat Wipe	Final Wipe	06/13/2016	06/13/2016	10/21/2016	130
463SET48	AEA09-BRS-02-PH	Painters Hat	Subject	06/15/2016	06/15/2016	12/14/2016	182
NA	AEA09-BRS-02-PH-ID	Painters Hat	Subject	06/15/2016	06/15/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET34	AEA09-BRS-02-AR	Air Sampling Tube	Subject	06/15/2016	06/15/2016	12/06/2016	174
463SET25	AEA09-BRS-02-RES-01	RespiCon	100 µm	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-BRS-02-RES-02	RespiCon	10 µm	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-BRS-02-RES-03	RespiCon	2.5 µm	06/15/2016	06/15/2016	11/14/2016	152
463SET07	AEA09-BRS-02-HW-01	Hand Wash	Final Rinse	06/15/2016	06/15/2016	10/19/2016	126
463SET16	AEA09-BRS-02-FW-01	Face/Neck Wipe	Final Wipe	06/15/2016	06/15/2016	10/21/2016	128
463SET49	AEA09-BRS-02-ID-UA	Inner Dosimeter	Upper Arm	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-02-ID-LA	Inner Dosimeter	Lower Arm	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-02-ID-FT	Inner Dosimeter	Front Torso	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-02-ID-RT	Inner Dosimeter	Rear Torso	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-02-ID-UL	Inner Dosimeter	Upper Leg	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-02-ID-LL	Inner Dosimeter	Lower Leg	06/15/2016	06/15/2016	12/15/2016	183
463SET47	AEA09-BRS-02-OD-UA	Outer Dosimeter	Upper Arm	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-02-OD-LA	Outer Dosimeter	Lower Arm	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-02-OD-FT	Outer Dosimeter	Front Torso	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-02-OD-RT	Outer Dosimeter	Rear Torso	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-02-OD-UL	Outer Dosimeter	Upper Leg	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-02-OD-LL	Outer Dosimeter	Lower Leg	06/15/2016	06/15/2016	12/14/2016	182
463SET16	AEA09-BRS-02-SW-01	Sweat Wipe	Final Wipe	06/15/2016	06/15/2016	10/21/2016	128
463SET48	AEA09-BRS-03-PH	Painters Hat	Subject	06/15/2016	06/15/2016	12/14/2016	182
463SET49	AEA09-BRS-03-PH-ID	Painters Hat	Subject	06/15/2016	06/15/2016	12/15/2016	183
463SET34	AEA09-BRS-03-AR	Air Sampling Tube	Subject	06/15/2016	06/15/2016	12/06/2016	174
463SET25	AEA09-BRS-03-RES-01	RespiCon	100 µm	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-BRS-03-RES-02	RespiCon	10 µm	06/15/2016	06/15/2016	11/14/2016	152

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET25	AEA09-BRS-03-RES-03	RespiCon	2.5 µm	06/15/2016	06/15/2016	11/14/2016	152
463SET07	AEA09-BRS-03-HW-01	Hand Wash	Final Rinse	06/15/2016	06/15/2016	10/19/2016	126
463SET16	AEA09-BRS-03-FW-01	Face/Neck Wipe	Final Wipe	06/15/2016	06/15/2016	10/21/2016	128
463SET49	AEA09-BRS-03-ID-UA	Inner Dosimeter	Upper Arm	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-03-ID-LA	Inner Dosimeter	Lower Arm	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-03-ID-FT	Inner Dosimeter	Front Torso	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-03-ID-RT	Inner Dosimeter	Rear Torso	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-03-ID-UL	Inner Dosimeter	Upper Leg	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-BRS-03-ID-LL	Inner Dosimeter	Lower Leg	06/15/2016	06/15/2016	12/15/2016	183
463SET47	AEA09-BRS-03-OD-UA	Outer Dosimeter	Upper Arm	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-03-OD-LA	Outer Dosimeter	Lower Arm	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-03-OD-FT	Outer Dosimeter	Front Torso	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-03-OD-RT	Outer Dosimeter	Rear Torso	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-03-OD-UL	Outer Dosimeter	Upper Leg	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-BRS-03-OD-LL	Outer Dosimeter	Lower Leg	06/15/2016	06/15/2016	12/14/2016	182
463SET51	AEA09-BRS-04-PH	Painters Hat	Subject	06/17/2016	06/17/2016	12/16/2016	182
463SET52	AEA09-BRS-04-PH-ID	Painters Hat	Subject	06/17/2016	06/17/2016	12/21/2016	187
463SET35	AEA09-BRS-04-AR	Air Sampling Tube	Subject	06/17/2016	06/17/2016	12/06/2016	172
463SET26	AEA09-BRS-04-RES-01	RespiCon	100 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-BRS-04-RES-02	RespiCon	10 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-BRS-04-RES-03	RespiCon	2.5 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET08	AEA09-BRS-04-HW-01	Hand Wash	Final Rinse	06/17/2016	06/17/2016	10/19/2016	124
463SET17	AEA09-BRS-04-FW-01	Face/Neck Wipe	Final Wipe	06/17/2016	06/17/2016	10/28/2016	133
463SET52	AEA09-BRS-04-ID-UA	Inner Dosimeter	Upper Arm	06/17/2016	06/17/2016	12/21/2016	187

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET52	AEA09-BRS-04-ID-LA	Inner Dosimeter	Lower Arm	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-04-ID-FT	Inner Dosimeter	Front Torso	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-04-ID-RT	Inner Dosimeter	Rear Torso	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-04-ID-UL	Inner Dosimeter	Upper Leg	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-04-ID-LL	Inner Dosimeter	Lower Leg	06/17/2016	06/17/2016	12/21/2016	187
463SET50	AEA09-BRS-04-OD-UA	Outer Dosimeter	Upper Arm	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-04-OD-LA	Outer Dosimeter	Lower Arm	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-04-OD-FT	Outer Dosimeter	Front Torso	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-04-OD-RT	Outer Dosimeter	Rear Torso	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-04-OD-UL	Outer Dosimeter	Upper Leg	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-04-OD-LL	Outer Dosimeter	Lower Leg	06/17/2016	06/17/2016	12/16/2016	182
463SET17	AEA09-BRS-04-SW-01	Sweat Wipe	Final Wipe	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-BRS-04-SW-02	Sweat Wipe	Final Wipe	06/17/2016	06/17/2016	10/28/2016	133
463SET51	AEA09-BRS-05-PH	Painters Hat	Subject	06/17/2016	06/17/2016	12/16/2016	182
463SET52	AEA09-BRS-05-PH-ID	Painters Hat	Subject	06/17/2016	06/17/2016	12/21/2016	187
463SET35	AEA09-BRS-05-AR	Air Sampling Tube	Subject	06/17/2016	06/17/2016	12/06/2016	172
463SET26	AEA09-BRS-05-RES-01	RespiCon	100 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-BRS-05-RES-02	RespiCon	10 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-BRS-05-RES-03	RespiCon	2.5 µm	06/17/2016	06/17/2016	11/14/2016	150
463SET08	AEA09-BRS-05-HW-01	Hand Wash	Final Rinse	06/17/2016	06/17/2016	10/19/2016	124
463SET17	AEA09-BRS-05-FW-01	Face/Neck Wipe	Final Wipe	06/17/2016	06/17/2016	10/28/2016	133
463SET52	AEA09-BRS-05-ID-UA	Inner Dosimeter	Upper Arm	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-05-ID-LA	Inner Dosimeter	Lower Arm	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-05-ID-FT	Inner Dosimeter	Front Torso	06/17/2016	06/17/2016	12/21/2016	187

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET52	AEA09-BRS-05-ID-RT	Inner Dosimeter	Rear Torso	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-05-ID-UL	Inner Dosimeter	Upper Leg	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-BRS-05-ID-LL	Inner Dosimeter	Lower Leg	06/17/2016	06/17/2016	12/21/2016	187
463SET50	AEA09-BRS-05-OD-UA	Outer Dosimeter	Upper Arm	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-05-OD-LA	Outer Dosimeter	Lower Arm	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-05-OD-FT	Outer Dosimeter	Front Torso	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-05-OD-RT	Outer Dosimeter	Rear Torso	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-05-OD-UL	Outer Dosimeter	Upper Leg	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-BRS-05-OD-LL	Outer Dosimeter	Lower Leg	06/17/2016	06/17/2016	12/16/2016	182
463SET54	AEA09-BRS-06-PH	Painters Hat	Subject	06/20/2016	06/20/2016	12/21/2016	184
NA	AEA09-BRS-06-PH-ID	Painters Hat	Subject	06/20/2016	06/20/2016	NA	NA
463SET37	AEA09-BRS-06-AR	Air Sampling Tube	Subject	06/20/2016	06/20/2016	12/07/2016	170
463SET27	AEA09-BRS-06-RES-01	RespiCon	100 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-BRS-06-RES-02	RespiCon	10 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-BRS-06-RES-03	RespiCon	2.5 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET09	AEA09-BRS-06-HW-01	Hand Wash	Final Rinse	06/20/2016	06/20/2016	10/20/2016	122
463SET18	AEA09-BRS-06-FW-01	Face/Neck Wipe	Final Wipe	06/20/2016	06/20/2016	10/28/2016	130
463SET55	AEA09-BRS-06-ID-UA	Inner Dosimeter	Upper Arm	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-06-ID-LA	Inner Dosimeter	Lower Arm	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-06-ID-FT	Inner Dosimeter	Front Torso	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-06-ID-RT	Inner Dosimeter	Rear Torso	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-06-ID-UL	Inner Dosimeter	Upper Leg	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-06-ID-LL	Inner Dosimeter	Lower Leg	06/20/2016	06/20/2016	12/27/2016	190
463SET53	AEA09-BRS-06-OD-UA	Outer Dosimeter	Upper Arm	06/20/2016	06/20/2016	12/21/2016	184

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET53	AEA09-BRS-06-OD-LA	Outer Dosimeter	Lower Arm	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-06-OD-FT	Outer Dosimeter	Front Torso	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-06-OD-RT	Outer Dosimeter	Rear Torso	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-06-OD-UL	Outer Dosimeter	Upper Leg	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-06-OD-LL	Outer Dosimeter	Lower Leg	06/20/2016	06/20/2016	12/21/2016	184
463SET18	AEA09-BRS-06-SW-01	Sweat Wipe	Final Wipe	06/20/2016	06/20/2016	10/28/2016	130
463SET54	AEA09-BRS-07-PH	Painters Hat	Subject	06/20/2016	06/20/2016	12/21/2016	184
463SET55	AEA09-BRS-07-PH-ID	Painters Hat	Subject	06/20/2016	06/20/2016	12/27/2016	190
463SET37	AEA09-BRS-07-AR	Air Sampling Tube	Subject	06/20/2016	06/20/2016	12/07/2016	170
463SET27	AEA09-BRS-07-RES-01	RespiCon	100 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-BRS-07-RES-02	RespiCon	10 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-BRS-07-RES-03	RespiCon	2.5 µm	06/20/2016	06/20/2016	11/14/2016	147
463SET09	AEA09-BRS-07-HW-01	Hand Wash	Final Rinse	06/20/2016	06/20/2016	10/20/2016	122
463SET18	AEA09-BRS-07-FW-01	Face/Neck Wipe	Final Wipe	06/20/2016	06/20/2016	10/28/2016	130
463SET55	AEA09-BRS-07-ID-UA	Inner Dosimeter	Upper Arm	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-07-ID-LA	Inner Dosimeter	Lower Arm	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-07-ID-FT	Inner Dosimeter	Front Torso	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-07-ID-RT	Inner Dosimeter	Rear Torso	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-07-ID-UL	Inner Dosimeter	Upper Leg	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-BRS-07-ID-LL	Inner Dosimeter	Lower Leg	06/20/2016	06/20/2016	12/27/2016	190
463SET53	AEA09-BRS-07-OD-UA	Outer Dosimeter	Upper Arm	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-07-OD-LA	Outer Dosimeter	Lower Arm	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-07-OD-FT	Outer Dosimeter	Front Torso	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-07-OD-RT	Outer Dosimeter	Rear Torso	06/20/2016	06/20/2016	12/21/2016	184

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET53	AEA09-BRS-07-OD-UL	Outer Dosimeter	Upper Leg	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-BRS-07-OD-LL	Outer Dosimeter	Lower Leg	06/20/2016	06/20/2016	12/21/2016	184
463SET57	AEA09-BRS-08-PH	Painters Hat	Subject	06/22/2016	06/22/2016	12/27/2016	188
NA	AEA09-BRS-08-PH-ID	Painters Hat	Subject	06/22/2016	06/22/2016	NA	NA
463SET38	AEA09-BRS-08-AR	Air Sampling Tube	Subject	06/22/2016	06/22/2016	12/07/2016	168
463SET28	AEA09-BRS-08-RES-01	RespiCon	100 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-BRS-08-RES-02	RespiCon	10 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-BRS-08-RES-03	RespiCon	2.5 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET10	AEA09-BRS-08-HW-01	Hand Wash	Final Rinse	06/22/2016	06/22/2016	10/20/2016	120
463SET19	AEA09-BRS-08-FW-01	Face/Neck Wipe	Final Wipe	06/22/2016	06/22/2016	11/09/2016	140
463SET60	AEA09-BRS-08-ID-UA	Inner Dosimeter	Upper Arm	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-08-ID-LA	Inner Dosimeter	Lower Arm	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-08-ID-FT	Inner Dosimeter	Front Torso	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-08-ID-RT	Inner Dosimeter	Rear Torso	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-08-ID-UL	Inner Dosimeter	Upper Leg	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-08-ID-LL	Inner Dosimeter	Lower Leg	06/22/2016	06/22/2016	12/29/2016	190
463SET56	AEA09-BRS-08-OD-UA	Outer Dosimeter	Upper Arm	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-08-OD-LA	Outer Dosimeter	Lower Arm	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-08-OD-FT	Outer Dosimeter	Front Torso	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-08-OD-RT	Outer Dosimeter	Rear Torso	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-08-OD-UL	Outer Dosimeter	Upper Leg	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-08-OD-LL	Outer Dosimeter	Lower Leg	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-BRS-09-PH	Painters Hat	Subject	06/22/2016	06/22/2016	12/27/2016	188
NA	AEA09-BRS-09-PH-ID	Painters Hat	Subject	06/22/2016	06/22/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET38	AEA09-BRS-09-AR	Air Sampling Tube	Subject	06/22/2016	06/22/2016	12/07/2016	168
463SET28	AEA09-BRS-09-RES-01	RespiCon	100 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-BRS-09-RES-02	RespiCon	10 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-BRS-09-RES-03	RespiCon	2.5 µm	06/22/2016	06/22/2016	11/16/2016	147
463SET10	AEA09-BRS-09-HW-01	Hand Wash	Final Rinse	06/22/2016	06/22/2016	10/20/2016	120
463SET19	AEA09-BRS-09-FW-01	Face/Neck Wipe	Final Wipe	06/22/2016	06/22/2016	11/09/2016	140
463SET60	AEA09-BRS-09-ID-UA	Inner Dosimeter	Upper Arm	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-09-ID-LA	Inner Dosimeter	Lower Arm	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-09-ID-FT	Inner Dosimeter	Front Torso	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-09-ID-RT	Inner Dosimeter	Rear Torso	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-09-ID-UL	Inner Dosimeter	Upper Leg	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-BRS-09-ID-LL	Inner Dosimeter	Lower Leg	06/22/2016	06/22/2016	12/29/2016	190
463SET56	AEA09-BRS-09-OD-UA	Outer Dosimeter	Upper Arm	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-09-OD-LA	Outer Dosimeter	Lower Arm	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-09-OD-FT	Outer Dosimeter	Front Torso	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-09-OD-RT	Outer Dosimeter	Rear Torso	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-09-OD-UL	Outer Dosimeter	Upper Leg	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-BRS-09-OD-LL	Outer Dosimeter	Lower Leg	06/22/2016	06/22/2016	12/27/2016	188
463SET59	AEA09-BRS-10-PH	Painters Hat	Subject	06/24/2016	06/24/2016	12/28/2016	187
463SET63	AEA09-BRS-10-PH-ID	Painters Hat	Subject	06/24/2016	06/24/2016	01/03/2017	193
463SET39	AEA09-BRS-10-AR	Air Sampling Tube	Subject	06/24/2016	06/24/2016	12/07/2016	166
463SET29	AEA09-BRS-10-RES-01	RespiCon	100 µm	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-BRS-10-RES-02	RespiCon	10 µm	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-BRS-10-RES-03	RespiCon	2.5 µm	06/24/2016	06/24/2016	11/16/2016	145

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET11	AEA09-BRS-10-HW-01	Hand Wash	Final Rinse	06/24/2016	06/24/2016	10/20/2016	118
463SET20	AEA09-BRS-10-FW-01	Face/Neck Wipe	Final Wipe	06/24/2016	06/24/2016	11/09/2016	138
463SET63	AEA09-BRS-10-ID-UA	Inner Dosimeter	Upper Arm	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-10-ID-LA	Inner Dosimeter	Lower Arm	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-10-ID-FT	Inner Dosimeter	Front Torso	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-10-ID-RT	Inner Dosimeter	Rear Torso	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-10-ID-UL	Inner Dosimeter	Upper Leg	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-10-ID-LL	Inner Dosimeter	Lower Leg	06/24/2016	06/24/2016	01/03/2017	193
463SET58	AEA09-BRS-10-OD-UA	Outer Dosimeter	Upper Arm	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-10-OD-LA	Outer Dosimeter	Lower Arm	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-10-OD-FT	Outer Dosimeter	Front Torso	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-10-OD-RT	Outer Dosimeter	Rear Torso	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-10-OD-UL	Outer Dosimeter	Upper Leg	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-10-OD-LL	Outer Dosimeter	Lower Leg	06/24/2016	06/24/2016	12/28/2016	187
463SET20	AEA09-BRS-10-SW-01	Sweat Wipe	Final Wipe	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-BRS-10-SW-02	Sweat Wipe	Final Wipe	06/24/2016	06/24/2016	11/09/2016	138
463SET59	AEA09-BRS-11-PH	Painters Hat	Subject	06/24/2016	06/24/2016	12/28/2016	187
463SET63	AEA09-BRS-11-PH-ID	Painters Hat	Subject	06/24/2016	06/24/2016	01/03/2017	193
463SET39	AEA09-BRS-11-AR	Air Sampling Tube	Subject	06/24/2016	06/24/2016	12/07/2016	166
463SET29	AEA09-BRS-11-RES-01	RespiCon	100 µm	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-BRS-11-RES-02	RespiCon	10 µm	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-BRS-11-RES-03	RespiCon	2.5 µm	06/24/2016	06/24/2016	11/16/2016	145
463SET11	AEA09-BRS-11-HW-01	Hand Wash	Final Rinse	06/24/2016	06/24/2016	10/20/2016	118
463SET20	AEA09-BRS-11-FW-01	Face/Neck Wipe	Final Wipe	06/24/2016	06/24/2016	11/09/2016	138

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET63	AEA09-BRS-11-ID-UA	Inner Dosimeter	Upper Arm	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-11-ID-LA	Inner Dosimeter	Lower Arm	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-11-ID-FT	Inner Dosimeter	Front Torso	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-11-ID-RT	Inner Dosimeter	Rear Torso	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-11-ID-UL	Inner Dosimeter	Upper Leg	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-BRS-11-ID-LL	Inner Dosimeter	Lower Leg	06/24/2016	06/24/2016	01/03/2017	193
463SET58	AEA09-BRS-11-OD-UA	Outer Dosimeter	Upper Arm	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-11-OD-LA	Outer Dosimeter	Lower Arm	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-11-OD-FT	Outer Dosimeter	Front Torso	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-11-OD-RT	Outer Dosimeter	Rear Torso	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-11-OD-UL	Outer Dosimeter	Upper Leg	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-BRS-11-OD-LL	Outer Dosimeter	Lower Leg	06/24/2016	06/24/2016	12/28/2016	187
463SET20	AEA09-BRS-11-SW-01	Sweat Wipe	Final Wipe	06/24/2016	06/24/2016	11/09/2016	138
463SET62	AEA09-BRS-12-PH	Painters Hat	Subject	06/27/2016	06/27/2016	12/29/2016	185
463SET64	AEA09-BRS-12-PH-ID	Painters Hat	Subject	06/27/2016	06/27/2016	01/03/2017	190
463SET40	AEA09-BRS-12-AR	Air Sampling Tube	Subject	06/27/2016	06/27/2016	12/07/2016	163
463SET30	AEA09-BRS-12-RES-01	RespiCon	100 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-BRS-12-RES-02	RespiCon	10 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-BRS-12-RES-03	RespiCon	2.5 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET12	AEA09-BRS-12-HW-01	Hand Wash	Final Rinse	06/27/2016	06/27/2016	10/20/2016	115
463SET21	AEA09-BRS-12-FW-01	Face/Neck Wipe	Final Wipe	06/27/2016	06/27/2016	11/10/2016	136
463SET64	AEA09-BRS-12-ID-UA	Inner Dosimeter	Upper Arm	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-12-ID-LA	Inner Dosimeter	Lower Arm	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-12-ID-FT	Inner Dosimeter	Front Torso	06/27/2016	06/27/2016	01/03/2017	190

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET64	AEA09-BRS-12-ID-RT	Inner Dosimeter	Rear Torso	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-12-ID-UL	Inner Dosimeter	Upper Leg	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-12-ID-LL	Inner Dosimeter	Lower Leg	06/27/2016	06/27/2016	01/03/2017	190
463SET61	AEA09-BRS-12-OD-UA	Outer Dosimeter	Upper Arm	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-12-OD-LA	Outer Dosimeter	Lower Arm	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-12-OD-FT	Outer Dosimeter	Front Torso	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-12-OD-RT	Outer Dosimeter	Rear Torso	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-12-OD-UL	Outer Dosimeter	Upper Leg	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-12-OD-LL	Outer Dosimeter	Lower Leg	06/27/2016	06/27/2016	12/29/2016	185
463SET21	AEA09-BRS-12-SW-01	Sweat Wipe	Final Wipe	06/27/2016	06/27/2016	11/10/2016	136
463SET62	AEA09-BRS-13-PH	Painters Hat	Subject	06/27/2016	06/27/2016	12/29/2016	185
463SET64	AEA09-BRS-13-PH-ID	Painters Hat	Subject	06/27/2016	06/27/2016	01/03/2017	190
463SET40	AEA09-BRS-13-AR	Air Sampling Tube	Subject	06/27/2016	06/27/2016	12/07/2016	163
463SET30	AEA09-BRS-13-RES-01	RespiCon	100 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-BRS-13-RES-02	RespiCon	10 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-BRS-13-RES-03	RespiCon	2.5 µm	06/27/2016	06/27/2016	11/16/2016	142
463SET12	AEA09-BRS-13-HW-01	Hand Wash	Final Rinse	06/27/2016	06/27/2016	10/20/2016	115
463SET21	AEA09-BRS-13-FW-01	Face/Neck Wipe	Final Wipe	06/27/2016	06/27/2016	11/10/2016	136
463SET64	AEA09-BRS-13-ID-UA	Inner Dosimeter	Upper Arm	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-13-ID-LA	Inner Dosimeter	Lower Arm	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-13-ID-FT	Inner Dosimeter	Front Torso	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-13-ID-RT	Inner Dosimeter	Rear Torso	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-13-ID-UL	Inner Dosimeter	Upper Leg	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-BRS-13-ID-LL	Inner Dosimeter	Lower Leg	06/27/2016	06/27/2016	01/03/2017	190

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET61	AEA09-BRS-13-OD-UA	Outer Dosimeter	Upper Arm	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-13-OD-LA	Outer Dosimeter	Lower Arm	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-13-OD-FT	Outer Dosimeter	Front Torso	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-13-OD-RT	Outer Dosimeter	Rear Torso	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-13-OD-UL	Outer Dosimeter	Upper Leg	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-BRS-13-OD-LL	Outer Dosimeter	Lower Leg	06/27/2016	06/27/2016	12/29/2016	185
463SET21	AEA09-BRS-13-SW-01	Sweat Wipe	Final Wipe	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-BRS-13-SW-02	Sweat Wipe	Final Wipe	06/27/2016	06/27/2016	11/10/2016	136
463SET66	AEA09-BRS-14-PH	Painters Hat	Subject	06/29/2016	06/29/2016	01/04/2017	189
463SET71	AEA09-BRS-14-PH-ID	Painters Hat	Subject	06/29/2016	06/29/2016	01/16/2017	201
463SET41	AEA09-BRS-14-AR	Air Sampling Tube	Subject	06/29/2016	06/29/2016	12/07/2016	161
463SET31	AEA09-BRS-14-RES-01	RespiCon	100 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-BRS-14-RES-02	RespiCon	10 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-BRS-14-RES-03	RespiCon	2.5 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET13	AEA09-BRS-14-HW-01	Hand Wash	Final Rinse	06/29/2016	06/29/2016	10/21/2016	114
463SET22	AEA09-BRS-14-FW-01	Face/Neck Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET71	AEA09-BRS-14-ID-UA	Inner Dosimeter	Upper Arm	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-14-ID-LA	Inner Dosimeter	Lower Arm	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-14-ID-FT	Inner Dosimeter	Front Torso	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-14-ID-RT	Inner Dosimeter	Rear Torso	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-14-ID-UL	Inner Dosimeter	Upper Leg	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-14-ID-LL	Inner Dosimeter	Lower Leg	06/29/2016	06/29/2016	01/16/2017	201
463SET65	AEA09-BRS-14-OD-UA	Outer Dosimeter	Upper Arm	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-14-OD-LA	Outer Dosimeter	Lower Arm	06/29/2016	06/29/2016	01/04/2017	189

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET65	AEA09-BRS-14-OD-FT	Outer Dosimeter	Front Torso	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-14-OD-RT	Outer Dosimeter	Rear Torso	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-14-OD-UL	Outer Dosimeter	Upper Leg	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-14-OD-LL	Outer Dosimeter	Lower Leg	06/29/2016	06/29/2016	01/04/2017	189
463SET22	AEA09-BRS-14-SW-01	Sweat Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-BRS-14-SW-02	Sweat Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-BRS-14-SW-03	Sweat Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET66	AEA09-BRS-15-PH	Painters Hat	Subject	06/29/2016	06/29/2016	01/04/2017	189
463SET71	AEA09-BRS-15-PH-ID	Painters Hat	Subject	06/29/2016	06/29/2016	01/16/2017	201
463SET41	AEA09-BRS-15-AR	Air Sampling Tube	Subject	06/29/2016	06/29/2016	12/07/2016	161
463SET31	AEA09-BRS-15-RES-01	RespiCon	100 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-BRS-15-RES-02	RespiCon	10 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-BRS-15-RES-03	RespiCon	2.5 µm	06/29/2016	06/29/2016	11/16/2016	140
463SET13	AEA09-BRS-15-HW-01	Hand Wash	Final Rinse	06/29/2016	06/29/2016	10/21/2016	114
463SET22	AEA09-BRS-15-FW-01	Face/Neck Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET71	AEA09-BRS-15-ID-UA	Inner Dosimeter	Upper Arm	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-15-ID-LA	Inner Dosimeter	Lower Arm	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-15-ID-FT	Inner Dosimeter	Front Torso	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-15-ID-RT	Inner Dosimeter	Rear Torso	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-15-ID-UL	Inner Dosimeter	Upper Leg	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-BRS-15-ID-LL	Inner Dosimeter	Lower Leg	06/29/2016	06/29/2016	01/16/2017	201
463SET65	AEA09-BRS-15-OD-UA	Outer Dosimeter	Upper Arm	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-15-OD-LA	Outer Dosimeter	Lower Arm	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-15-OD-FT	Outer Dosimeter	Front Torso	06/29/2016	06/29/2016	01/04/2017	189

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET65	AEA09-BRS-15-OD-RT	Outer Dosimeter	Rear Torso	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-15-OD-UL	Outer Dosimeter	Upper Leg	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-BRS-15-OD-LL	Outer Dosimeter	Lower Leg	06/29/2016	06/29/2016	01/04/2017	189
463SET22	AEA09-BRS-15-SW-01	Sweat Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-BRS-15-SW-02	Sweat Wipe	Final Wipe	06/29/2016	06/29/2016	11/10/2016	134
463SET69	AEA09-BRS-16-PH	Painters Hat	Subject	07/01/2016	07/01/2016	01/11/2017	194
463SET72	AEA09-BRS-16-PH-ID	Painters Hat	Subject	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-BRS-16-AR	Air Sampling Tube	Subject	07/01/2016	07/01/2016	01/16/2017	199
463SET32	AEA09-BRS-16-RES-01	RespiCon	100 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-16-RES-02	RespiCon	10 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-16-RES-03	RespiCon	2.5 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET14	AEA09-BRS-16-HW-01	Hand Wash	Final Rinse	07/01/2016	07/01/2016	11/09/2016	131
463SET23	AEA09-BRS-16-FW-01	Face/Neck Wipe	Final Wipe	07/01/2016	07/01/2016	11/10/2016	132
463SET72	AEA09-BRS-16-ID-UA	Inner Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-16-ID-LA	Inner Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-16-ID-FT	Inner Dosimeter	Front Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-16-ID-RT	Inner Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-16-ID-UL	Inner Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-16-ID-LL	Inner Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET67	AEA09-BRS-16-OD-UA	Outer Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-16-OD-LA	Outer Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-16-OD-FT	Outer Dosimeter	Front Torso	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-16-OD-RT	Outer Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-16-OD-UL	Outer Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/11/2017	194

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET67	AEA09-BRS-16-OD-LL	Outer Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-BRS-17-PH	Painters Hat	Subject	07/01/2016	07/01/2016	01/11/2017	194
463SET72	AEA09-BRS-17-PH-ID	Painters Hat	Subject	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-BRS-17-AR	Air Sampling Tube	Subject	07/01/2016	07/01/2016	01/16/2017	199
463SET32	AEA09-BRS-17-RES-01	RespiCon	100 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-17-RES-02	RespiCon	10 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-17-RES-03	RespiCon	2.5 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET14	AEA09-BRS-17-HW-01	Hand Wash	Final Rinse	07/01/2016	07/01/2016	11/09/2016	131
463SET23	AEA09-BRS-17-FW-01	Face/Neck Wipe	Final Wipe	07/01/2016	07/01/2016	11/10/2016	132
463SET72	AEA09-BRS-17-ID-UA	Inner Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-17-ID-LA	Inner Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-17-ID-FT	Inner Dosimeter	Front Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-17-ID-RT	Inner Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-17-ID-UL	Inner Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-BRS-17-ID-LL	Inner Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET67	AEA09-BRS-17-OD-UA	Outer Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-17-OD-LA	Outer Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-17-OD-FT	Outer Dosimeter	Front Torso	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-17-OD-RT	Outer Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-17-OD-UL	Outer Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-BRS-17-OD-LL	Outer Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-BRS-18-PH	Painters Hat	Subject	07/01/2016	07/01/2016	01/11/2017	194
NA	AEA09-BRS-18-PH-ID	Painters Hat	Subject	07/01/2016	07/01/2016	NA	NA
463SET70	AEA09-BRS-18-AR	Air Sampling Tube	Subject	07/01/2016	07/01/2016	01/16/2017	199

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET32	AEA09-BRS-18-RES-01	RespiCon	100 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-18-RES-02	RespiCon	10 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-BRS-18-RES-03	RespiCon	2.5 µm	07/01/2016	07/01/2016	11/16/2016	138
463SET14	AEA09-BRS-18-HW-01	Hand Wash	Final Rinse	07/01/2016	07/01/2016	11/09/2016	131
463SET23	AEA09-BRS-18-FW-01	Face/Neck Wipe	Final Wipe	07/01/2016	07/01/2016	11/10/2016	132
463SET73	AEA09-BRS-18-ID-UA	Inner Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/25/2017	208
463SET73	AEA09-BRS-18-ID-LA	Inner Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/25/2017	208
463SET73	AEA09-BRS-18-ID-FT	Inner Dosimeter	Front Torso	07/01/2016	07/01/2016	01/25/2017	208
463SET73	AEA09-BRS-18-ID-RT	Inner Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/25/2017	208
463SET73	AEA09-BRS-18-ID-UL	Inner Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/25/2017	208
463SET73	AEA09-BRS-18-ID-LL	Inner Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/25/2017	208
463SET68	AEA09-BRS-18-OD-UA	Outer Dosimeter	Upper Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET68	AEA09-BRS-18-OD-LA	Outer Dosimeter	Lower Arm	07/01/2016	07/01/2016	01/16/2017	199
463SET68	AEA09-BRS-18-OD-FT	Outer Dosimeter	Front Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET68	AEA09-BRS-18-OD-RT	Outer Dosimeter	Rear Torso	07/01/2016	07/01/2016	01/16/2017	199
463SET68	AEA09-BRS-18-OD-UL	Outer Dosimeter	Upper Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET68	AEA09-BRS-18-OD-LL	Outer Dosimeter	Lower Leg	07/01/2016	07/01/2016	01/16/2017	199
463SET23	AEA09-BRS-18-SW-01	Sweat Wipe	Final Wipe	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-BRS-18-SW-02	Sweat Wipe	Final Wipe	07/01/2016	07/01/2016	11/10/2016	132
463SET45	AEA09-FF-01-PH-C1	Painters Hat	Field Control	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-C2	Painters Hat	Field Control	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-L1	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-L2	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-L3	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET45	AEA09-FF-01-PH-H1	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-H2	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET45	AEA09-FF-01-PH-H3	Painters Hat	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET33	AEA09-FF-01-AR-C1	Air Sampling Tube	Field Control	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-C2	Air Sampling Tube	Field Control	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-L1	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-L2	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-L3	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-H1	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-H2	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET33	AEA09-FF-01-AR-H3	Air Sampling Tube	Field Fortification	06/13/2016	06/13/2016	12/06/2016	176
463SET24	AEA09-FF-01-RES-C1	RespiCon	Field Control	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-C2	RespiCon	Field Control	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-L1	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-L2	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-L3	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-H1	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-H2	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET24	AEA09-FF-01-RES-H3	RespiCon	Field Fortification	06/13/2016	06/13/2016	11/14/2016	154
463SET06	AEA09-FF-01-HW-C1	Hand Wash	Field Control	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-C2	Hand Wash	Field Control	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-L1	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-L2	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-L3	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET06	AEA09-FF-01-HW-H1	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-H2	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128
463SET06	AEA09-FF-01-HW-H3	Hand Wash	Field Fortification	06/13/2016	06/13/2016	10/19/2016	128
463SET15	AEA09-FF-01-FW-C1	Face/Neck Wipe	Field Control	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-C2	Face/Neck Wipe	Field Control	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-L1	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-L2	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-L3	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-H1	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-H2	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET15	AEA09-FF-01-FW-H3	Face/Neck Wipe	Field Fortification	06/13/2016	06/13/2016	10/21/2016	130
463SET46	AEA09-FF-01-ID-C1	Inner Dosimeter	Field Control	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-C2	Inner Dosimeter	Field Control	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-L1	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-L2	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-L3	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-H1	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-H2	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET46	AEA09-FF-01-ID-H3	Inner Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/12/2016	182
463SET44	AEA09-FF-01-OD-C1	Outer Dosimeter	Field Control	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-C2	Outer Dosimeter	Field Control	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-L1	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-L2	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-L3	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET44	AEA09-FF-01-OD-H1	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-H2	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
463SET44	AEA09-FF-01-OD-H3	Outer Dosimeter	Field Fortification	06/13/2016	06/13/2016	12/09/2016	179
NA	AEA09-FF-01-PH-T1	Painters Hat	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-PH-T2	Painters Hat	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-AR-T1	Air Sampling Tube	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-AR-T2	Air Sampling Tube	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-ID-T1	Inner Dosimeter	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-ID-T2	Inner Dosimeter	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-OD-T1	Outer Dosimeter	Travel Spike	06/13/2016	06/13/2016	NA	NA
NA	AEA09-FF-01-OD-T2	Outer Dosimeter	Travel Spike	06/13/2016	06/13/2016	NA	NA
463SET48	AEA09-FF-02-PH-C1	Painters Hat	Field Control	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-C2	Painters Hat	Field Control	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-L1	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-L2	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-L3	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-H1	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-H2	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET48	AEA09-FF-02-PH-H3	Painters Hat	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET34	AEA09-FF-02-AR-C1	Air Sampling Tube	Field Control	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-C2	Air Sampling Tube	Field Control	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-L1	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-L2	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-L3	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET34	AEA09-FF-02-AR-H1	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-H2	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174
463SET34	AEA09-FF-02-AR-H3	Air Sampling Tube	Field Fortification	06/15/2016	06/15/2016	12/06/2016	174
463SET25	AEA09-FF-02-RES-C1	RespiCon	Field Control	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-C2	RespiCon	Field Control	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-L1	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-L2	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-L3	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-H1	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-H2	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET25	AEA09-FF-02-RES-H3	RespiCon	Field Fortification	06/15/2016	06/15/2016	11/14/2016	152
463SET07	AEA09-FF-02-HW-C1	Hand Wash	Field Control	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-C2	Hand Wash	Field Control	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-L1	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-L2	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-L3	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-H1	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-H2	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET07	AEA09-FF-02-HW-H3	Hand Wash	Field Fortification	06/15/2016	06/15/2016	10/19/2016	126
463SET16	AEA09-FF-02-FW-C1	Face/Neck Wipe	Field Control	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-C2	Face/Neck Wipe	Field Control	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-L1	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-L2	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-L3	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET16	AEA09-FF-02-FW-H1	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-H2	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128
463SET16	AEA09-FF-02-FW-H3	Face/Neck Wipe	Field Fortification	06/15/2016	06/15/2016	10/21/2016	128
463SET49	AEA09-FF-02-ID-C1	Inner Dosimeter	Field Control	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-C2	Inner Dosimeter	Field Control	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-L1	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-L2	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-L3	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-H1	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-H2	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET49	AEA09-FF-02-ID-H3	Inner Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/15/2016	183
463SET47	AEA09-FF-02-OD-C1	Outer Dosimeter	Field Control	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-C2	Outer Dosimeter	Field Control	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-L1	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-L2	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-L3	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-H1	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-H2	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
463SET47	AEA09-FF-02-OD-H3	Outer Dosimeter	Field Fortification	06/15/2016	06/15/2016	12/14/2016	182
NA	AEA09-FF-02-PH-T1	Painters Hat	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-PH-T2	Painters Hat	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-AR-T1	Air Sampling Tube	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-AR-T2	Air Sampling Tube	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-ID-T1	Inner Dosimeter	Travel Spike	06/15/2016	06/15/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-FF-02-ID-T2	Inner Dosimeter	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-OD-T1	Outer Dosimeter	Travel Spike	06/15/2016	06/15/2016	NA	NA
NA	AEA09-FF-02-OD-T2	Outer Dosimeter	Travel Spike	06/15/2016	06/15/2016	NA	NA
463SET51	AEA09-FF-03-PH-C1	Painters Hat	Field Control	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-C2	Painters Hat	Field Control	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-L1	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-L2	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-L3	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-H1	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-H2	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET51	AEA09-FF-03-PH-H3	Painters Hat	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET35	AEA09-FF-03-AR-C1	Air Sampling Tube	Field Control	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-C2	Air Sampling Tube	Field Control	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-L1	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-L2	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-L3	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-H1	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-H2	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET35	AEA09-FF-03-AR-H3	Air Sampling Tube	Field Fortification	06/17/2016	06/17/2016	12/06/2016	172
463SET26	AEA09-FF-03-RES-C1	RespiCon	Field Control	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-C2	RespiCon	Field Control	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-L1	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-L2	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-L3	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-H1	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET26	AEA09-FF-03-RES-H2	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150
463SET26	AEA09-FF-03-RES-H3	RespiCon	Field Fortification	06/17/2016	06/17/2016	11/14/2016	150
463SET08	AEA09-FF-03-HW-C1	Hand Wash	Field Control	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-C2	Hand Wash	Field Control	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-L1	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-L2	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-L3	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-H1	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-H2	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET08	AEA09-FF-03-HW-H3	Hand Wash	Field Fortification	06/17/2016	06/17/2016	10/19/2016	124
463SET17	AEA09-FF-03-FW-C1	Face/Neck Wipe	Field Control	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-C2	Face/Neck Wipe	Field Control	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-L1	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-L2	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-L3	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-H1	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-H2	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET17	AEA09-FF-03-FW-H3	Face/Neck Wipe	Field Fortification	06/17/2016	06/17/2016	10/28/2016	133
463SET52	AEA09-FF-03-ID-C1	Inner Dosimeter	Field Control	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-C2	Inner Dosimeter	Field Control	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-L1	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-L2	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-L3	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-H1	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET52	AEA09-FF-03-ID-H2	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187
463SET52	AEA09-FF-03-ID-H3	Inner Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/21/2016	187
463SET50	AEA09-FF-03-OD-C1	Outer Dosimeter	Field Control	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-C2	Outer Dosimeter	Field Control	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-L1	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-L2	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-L3	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-H1	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-H2	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
463SET50	AEA09-FF-03-OD-H3	Outer Dosimeter	Field Fortification	06/17/2016	06/17/2016	12/16/2016	182
NA	AEA09-FF-03-PH-T1	Painters Hat	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-PH-T2	Painters Hat	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-AR-T1	Air Sampling Tube	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-AR-T2	Air Sampling Tube	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-ID-T1	Inner Dosimeter	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-ID-T2	Inner Dosimeter	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-OD-T1	Outer Dosimeter	Travel Spike	06/17/2016	06/17/2016	NA	NA
NA	AEA09-FF-03-OD-T2	Outer Dosimeter	Travel Spike	06/17/2016	06/17/2016	NA	NA
463SET54	AEA09-FF-04-PH-C1	Painters Hat	Field Control	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-C2	Painters Hat	Field Control	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-L1	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-L2	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-L3	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-H1	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET54	AEA09-FF-04-PH-H2	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET54	AEA09-FF-04-PH-H3	Painters Hat	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET37	AEA09-FF-04-AR-C1	Air Sampling Tube	Field Control	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-C2	Air Sampling Tube	Field Control	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-L1	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-L2	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-L3	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-H1	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-H2	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET37	AEA09-FF-04-AR-H3	Air Sampling Tube	Field Fortification	06/20/2016	06/20/2016	12/07/2016	170
463SET27	AEA09-FF-04-RES-C1	RespiCon	Field Control	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-C2	RespiCon	Field Control	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-L1	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-L2	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-L3	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-H1	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-H2	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET27	AEA09-FF-04-RES-H3	RespiCon	Field Fortification	06/20/2016	06/20/2016	11/14/2016	147
463SET09	AEA09-FF-04-HW-C1	Hand Wash	Field Control	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-C2	Hand Wash	Field Control	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-L1	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-L2	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-L3	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-H1	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET09	AEA09-FF-04-HW-H2	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122
463SET09	AEA09-FF-04-HW-H3	Hand Wash	Field Fortification	06/20/2016	06/20/2016	10/20/2016	122
463SET18	AEA09-FF-04-FW-C1	Face/Neck Wipe	Field Control	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-C2	Face/Neck Wipe	Field Control	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-L1	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-L2	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-L3	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-H1	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-H2	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET18	AEA09-FF-04-FW-H3	Face/Neck Wipe	Field Fortification	06/20/2016	06/20/2016	10/28/2016	130
463SET55	AEA09-FF-04-ID-C1	Inner Dosimeter	Field Control	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-C2	Inner Dosimeter	Field Control	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-L1	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-L2	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-L3	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-H1	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-H2	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET55	AEA09-FF-04-ID-H3	Inner Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/27/2016	190
463SET53	AEA09-FF-04-OD-C1	Outer Dosimeter	Field Control	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-C2	Outer Dosimeter	Field Control	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-L1	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-L2	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-L3	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-H1	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET53	AEA09-FF-04-OD-H2	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
463SET53	AEA09-FF-04-OD-H3	Outer Dosimeter	Field Fortification	06/20/2016	06/20/2016	12/21/2016	184
NA	AEA09-FF-04-PH-T1	Painters Hat	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-PH-T2	Painters Hat	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-AR-T1	Air Sampling Tube	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-AR-T2	Air Sampling Tube	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-ID-T1	Inner Dosimeter	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-ID-T2	Inner Dosimeter	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-OD-T1	Outer Dosimeter	Travel Spike	06/20/2016	06/20/2016	NA	NA
NA	AEA09-FF-04-OD-T2	Outer Dosimeter	Travel Spike	06/20/2016	06/20/2016	NA	NA
463SET57	AEA09-FF-05-PH-C1	Painters Hat	Field Control	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-C2	Painters Hat	Field Control	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-L1	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-L2	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-L3	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-H1	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-H2	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET57	AEA09-FF-05-PH-H3	Painters Hat	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET38	AEA09-FF-05-AR-C1	Air Sampling Tube	Field Control	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-C2	Air Sampling Tube	Field Control	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-L1	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-L2	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-L3	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-H1	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET38	AEA09-FF-05-AR-H2	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168
463SET38	AEA09-FF-05-AR-H3	Air Sampling Tube	Field Fortification	06/22/2016	06/22/2016	12/07/2016	168
463SET28	AEA09-FF-05-RES-C1	RespiCon	Field Control	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-C2	RespiCon	Field Control	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-L1	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-L2	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-L3	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-H1	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-H2	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET28	AEA09-FF-05-RES-H3	RespiCon	Field Fortification	06/22/2016	06/22/2016	11/16/2016	147
463SET10	AEA09-FF-05-HW-C1	Hand Wash	Field Control	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-C2	Hand Wash	Field Control	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-L1	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-L2	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-L3	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-H1	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-H2	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET10	AEA09-FF-05-HW-H3	Hand Wash	Field Fortification	06/22/2016	06/22/2016	10/20/2016	120
463SET19	AEA09-FF-05-FW-C1	Face/Neck Wipe	Field Control	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-C2	Face/Neck Wipe	Field Control	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-L1	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-L2	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-L3	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-H1	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET19	AEA09-FF-05-FW-H2	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140
463SET19	AEA09-FF-05-FW-H3	Face/Neck Wipe	Field Fortification	06/22/2016	06/22/2016	11/09/2016	140
463SET60	AEA09-FF-05-ID-C1	Inner Dosimeter	Field Control	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-C2	Inner Dosimeter	Field Control	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-L1	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-L2	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-L3	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-H1	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-H2	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET60	AEA09-FF-05-ID-H3	Inner Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/29/2016	190
463SET56	AEA09-FF-05-OD-C1	Outer Dosimeter	Field Control	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-C2	Outer Dosimeter	Field Control	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-L1	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-L2	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-L3	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-H1	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-H2	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
463SET56	AEA09-FF-05-OD-H3	Outer Dosimeter	Field Fortification	06/22/2016	06/22/2016	12/27/2016	188
NA	AEA09-FF-05-PH-T1	Painters Hat	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-PH-T2	Painters Hat	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-AR-T1	Air Sampling Tube	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-AR-T2	Air Sampling Tube	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-ID-T1	Inner Dosimeter	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-ID-T2	Inner Dosimeter	Travel Spike	06/22/2016	06/22/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-FF-05-OD-T1	Outer Dosimeter	Travel Spike	06/22/2016	06/22/2016	NA	NA
NA	AEA09-FF-05-OD-T2	Outer Dosimeter	Travel Spike	06/22/2016	06/22/2016	NA	NA
463SET59	AEA09-FF-06-PH-C1	Painters Hat	Field Control	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-C2	Painters Hat	Field Control	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-L1	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-L2	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-L3	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-H1	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-H2	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET59	AEA09-FF-06-PH-H3	Painters Hat	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET39	AEA09-FF-06-AR-C1	Air Sampling Tube	Field Control	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-C2	Air Sampling Tube	Field Control	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-L1	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-L2	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-L3	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-H1	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-H2	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET39	AEA09-FF-06-AR-H3	Air Sampling Tube	Field Fortification	06/24/2016	06/24/2016	12/07/2016	166
463SET29	AEA09-FF-06-RES-C1	RespiCon	Field Control	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-C2	RespiCon	Field Control	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-L1	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-L2	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-L3	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-H1	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET29	AEA09-FF-06-RES-H2	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145
463SET29	AEA09-FF-06-RES-H3	RespiCon	Field Fortification	06/24/2016	06/24/2016	11/16/2016	145
463SET11	AEA09-FF-06-HW-C1	Hand Wash	Field Control	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-C2	Hand Wash	Field Control	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-L1	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-L2	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-L3	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-H1	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-H2	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET11	AEA09-FF-06-HW-H3	Hand Wash	Field Fortification	06/24/2016	06/24/2016	10/20/2016	118
463SET20	AEA09-FF-06-FW-C1	Face/Neck Wipe	Field Control	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-C2	Face/Neck Wipe	Field Control	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-L1	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-L2	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-L3	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-H1	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-H2	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET20	AEA09-FF-06-FW-H3	Face/Neck Wipe	Field Fortification	06/24/2016	06/24/2016	11/09/2016	138
463SET63	AEA09-FF-06-ID-C1	Inner Dosimeter	Field Control	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-C2	Inner Dosimeter	Field Control	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-L1	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-L2	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-L3	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-H1	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET63	AEA09-FF-06-ID-H2	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193
463SET63	AEA09-FF-06-ID-H3	Inner Dosimeter	Field Fortification	06/24/2016	06/24/2016	01/03/2017	193
463SET58	AEA09-FF-06-OD-C1	Outer Dosimeter	Field Control	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-C2	Outer Dosimeter	Field Control	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-L1	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-L2	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-L3	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-H1	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-H2	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
463SET58	AEA09-FF-06-OD-H3	Outer Dosimeter	Field Fortification	06/24/2016	06/24/2016	12/28/2016	187
NA	AEA09-FF-06-PH-T1	Painters Hat	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-PH-T2	Painters Hat	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-AR-T1	Air Sampling Tube	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-AR-T2	Air Sampling Tube	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-ID-T1	Inner Dosimeter	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-ID-T2	Inner Dosimeter	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-OD-T1	Outer Dosimeter	Travel Spike	06/24/2016	06/24/2016	NA	NA
NA	AEA09-FF-06-OD-T2	Outer Dosimeter	Travel Spike	06/24/2016	06/24/2016	NA	NA
463SET62	AEA09-FF-07-PH-C1	Painters Hat	Field Control	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-C2	Painters Hat	Field Control	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-L1	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-L2	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-L3	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-H1	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET62	AEA09-FF-07-PH-H2	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET62	AEA09-FF-07-PH-H3	Painters Hat	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET40	AEA09-FF-07-AR-C1	Air Sampling Tube	Field Control	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-C2	Air Sampling Tube	Field Control	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-L1	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-L2	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-L3	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-H1	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-H2	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET40	AEA09-FF-07-AR-H3	Air Sampling Tube	Field Fortification	06/27/2016	06/27/2016	12/07/2016	163
463SET30	AEA09-FF-07-RES-C1	RespiCon	Field Control	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-C2	RespiCon	Field Control	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-L1	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-L2	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-L3	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-H1	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-H2	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET30	AEA09-FF-07-RES-H3	RespiCon	Field Fortification	06/27/2016	06/27/2016	11/16/2016	142
463SET12	AEA09-FF-07-HW-C1	Hand Wash	Field Control	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-C2	Hand Wash	Field Control	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-L1	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-L2	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-L3	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-H1	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET12	AEA09-FF-07-HW-H2	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115
463SET12	AEA09-FF-07-HW-H3	Hand Wash	Field Fortification	06/27/2016	06/27/2016	10/20/2016	115
463SET21	AEA09-FF-07-FW-C1	Face/Neck Wipe	Field Control	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-C2	Face/Neck Wipe	Field Control	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-L1	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-L2	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-L3	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-H1	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-H2	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET21	AEA09-FF-07-FW-H3	Face/Neck Wipe	Field Fortification	06/27/2016	06/27/2016	11/10/2016	136
463SET64	AEA09-FF-07-ID-C1	Inner Dosimeter	Field Control	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-C2	Inner Dosimeter	Field Control	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-L1	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-L2	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-L3	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-H1	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-H2	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET64	AEA09-FF-07-ID-H3	Inner Dosimeter	Field Fortification	06/27/2016	06/27/2016	01/03/2017	190
463SET61	AEA09-FF-07-OD-C1	Outer Dosimeter	Field Control	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-C2	Outer Dosimeter	Field Control	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-L1	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-L2	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-L3	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-H1	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET61	AEA09-FF-07-OD-H2	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
463SET61	AEA09-FF-07-OD-H3	Outer Dosimeter	Field Fortification	06/27/2016	06/27/2016	12/29/2016	185
NA	AEA09-FF-07-PH-T1	Painters Hat	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-PH-T2	Painters Hat	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-AR-T1	Air Sampling Tube	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-AR-T2	Air Sampling Tube	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-ID-T1	Inner Dosimeter	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-ID-T2	Inner Dosimeter	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-OD-T1	Outer Dosimeter	Travel Spike	06/27/2016	06/27/2016	NA	NA
NA	AEA09-FF-07-OD-T2	Outer Dosimeter	Travel Spike	06/27/2016	06/27/2016	NA	NA
463SET66	AEA09-FF-08-PH-C1	Painters Hat	Field Control	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-C2	Painters Hat	Field Control	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-L1	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-L2	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-L3	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-H1	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-H2	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET66	AEA09-FF-08-PH-H3	Painters Hat	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET41	AEA09-FF-08-AR-C1	Air Sampling Tube	Field Control	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-C2	Air Sampling Tube	Field Control	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-L1	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-L2	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-L3	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-H1	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET41	AEA09-FF-08-AR-H2	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161
463SET41	AEA09-FF-08-AR-H3	Air Sampling Tube	Field Fortification	06/29/2016	06/29/2016	12/07/2016	161
463SET31	AEA09-FF-08-RES-C1	RespiCon	Field Control	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-C2	RespiCon	Field Control	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-L1	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-L2	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-L3	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-H1	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-H2	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET31	AEA09-FF-08-RES-H3	RespiCon	Field Fortification	06/29/2016	06/29/2016	11/16/2016	140
463SET13	AEA09-FF-08-HW-C1	Hand Wash	Field Control	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-C2	Hand Wash	Field Control	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-L1	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-L2	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-L3	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-H1	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-H2	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET13	AEA09-FF-08-HW-H3	Hand Wash	Field Fortification	06/29/2016	06/29/2016	10/21/2016	114
463SET22	AEA09-FF-08-FW-C1	Face/Neck Wipe	Field Control	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-C2	Face/Neck Wipe	Field Control	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-L1	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-L2	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-L3	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-H1	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET22	AEA09-FF-08-FW-H2	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134
463SET22	AEA09-FF-08-FW-H3	Face/Neck Wipe	Field Fortification	06/29/2016	06/29/2016	11/10/2016	134
463SET71	AEA09-FF-08-ID-C1	Inner Dosimeter	Field Control	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-C2	Inner Dosimeter	Field Control	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-L1	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-L2	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-L3	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-H1	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-H2	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET71	AEA09-FF-08-ID-H3	Inner Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/16/2017	201
463SET65	AEA09-FF-08-OD-C1	Outer Dosimeter	Field Control	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-C2	Outer Dosimeter	Field Control	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-L1	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-L2	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-L3	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-H1	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-H2	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	189
463SET65	AEA09-FF-08-OD-H3	Outer Dosimeter	Field Fortification	06/29/2016	06/29/2016	01/04/2017	198
NA	AEA09-FF-08-PH-T1	Painters Hat	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-PH-T2	Painters Hat	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-AR-T1	Air Sampling Tube	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-AR-T2	Air Sampling Tube	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-ID-T1	Inner Dosimeter	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-ID-T2	Inner Dosimeter	Travel Spike	06/29/2016	06/29/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-FF-08-OD-T1	Outer Dosimeter	Travel Spike	06/29/2016	06/29/2016	NA	NA
NA	AEA09-FF-08-OD-T2	Outer Dosimeter	Travel Spike	06/29/2016	06/29/2016	NA	NA
463SET69	AEA09-FF-09-PH-C1	Painters Hat	Field Control	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-C2	Painters Hat	Field Control	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-L1	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-L2	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-L3	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-H1	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-H2	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET69	AEA09-FF-09-PH-H3	Painters Hat	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET70	AEA09-FF-09-AR-C1	Air Sampling Tube	Field Control	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-C2	Air Sampling Tube	Field Control	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-L1	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-L2	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-L3	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-H1	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-H2	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET70	AEA09-FF-09-AR-H3	Air Sampling Tube	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET32	AEA09-FF-09-RES-C1	RespiCon	Field Control	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-C2	RespiCon	Field Control	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-L1	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-L2	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-L3	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-H1	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET32	AEA09-FF-09-RES-H2	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138
463SET32	AEA09-FF-09-RES-H3	RespiCon	Field Fortification	07/01/2016	07/01/2016	11/16/2016	138
463SET14	AEA09-FF-09-HW-C1	Hand Wash	Field Control	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-C2	Hand Wash	Field Control	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-L1	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-L2	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-L3	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-H1	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-H2	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET14	AEA09-FF-09-HW-H3	Hand Wash	Field Fortification	07/01/2016	07/01/2016	11/09/2016	131
463SET23	AEA09-FF-09-FW-C1	Face/Neck Wipe	Field Control	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-C2	Face/Neck Wipe	Field Control	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-L1	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-L2	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-L3	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-H1	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-H2	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET23	AEA09-FF-09-FW-H3	Face/Neck Wipe	Field Fortification	07/01/2016	07/01/2016	11/10/2016	132
463SET72	AEA09-FF-09-ID-C1	Inner Dosimeter	Field Control	07/01/2016	07/01/2016	01/16/2017	199
463SET73	AEA09-FF-09-ID-C2	Inner Dosimeter	Field Control	07/01/2016	07/01/2016	01/25/2017	208
463SET72	AEA09-FF-09-ID-L1	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET72	AEA09-FF-09-ID-L2	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET73	AEA09-FF-09-ID-L3	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/25/2017	208
463SET72	AEA09-FF-09-ID-H1	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET72	AEA09-FF-09-ID-H2	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET73	AEA09-FF-09-ID-H3	Inner Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/25/2017	208
463SET67	AEA09-FF-09-OD-C1	Outer Dosimeter	Field Control	07/01/2016	07/01/2016	01/11/2017	194
463SET68	AEA09-FF-09-OD-C2	Outer Dosimeter	Field Control	07/01/2016	07/01/2016	01/16/2017	199
463SET67	AEA09-FF-09-OD-L1	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-FF-09-OD-L2	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET68	AEA09-FF-09-OD-L3	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
463SET67	AEA09-FF-09-OD-H1	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET67	AEA09-FF-09-OD-H2	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/11/2017	194
463SET68	AEA09-FF-09-OD-H3	Outer Dosimeter	Field Fortification	07/01/2016	07/01/2016	01/16/2017	199
NA	AEA09-FF-09-PH-T1	Painters Hat	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-PH-T2	Painters Hat	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-AR-T1	Air Sampling Tube	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-AR-T2	Air Sampling Tube	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-ID-T1	Inner Dosimeter	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-ID-T2	Inner Dosimeter	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-OD-T1	Outer Dosimeter	Travel Spike	07/01/2016	07/01/2016	NA	NA
NA	AEA09-FF-09-OD-T2	Outer Dosimeter	Travel Spike	07/01/2016	07/01/2016	NA	NA
463SET36	AEA09-BS-1-R1-AR-H1	Air Sampling Tube	Background	06/13/2016	06/13/2016	12/06/2016	176
463SET36	AEA09-BS-1-R1-AR-H2	Air Sampling Tube	Background	06/13/2016	06/13/2016	12/06/2016	176
NA	AEA09-BS-1-R2-AR-H1	Air Sampling Tube	Background	06/13/2016	06/13/2016	NA	NA
NA	AEA09-BS-1-R2-AR-H2	Air Sampling Tube	Background	06/13/2016	06/13/2016	NA	NA
NA	AEA09-BS-1-R3-AR-H1	Air Sampling Tube	Background	06/13/2016	06/13/2016	NA	NA
NA	AEA09-BS-1-R3-AR-H2	Air Sampling Tube	Background	06/13/2016	06/13/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET36	AEA09-BS-1-CR-AR-H1	Air Sampling Tube	Background	06/13/2016	06/13/2016	12/06/2016	176
463SET36	AEA09-BS-1-CR-AR-H2	Air Sampling Tube	Background	06/13/2016	06/13/2016	12/06/2016	176
463SET75	AEA09-BS-1-R1-WW-H1	Wall Wipe	Background	06/13/2016	06/13/2016	4/26/2017	317
NA	AEA09-BS-1-R1-WW-H2	Wall Wipe	Background	06/13/2016	06/13/2016	NA	NA
NA	AEA09-BS-1-R2-WW-H1	Wall Wipe	Background	06/13/2016	06/13/2016	NA	NA
463SET75	AEA09-BS-1-R2-WW-H2	Wall Wipe	Background	06/13/2016	06/13/2016	4/26/2017	317
NA	AEA09-BS-1-R3-WW-H1	Wall Wipe	Background	06/13/2016	06/13/2016	NA	NA
NA	AEA09-BS-1-R3-WW-H2	Wall Wipe	Background	06/13/2016	06/13/2016	NA	NA
463SET75	AEA09-BS-1-CR-WW-H1	Wall Wipe	Background	06/13/2016	06/13/2016	4/26/2017	317
463SET75	AEA09-BS-1-CR-WW-H2	Wall Wipe	Background	06/13/2016	06/13/2016	4/26/2017	317
NA	AEA09-BS-2-R1-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R1-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R2-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R2-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R3-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R3-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R4-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R4-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R5-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R5-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R6-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R6-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA
463SET36	AEA09-BS-2-CR-AR-H1	Air Sampling Tube	Background	06/15/2016	06/15/2016	12/06/2016	174
NA	AEA09-BS-2-CR-AR-H2	Air Sampling Tube	Background	06/15/2016	06/15/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET75	AEA09-BS-2-R1-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	4/26/2017	315
NA	AEA09-BS-2-R1-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R2-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R2-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R3-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R3-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R4-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
463SET75	AEA09-BS-2-R4-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	4/26/2017	315
NA	AEA09-BS-2-R5-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R5-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R6-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-R6-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-CR-WW-H1	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
NA	AEA09-BS-2-CR-WW-H2	Wall Wipe	Background	06/15/2016	06/15/2016	NA	NA
463SET36	AEA09-BS-3-R1-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	12/06/2016	172
NA	AEA09-BS-3-R1-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R2-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R2-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R3-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R3-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R4-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R4-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R5-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R5-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-3-R6-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R6-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-CR-AR-H1	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-CR-AR-H2	Air Sampling Tube	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R1-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R1-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R2-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
463SET75	AEA09-BS-3-R2-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	4/26/2017	313
NA	AEA09-BS-3-R3-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R3-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R4-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R4-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R5-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R5-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R6-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-3-R6-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
463SET75	AEA09-BS-3-CR-WW-H1	Wall Wipe	Background	06/17/2016	06/17/2016	4/26/2017	313
NA	AEA09-BS-3-CR-WW-H2	Wall Wipe	Background	06/17/2016	06/17/2016	NA	NA
NA	AEA09-BS-4-R1-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R1-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R2-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R2-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R3-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R3-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-4-R4-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R4-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R5-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R5-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R6-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R6-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-CR-AR-H1	Air Sampling Tube	Background	06/20/2016	06/20/2016	NA	NA
463SET36	AEA09-BS-4-CR-AR-H2	Air Sampling Tube	Background	06/20/2016	06/20/2016	12/06/2016	169
NA	AEA09-BS-4-R1-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R1-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R2-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R2-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
463SET75	AEA09-BS-4-R3-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	4/26/2017	310
NA	AEA09-BS-4-R3-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R4-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R4-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R5-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
463SET75	AEA09-BS-4-R5-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	4/26/2017	310
NA	AEA09-BS-4-R6-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-R6-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-CR-WW-H1	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-4-CR-WW-H2	Wall Wipe	Background	06/20/2016	06/20/2016	NA	NA
NA	AEA09-BS-5-R1-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
463SET36	AEA09-BS-5-R1-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	12/06/2016	167

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-5-R2-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R2-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R3-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R3-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R4-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R4-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R5-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R5-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R6-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R6-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-CR-AR-H1	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-CR-AR-H2	Air Sampling Tube	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R1-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R1-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R2-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R2-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R3-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R3-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R4-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R4-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R5-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R5-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-5-R6-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
463SET75	AEA09-BS-5-R6-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	4/26/2017	308

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
463SET75	AEA09-BS-5-CR-WW-H1	Wall Wipe	Background	06/22/2016	06/22/2016	4/26/2017	308
NA	AEA09-BS-5-CR-WW-H2	Wall Wipe	Background	06/22/2016	06/22/2016	NA	NA
NA	AEA09-BS-6-R1-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R1-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R2-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R2-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R3-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R3-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R4-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R4-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R5-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R5-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R6-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R6-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
463SET36	AEA09-BS-6-CR-AR-H1	Air Sampling Tube	Background	06/24/2016	06/24/2016	12/06/2016	165
NA	AEA09-BS-6-CR-AR-H2	Air Sampling Tube	Background	06/24/2016	06/24/2016	NA	NA
463SET75	AEA09-BS-6-R1-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	4/26/2017	306
NA	AEA09-BS-6-R1-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R2-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R2-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R3-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R3-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R4-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
463SET75	AEA09-BS-6-R4-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	4/26/2017	306

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-6-R5-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R5-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R6-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-R6-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-CR-WW-H1	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
NA	AEA09-BS-6-CR-WW-H2	Wall Wipe	Background	06/24/2016	06/24/2016	NA	NA
463SET36	AEA09-BS-7-R1-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	12/06/2016	162
NA	AEA09-BS-7-R1-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R2-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R2-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R3-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R3-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R4-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R4-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R5-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R5-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R6-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R6-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-CR-AR-H1	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-CR-AR-H2	Air Sampling Tube	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R1-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R1-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R2-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
463SET75	AEA09-BS-7-R2-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	4/26/2017	303

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-7-R3-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R3-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R4-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R4-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R5-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R5-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R6-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-7-R6-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
463SET75	AEA09-BS-7-CR-WW-H1	Wall Wipe	Background	06/27/2016	06/27/2016	4/26/2017	303
NA	AEA09-BS-7-CR-WW-H2	Wall Wipe	Background	06/27/2016	06/27/2016	NA	NA
NA	AEA09-BS-8-R1-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R1-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R2-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R2-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R3-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R3-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R4-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R4-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R5-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R5-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R6-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R6-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-CR-AR-H1	Air Sampling Tube	Background	06/29/2016	06/29/2016	NA	NA
463SET36	AEA09-BS-8-CR-AR-H2	Air Sampling Tube	Background	06/29/2016	06/29/2016	12/06/2016	160

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-8-R1-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R1-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R2-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R2-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
463SET75	AEA09-BS-8-R3-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	4/26/2017	301
NA	AEA09-BS-8-R3-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R4-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R4-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R5-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
463SET75	AEA09-BS-8-R5-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	4/26/2017	301
NA	AEA09-BS-8-R6-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-R6-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-CR-WW-H1	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-8-CR-WW-H2	Wall Wipe	Background	06/29/2016	06/29/2016	NA	NA
NA	AEA09-BS-9-R1-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
463SET36	AEA09-BS-9-R1-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	12/06/2016	158
NA	AEA09-BS-9-R2-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R2-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R3-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R3-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R4-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R4-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R5-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R5-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA

Sample Tracking Table (continued)

Lab Set	Sample ID	Matrix	Sample Type	Sampling Date	Date Received at Analytical Laboratory	Extraction Date	Maximum Storage (Days)
NA	AEA09-BS-9-R6-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R6-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-CR-AR-H1	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-CR-AR-H2	Air Sampling Tube	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R1-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R1-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R2-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R2-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R3-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R3-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R4-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R4-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R5-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R5-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
NA	AEA09-BS-9-R6-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA
463SET75	AEA09-BS-9-R6-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	4/26/2017	299
463SET75	AEA09-BS-9-CR-WW-H1	Wall Wipe	Background	07/01/2016	07/01/2016	4/26/2017	299
NA	AEA09-BS-9-CR-WW-H2	Wall Wipe	Background	07/01/2016	07/01/2016	NA	NA

APPENDIX J.

REPRESENTATIVE CHROMATOGRAMS

Figure 1 Representative Chromatogram of a 0.250 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

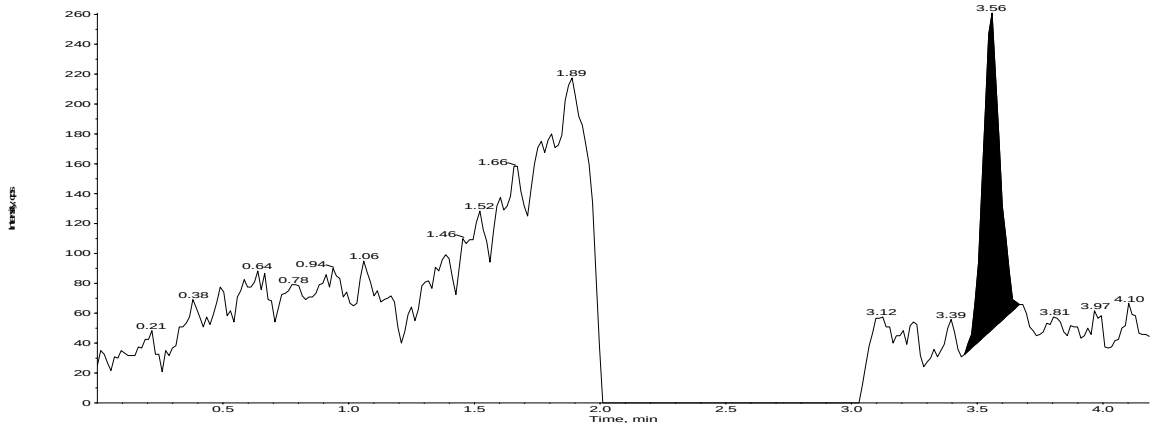


Figure 2 Representative Chromatogram of a 0.500 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

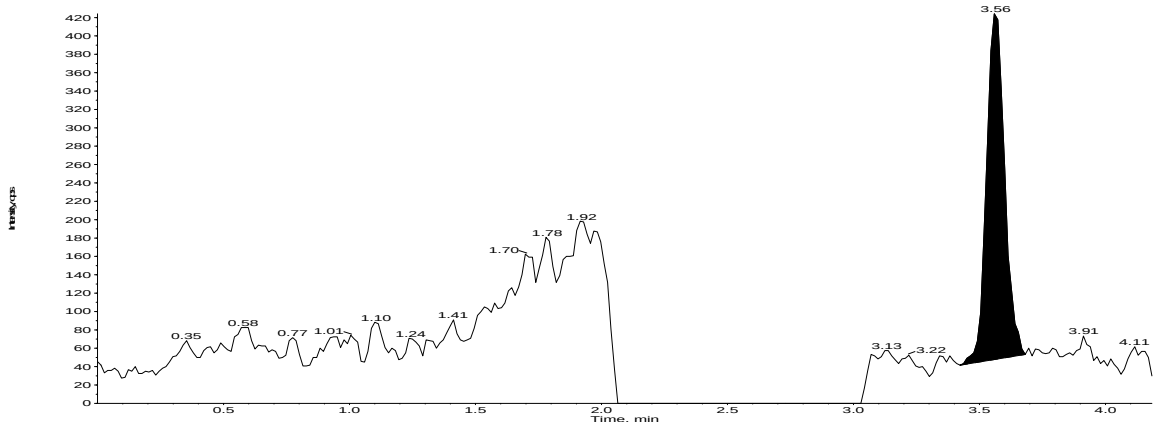


Figure 3 Representative Chromatogram of a 1.00 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

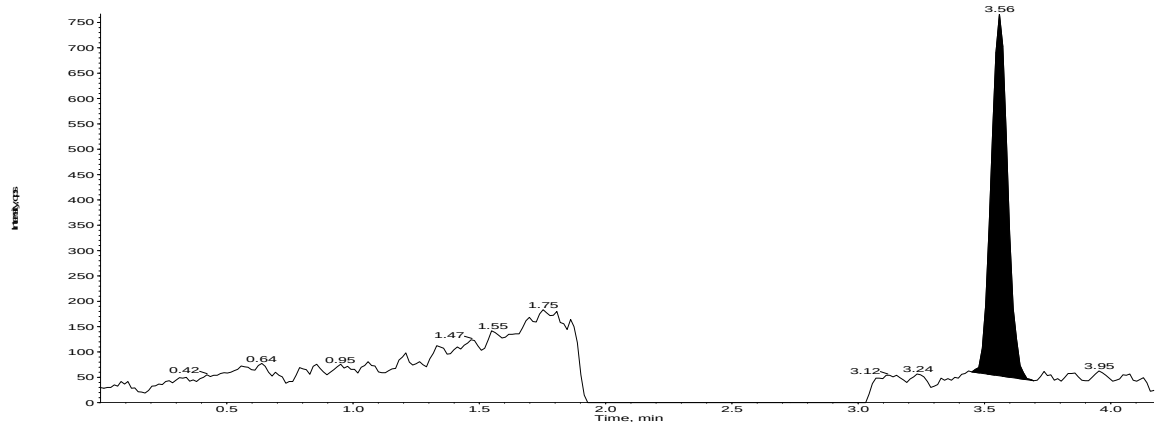


Figure 4 Representative Chromatogram of a 2.50 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

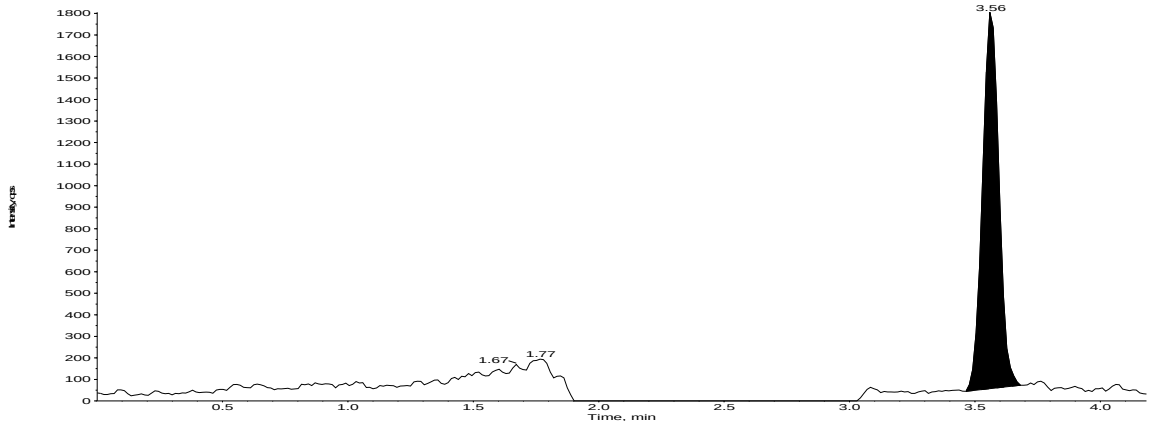


Figure 5 Representative Chromatogram of a 10.0 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

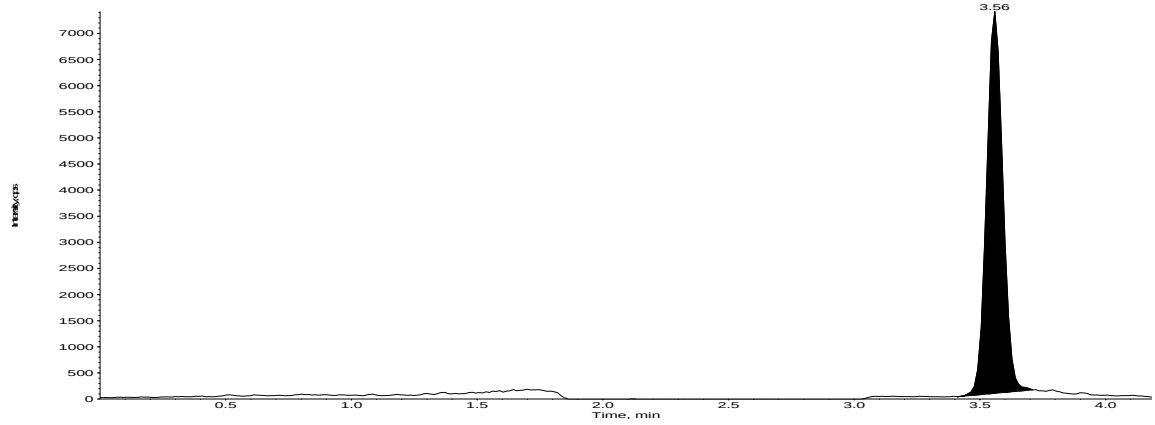


Figure 6 Representative Chromatogram of a 25.0 ng/mL BIT Standard

463SET33 (Air Sampling Tubes)

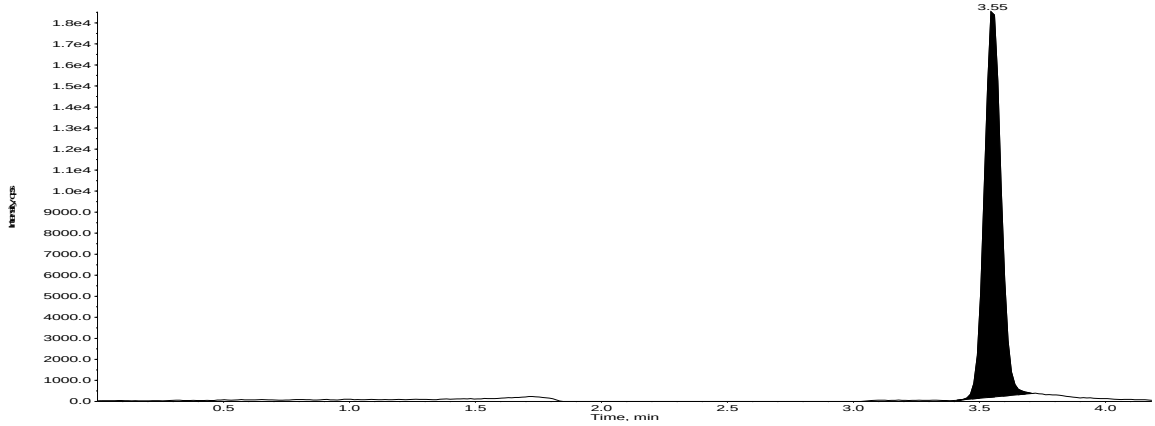


Figure 7 Representative Chromatogram of a 25.0 ng/mL BIT-IS Standard

463SET33 (Air Sampling Tubes)

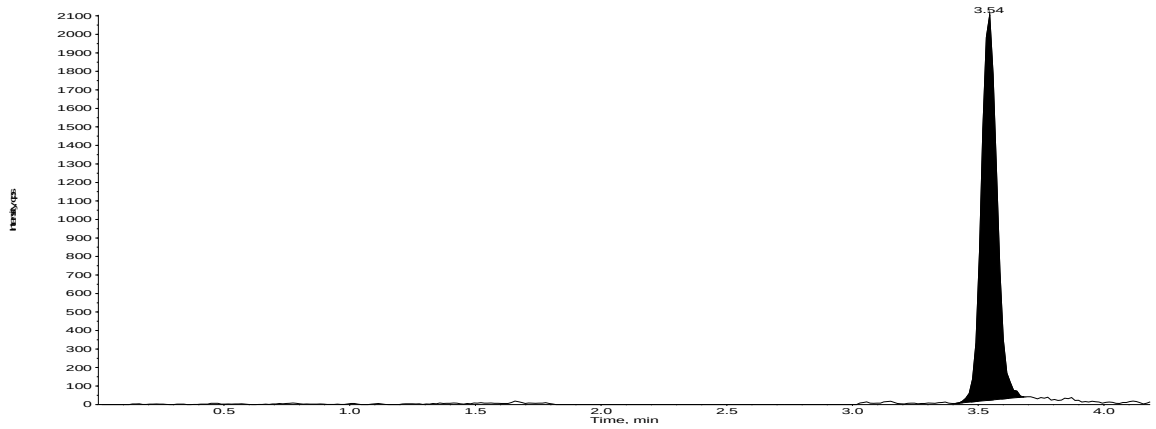


Figure 8 Representative BIT Standard Curve

463SET33 (Air Sampling Tubes)
y = 9.25 x + 0.00855
r = 0.9995

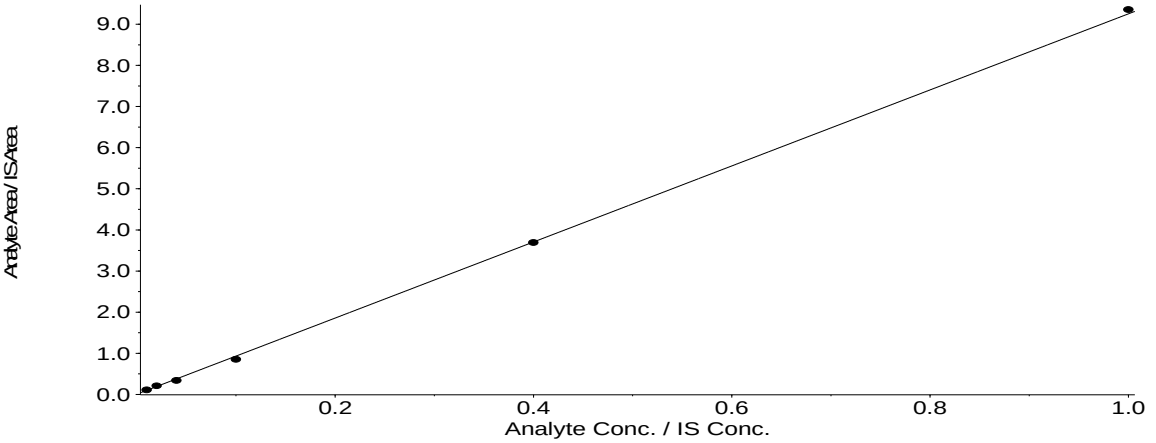


Figure 9 Representative Chromatogram of a Laboratory Control Air Sampling Tube Sample

463SET33-1

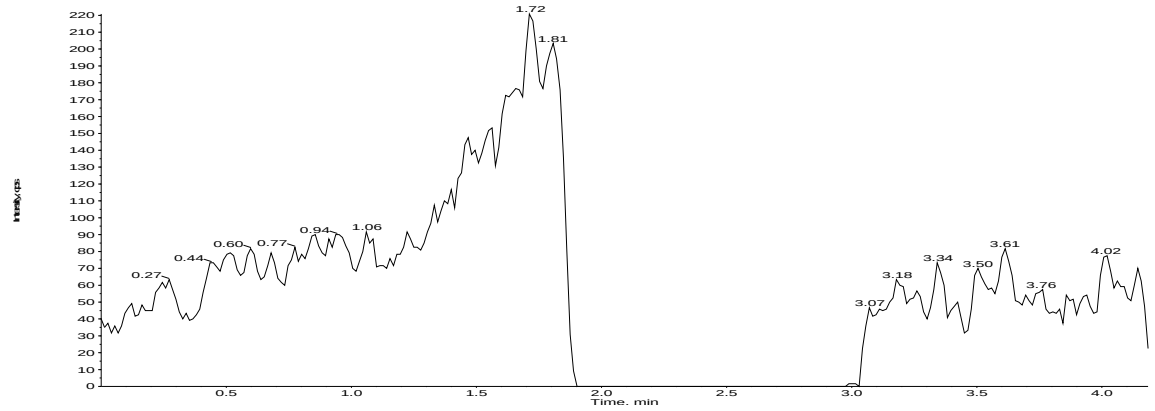


Figure 10 Representative Chromatogram of a Low Laboratory Fortification of an Air Sampling Tube Sample

463SET33-2

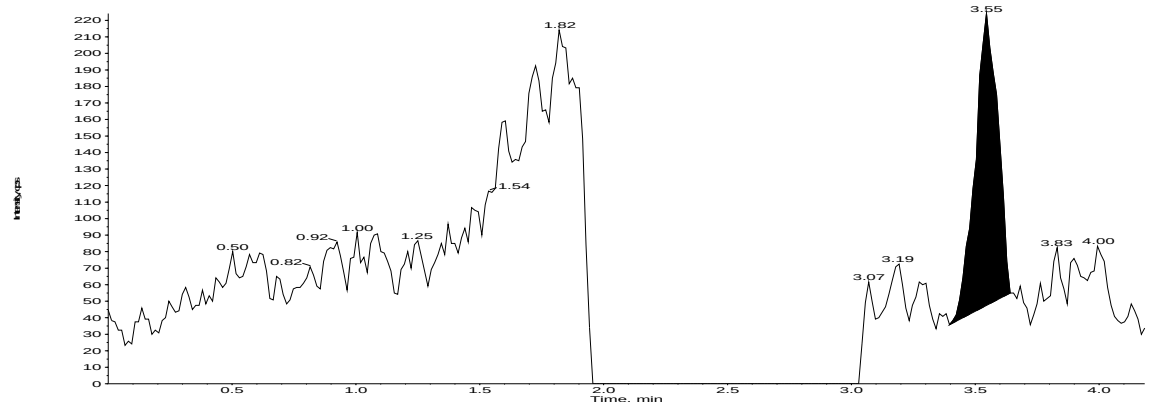


Figure 11 Representative Chromatogram of a High Laboratory Fortification of an Air Sampling Tube Sample

463SET33-3

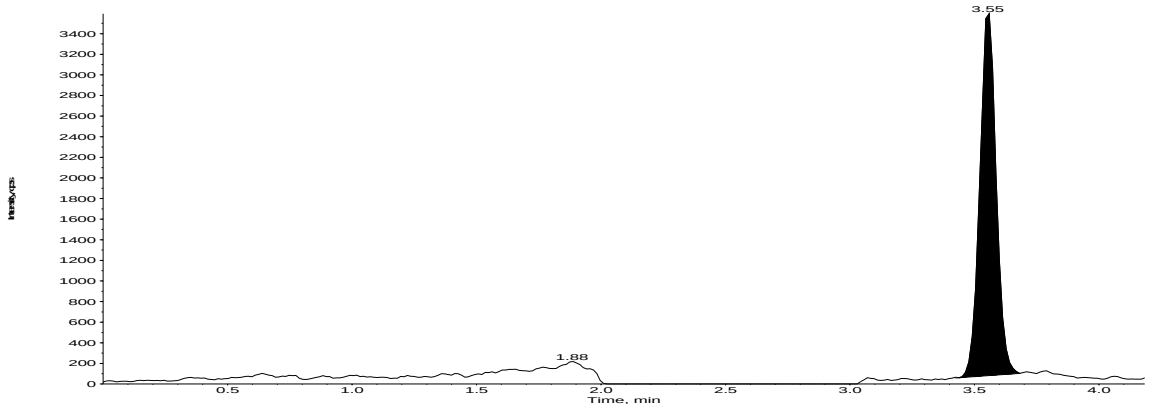


Figure 12 Representative Chromatogram of a Field Control Air Sampling Tube Sample

463SET33-5

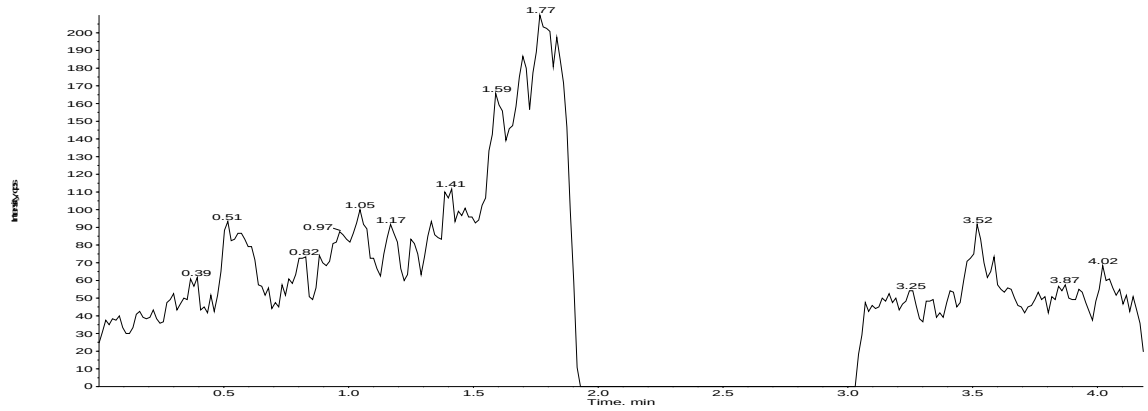


Figure 13 Representative Chromatogram of a Field Fortified Low Air Sampling Tube Sample

463SET33-7

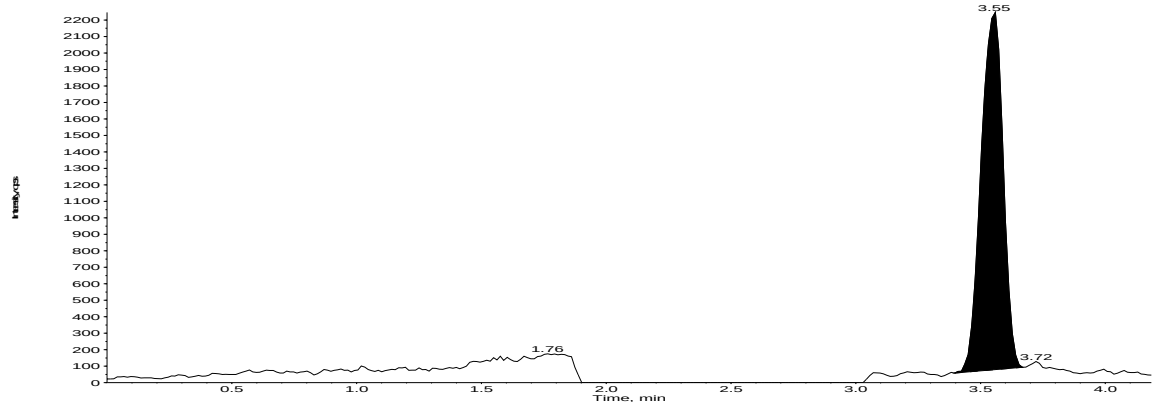


Figure 14 Representative Chromatogram of a Field Fortified High Air Sampling Tube Sample

463SET33-10

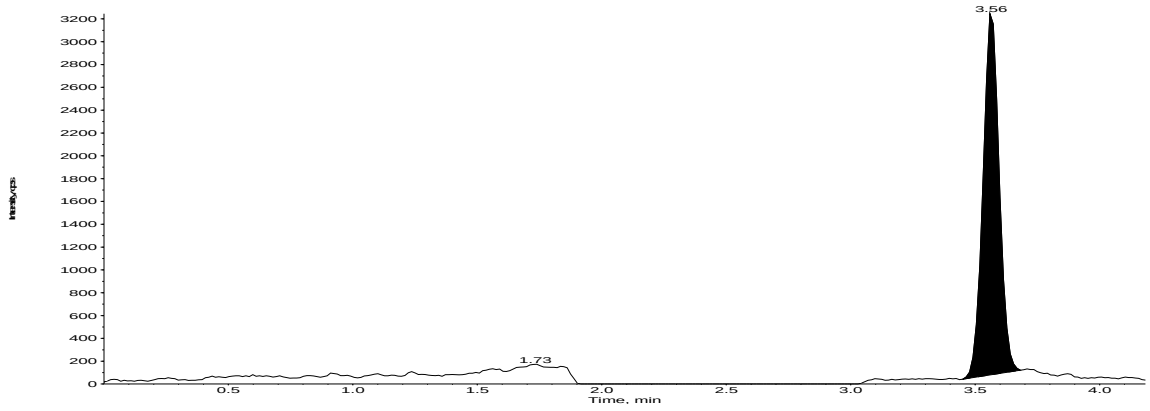


Figure 15 Representative Chromatogram of an Air Sampling Tube Field Sample

463SET33-4

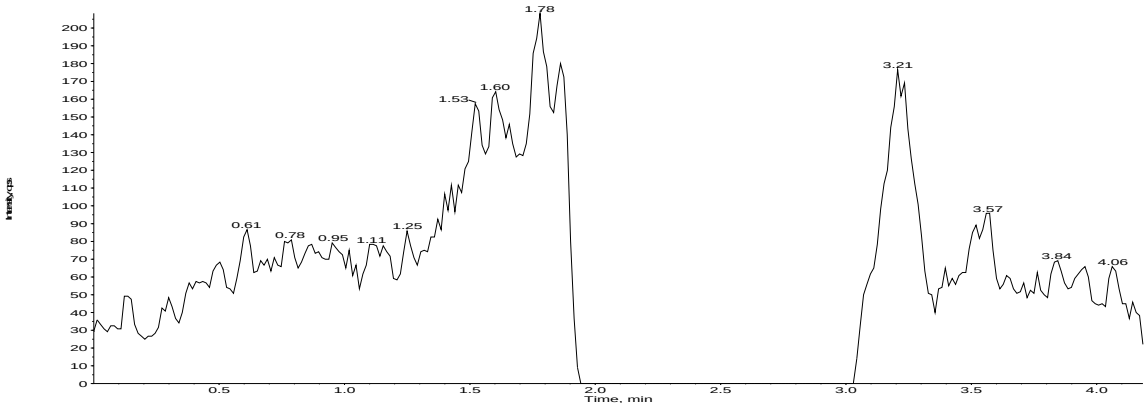


Figure 16 Representative Chromatogram of a Laboratory Control Fiberglass Sample

463SET24-1

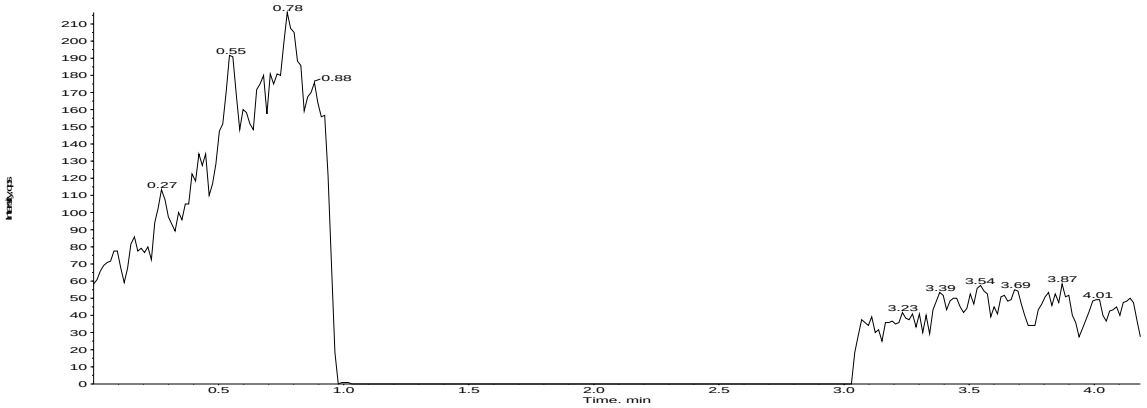


Figure 17 Representative Chromatogram of a Low Laboratory Fortification of a Fiberglass Filter Sample

463SET24-2

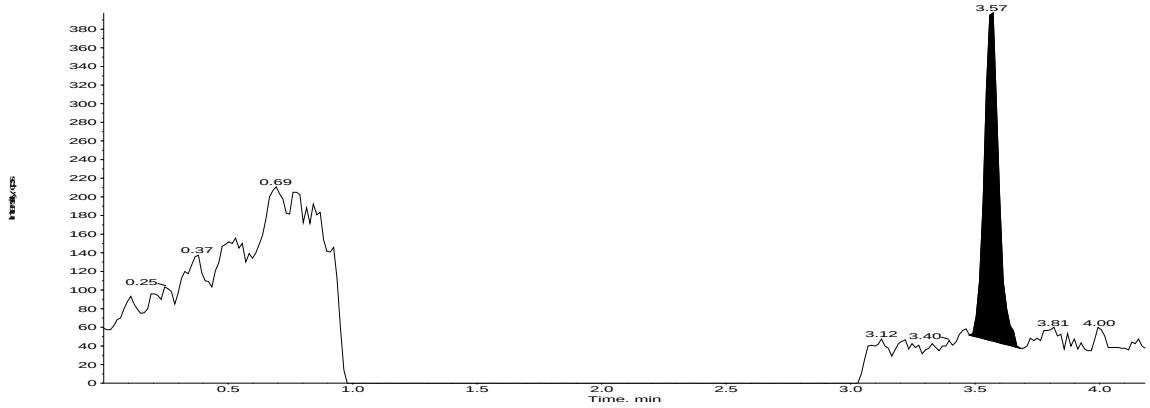


Figure 18 Representative Chromatogram of a High Laboratory Fortification of a Fiberglass Filter Sample

463SET24-3

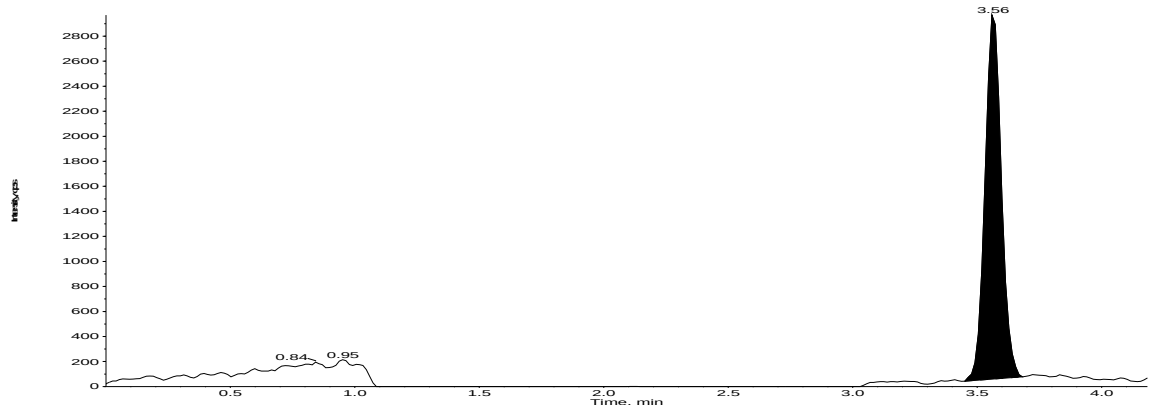


Figure 19 Representative Chromatogram of a Field Control Fiberglass Filter Sample

463SET24-7

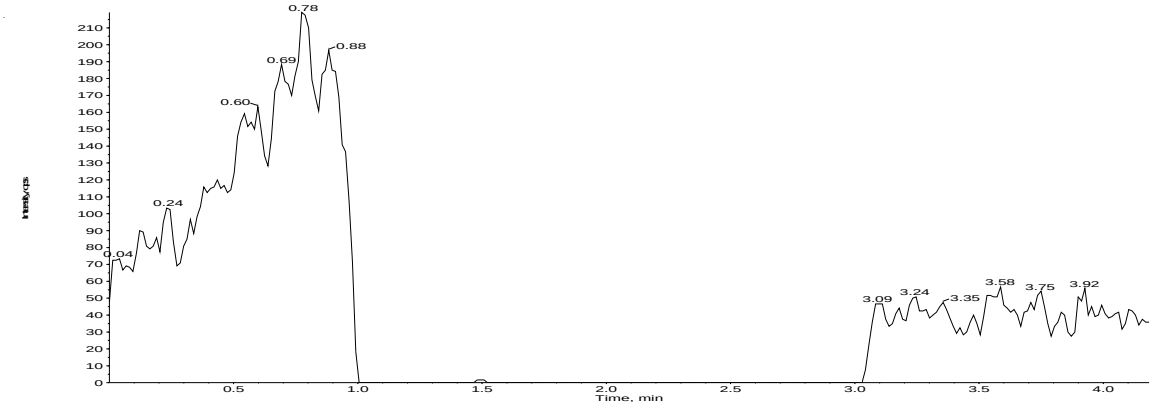


Figure 20 Representative Chromatogram of a Field Fortified Low Fiberglass Filter Sample

463SET24-9

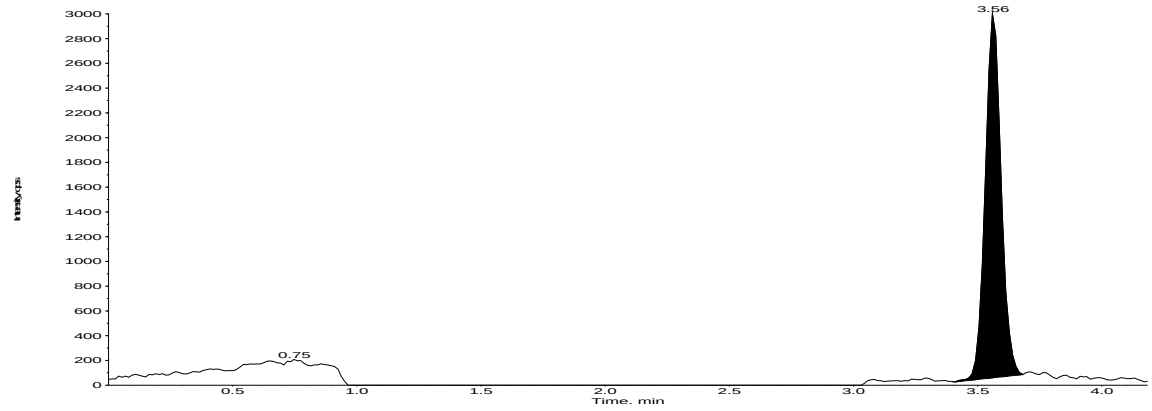


Figure 21 Representative Chromatogram of a Field Fortified High Fiberglass Filter Sample

463SET24-12

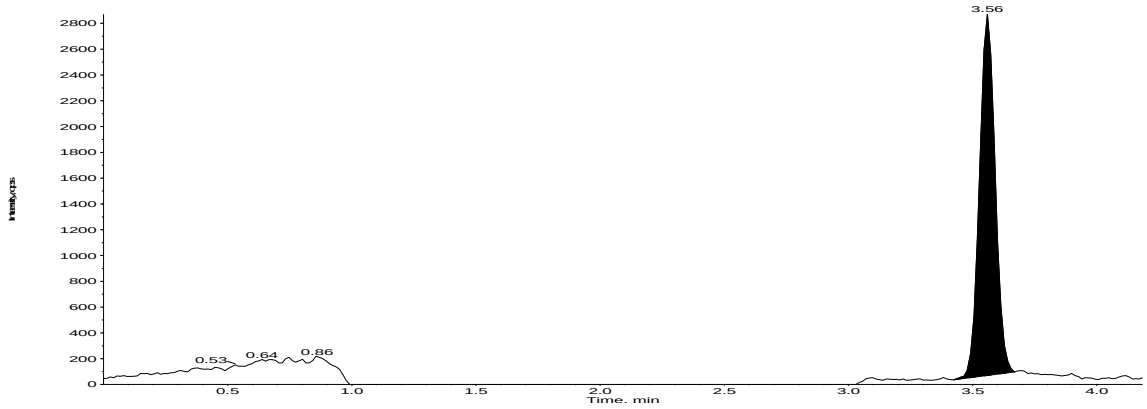


Figure 22 Representative Chromatogram of a Fiberglass Filter Field Sample

463SET24-4

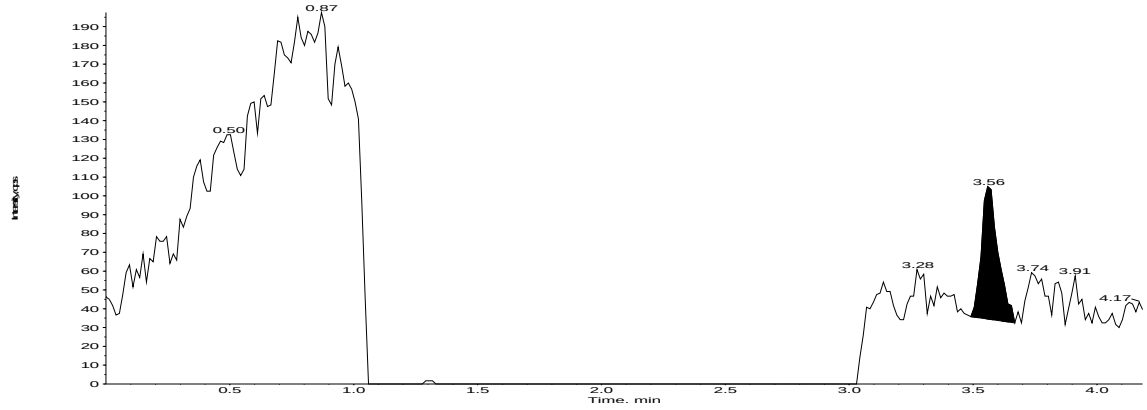


Figure 23 Representative Chromatogram of a Laboratory Control Hand Wash Sample

463SET06-1

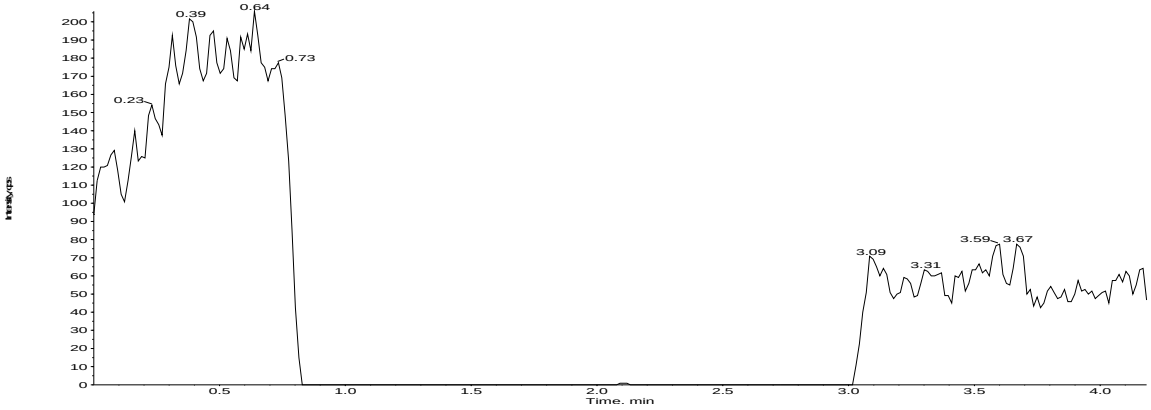


Figure 24 Representative Chromatogram of a Low Laboratory Fortification of a Hand Wash Sample

463SET06-2

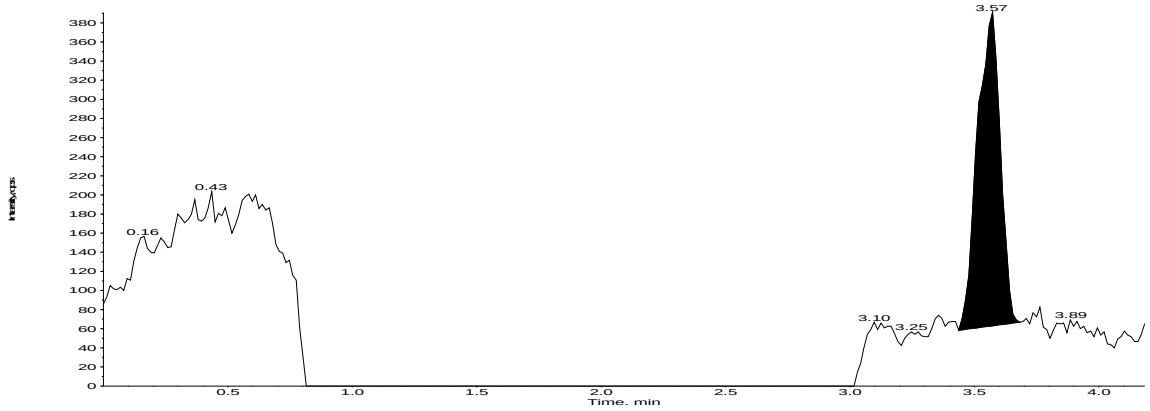


Figure 25 Representative Chromatogram of a High Laboratory Fortification of a Hand Wash Sample

463SET06-3

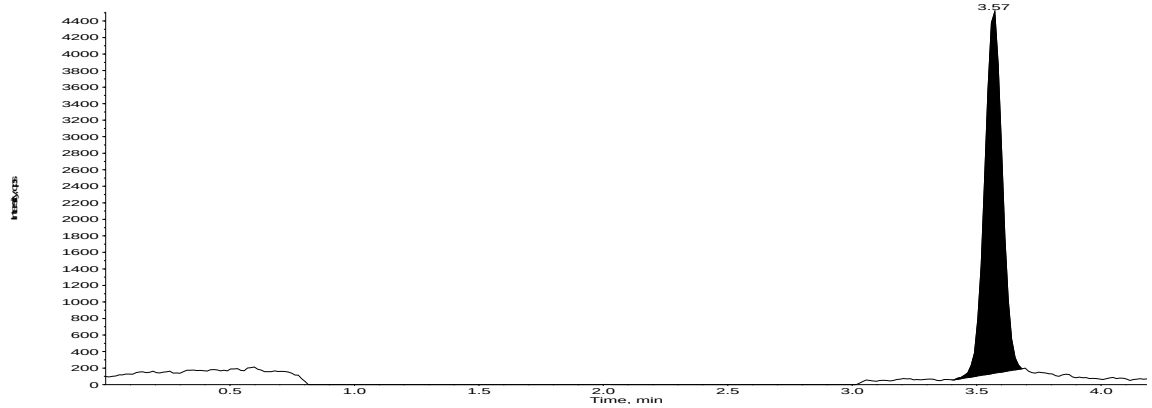


Figure 26 Representative Chromatogram of a Field Control Hand Wash Sample

463SET06-5

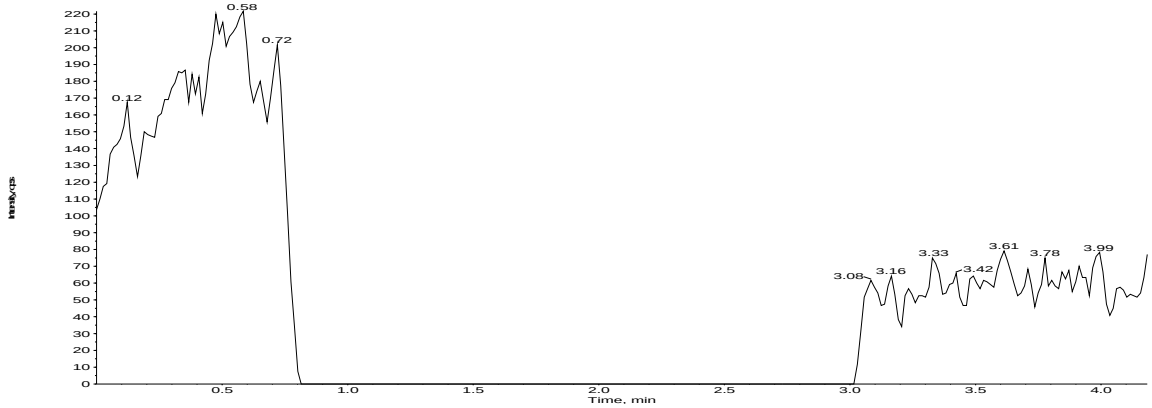


Figure 27 Representative Chromatogram of a Field Fortified Low Hand Wash Sample

463SET06-7

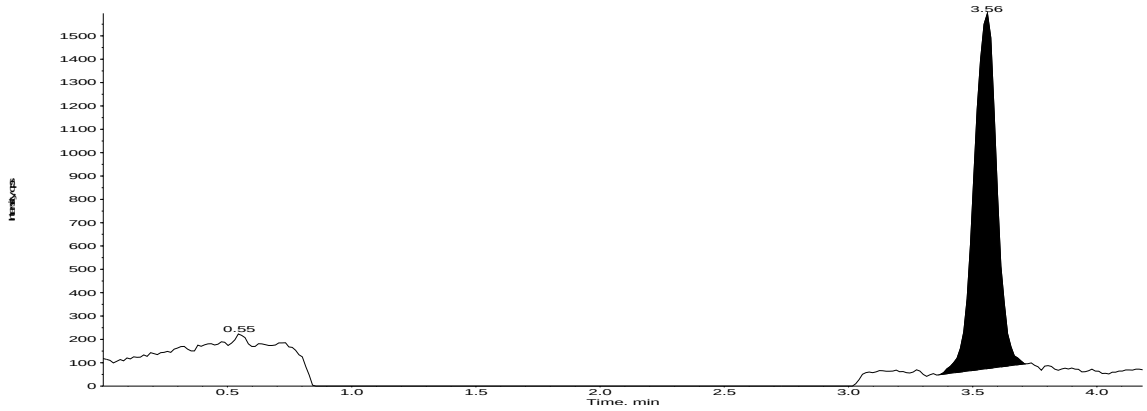


Figure 28 Representative Chromatogram of a Field Fortified High Hand Wash Sample

463SET06-10

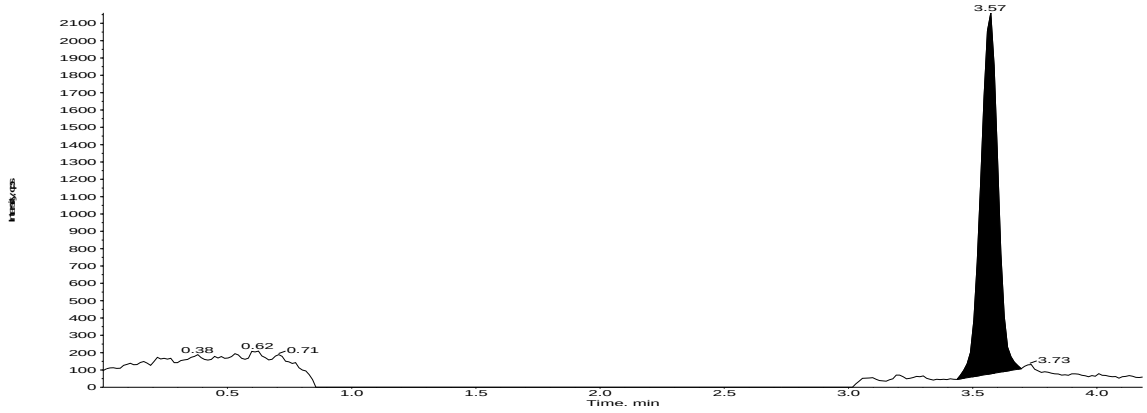


Figure 29 Representative Chromatogram of a Hand Wash Field Sample

463SET06-4

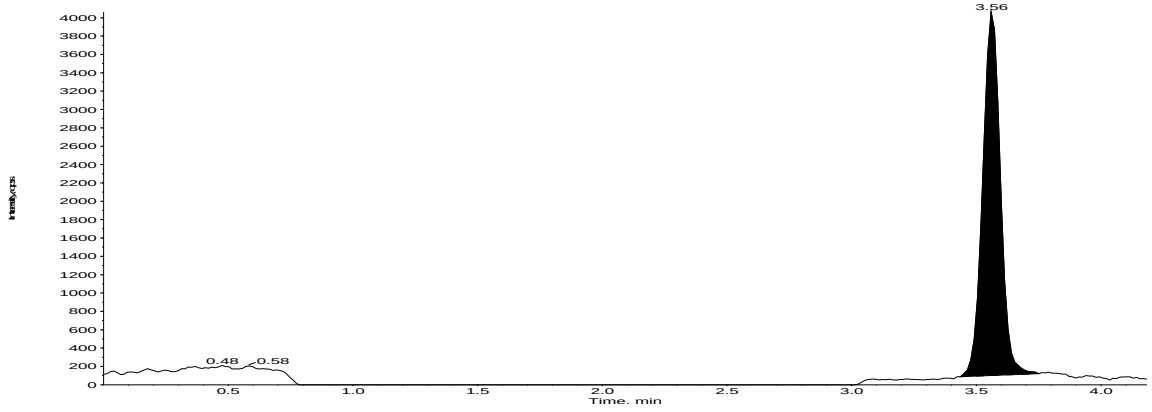


Figure 30 Representative Chromatogram of a Laboratory Control Face/Neck Wipe Sample

463SET16-1

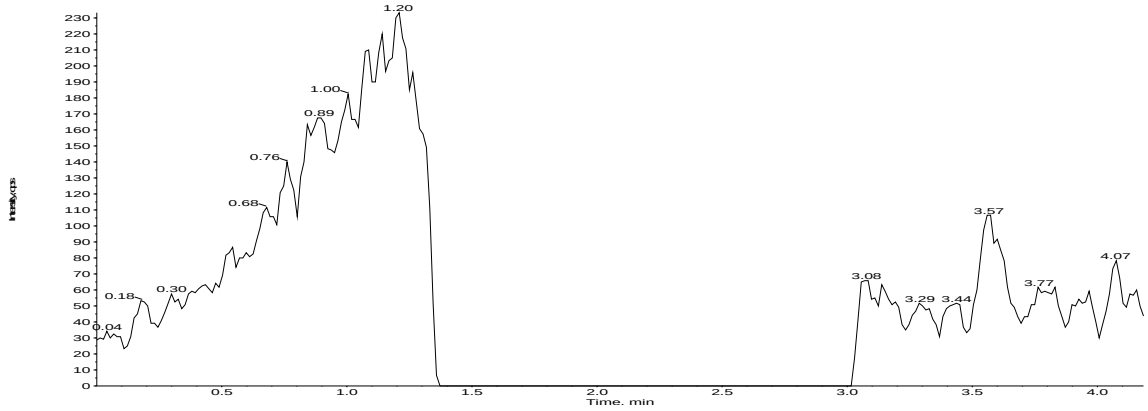


Figure 31 Representative Chromatogram of a Low Laboratory Fortification of a Face/Neck Wipe Sample

463SET16-2

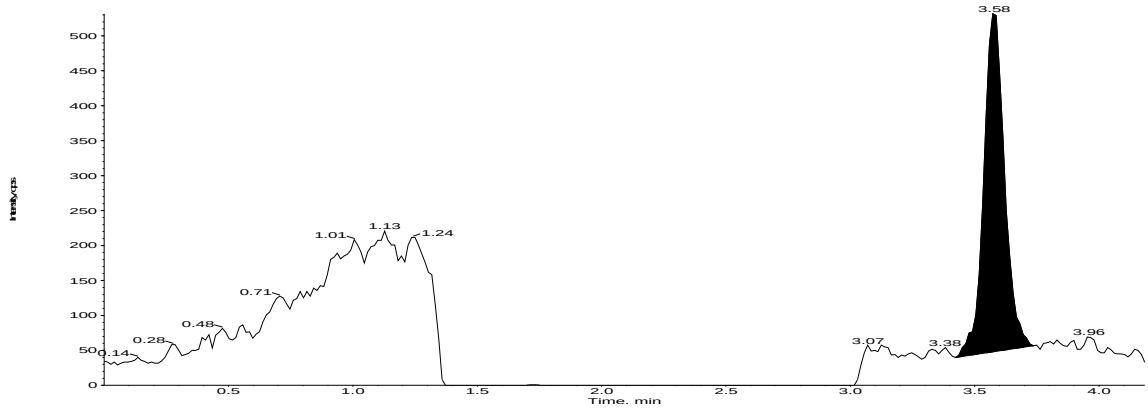


Figure 32 Representative Chromatogram of a High Laboratory Fortification of a Face/Neck Wipe Sample

463SET16-3

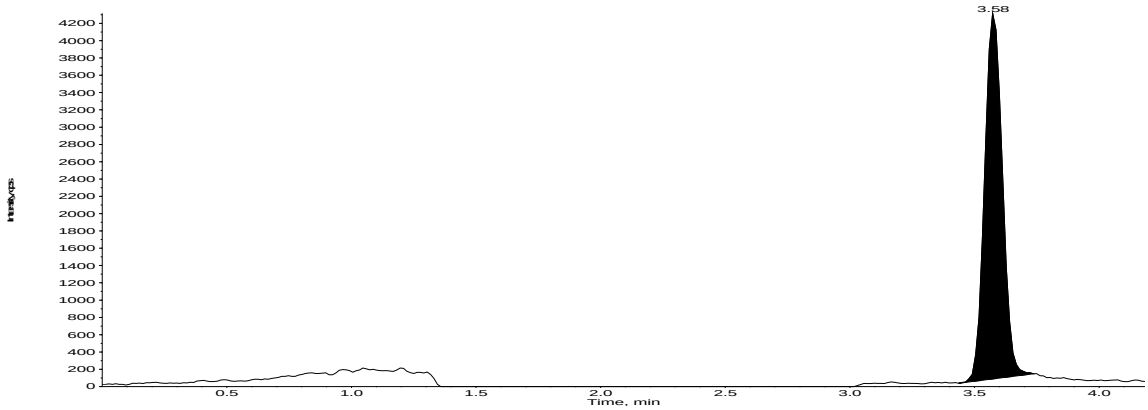


Figure 33 Representative Chromatogram of a Field Control Face/Neck Wipe Sample

463SET16-7

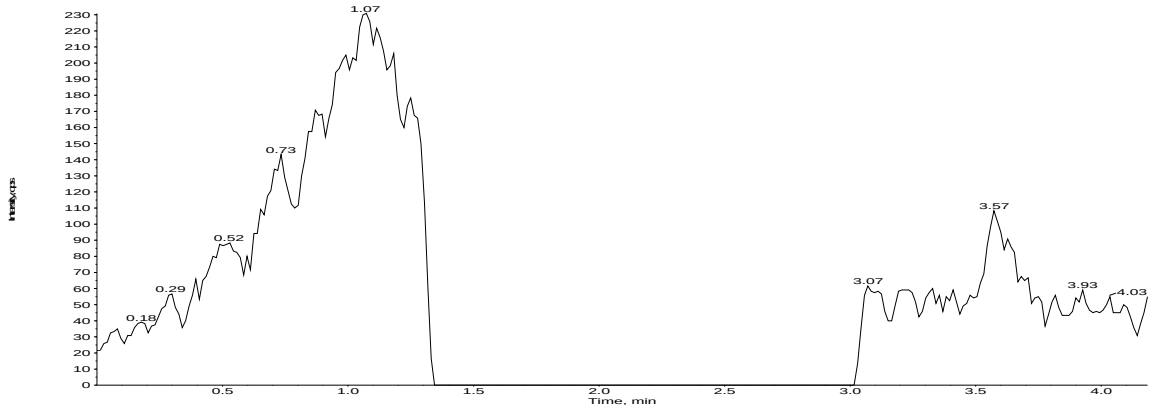


Figure 34 Representative Chromatogram of a Field Fortified Low Face/Neck Wipe Sample

463SET16-9

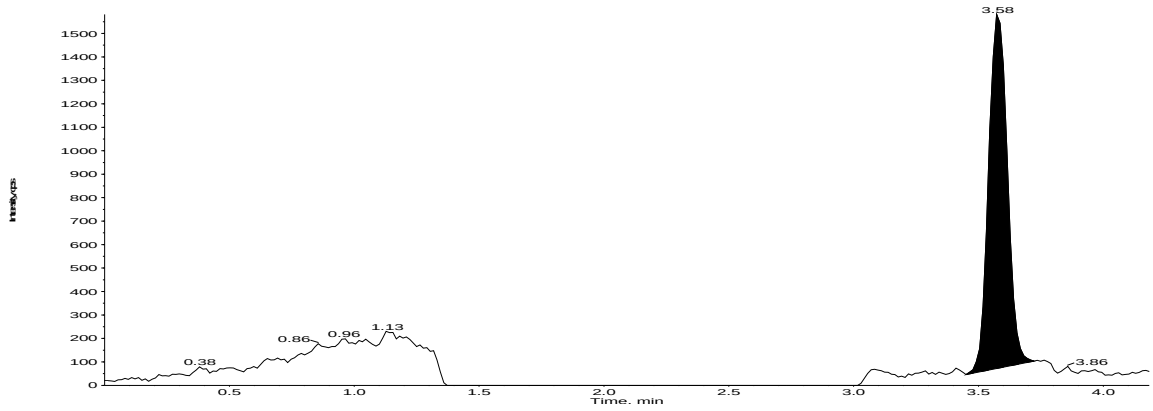


Figure 35 Representative Chromatogram of a Field Fortified High Face/Neck Wipe Sample

463SET16-12

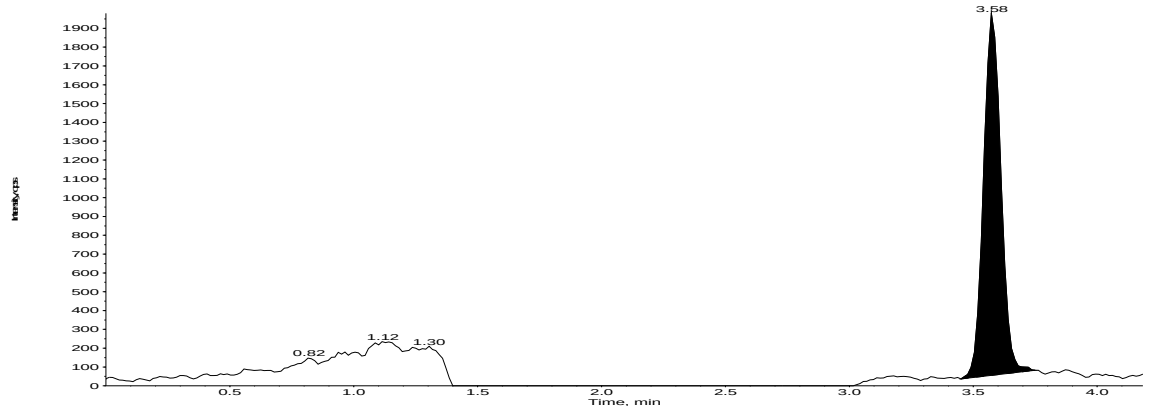


Figure 36 Representative Chromatogram of a Face/Neck Wipe Field Sample

463SET16-6

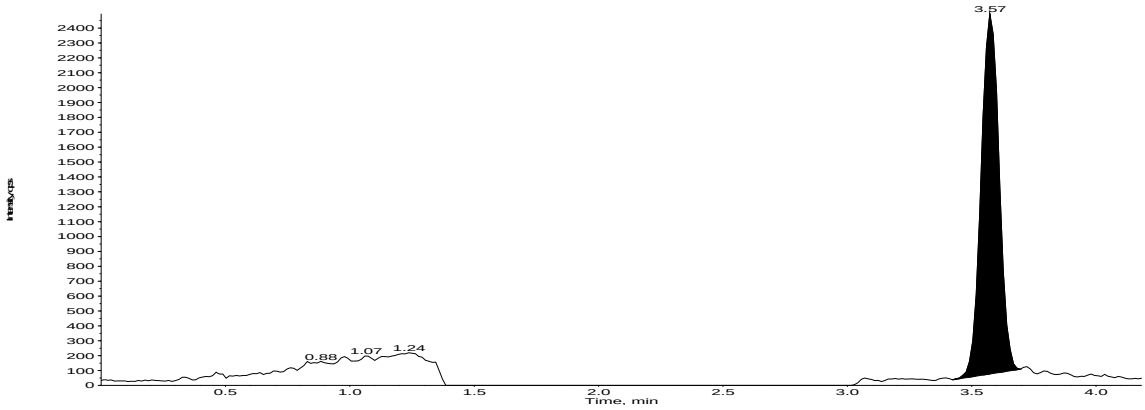


Figure 37 Representative Chromatogram of a Laboratory Control Inner Dosimeter Sample

463SET46-1

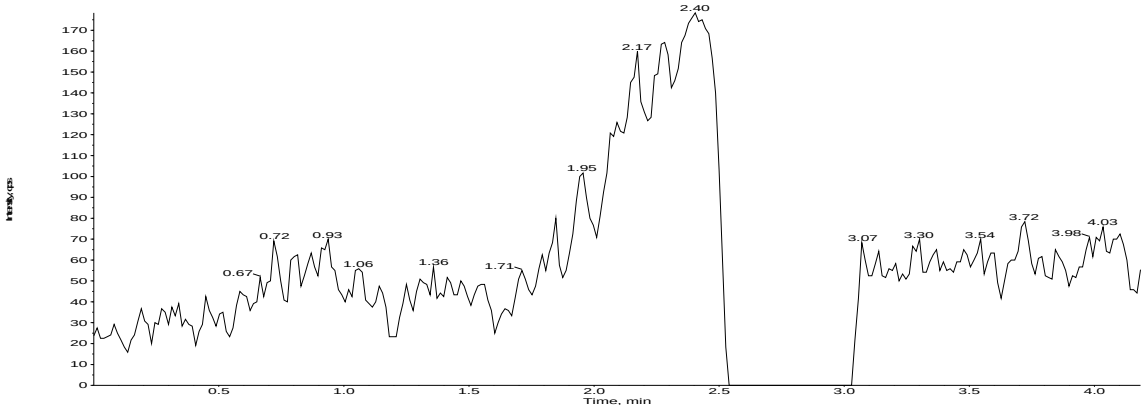


Figure 38 Representative Chromatogram of a Low Laboratory Fortification of an Inner Dosimeter Sample

463SET46-2

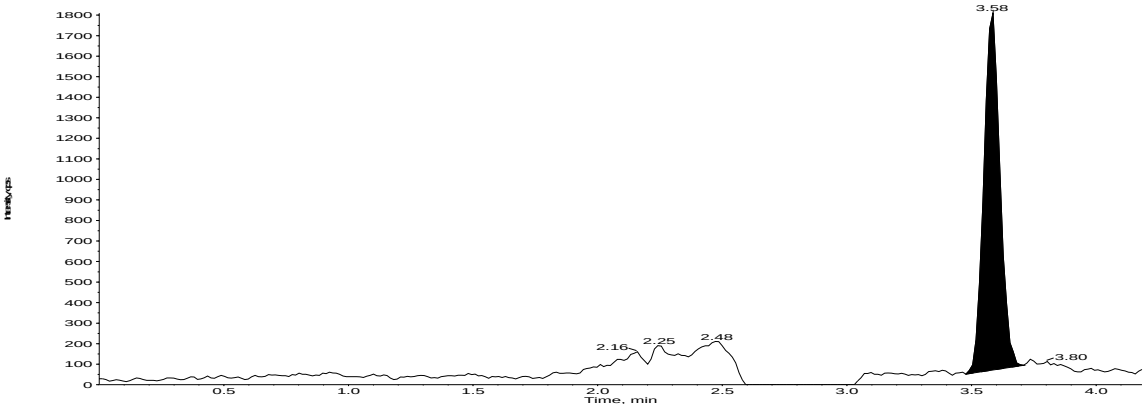


Figure 39 Representative Chromatogram of a High Laboratory Fortification of an Inner Dosimeter Sample

463SET46-3

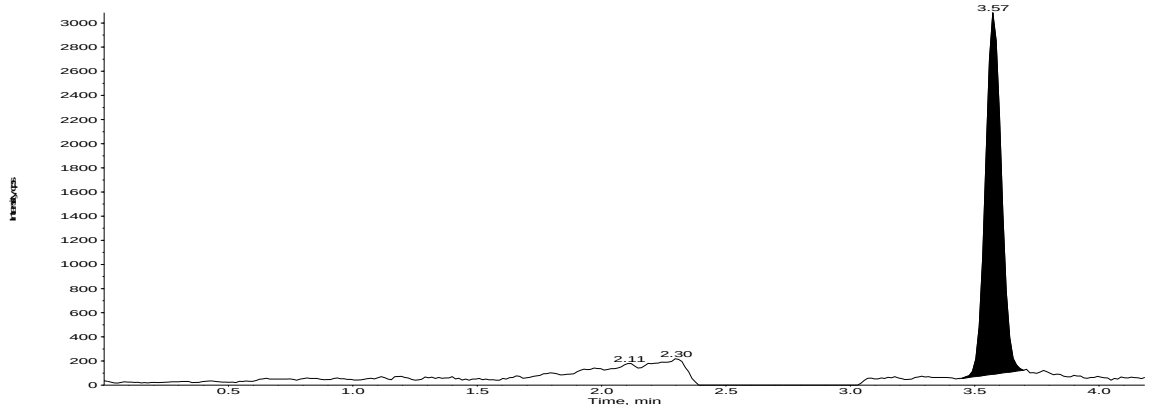


Figure 40 Representative Chromatogram of a Field Control Inner Dosimeter Sample

463SET46-11

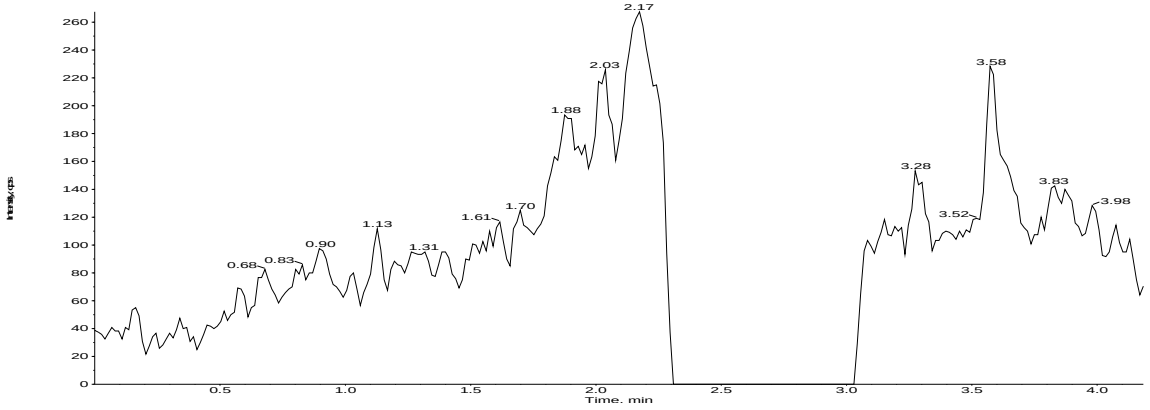


Figure 41 Representative Chromatogram of a Field Fortified Low Inner Dosimeter Sample

463SET46-13

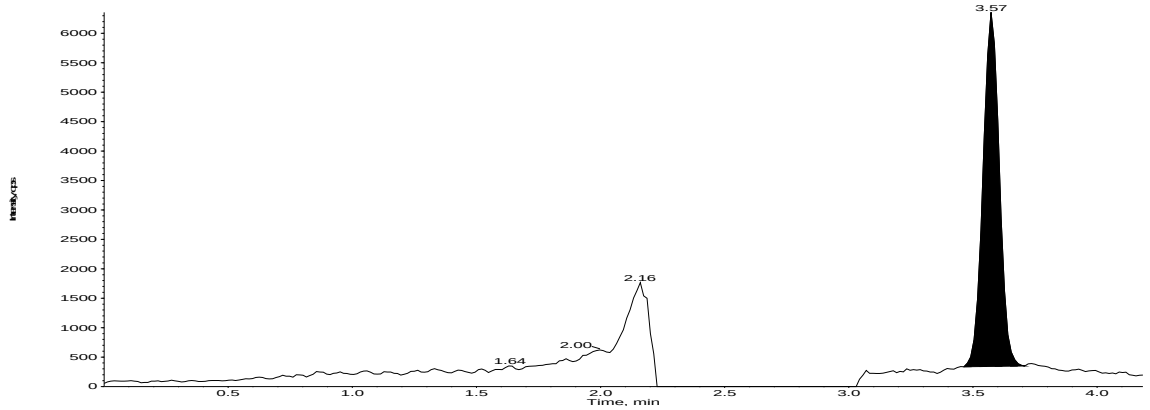


Figure 42 Representative Chromatogram of a Field Fortified High Inner Dosimeter Sample

463SET46-16

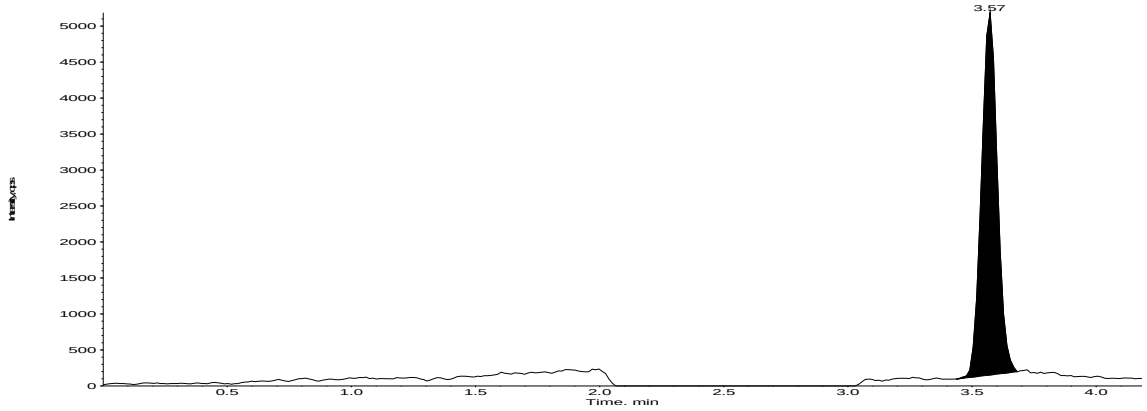


Figure 43 Representative Chromatogram of an Inner Dosimeter Field Sample

463SET46-4 (463SET46A)

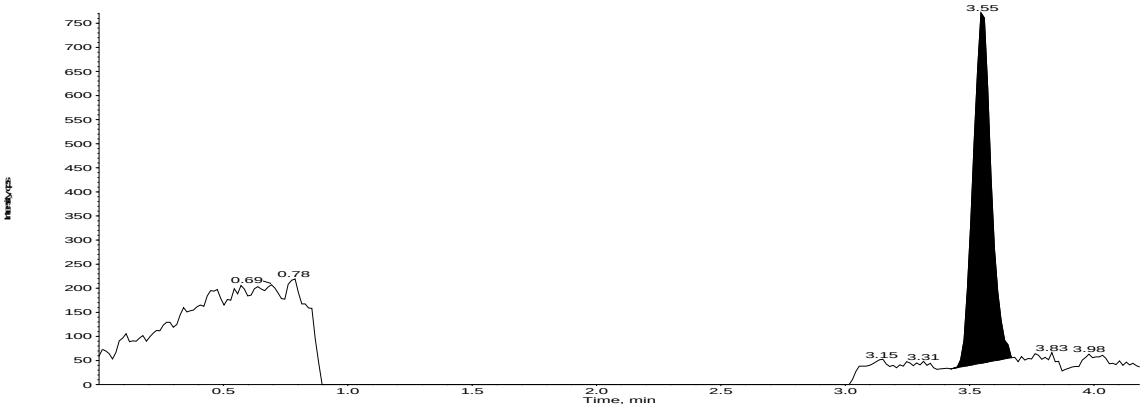


Figure 44 Representative Chromatogram of a Laboratory Control Painter's Hat Sample

463SET45-1

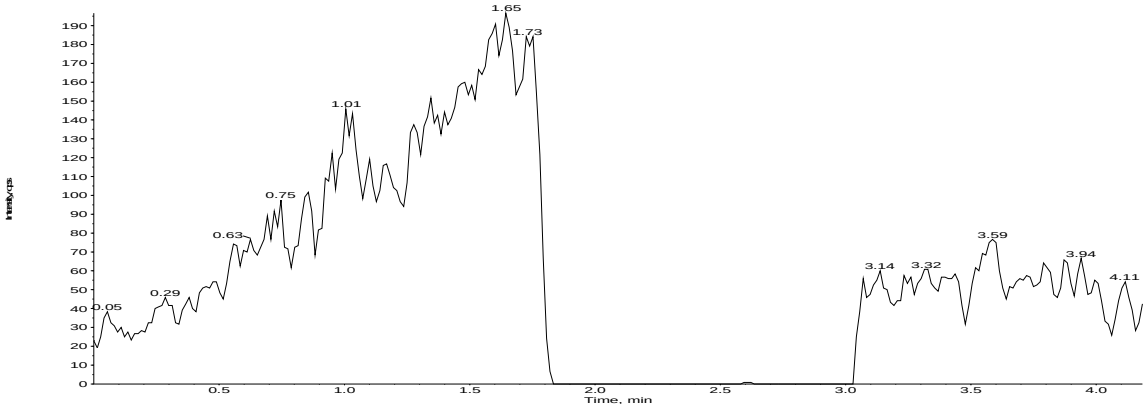


Figure 45 Representative Chromatogram of a Low Laboratory Fortification of a Painter's Hat Sample

463SET45-2

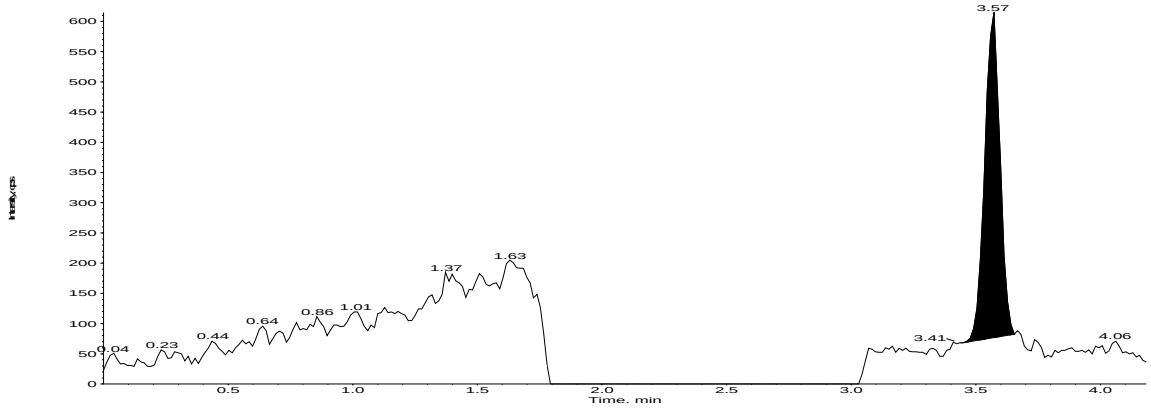


Figure 46 Representative Chromatogram of a High Laboratory Fortification of an Painter's Hat Sample

463SET45-3

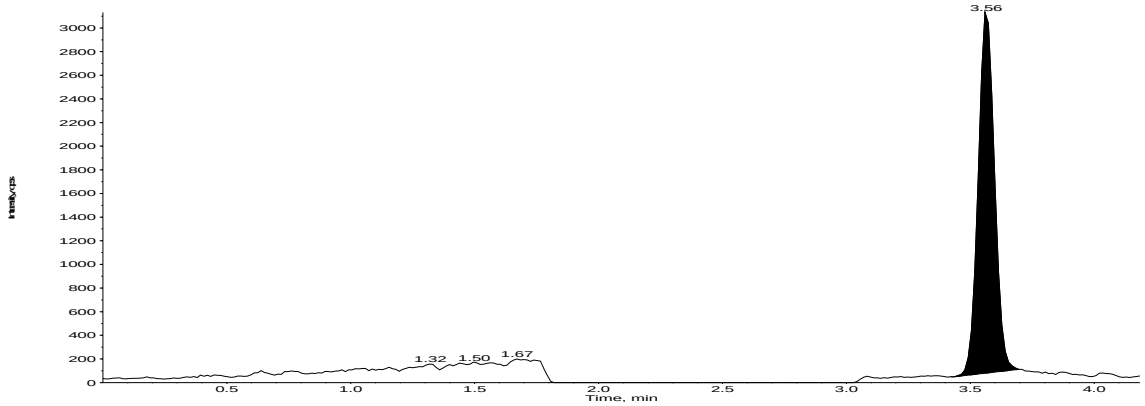


Figure 47 Representative Chromatogram of a Field Control Painter's Hat Sample

463SET45-5

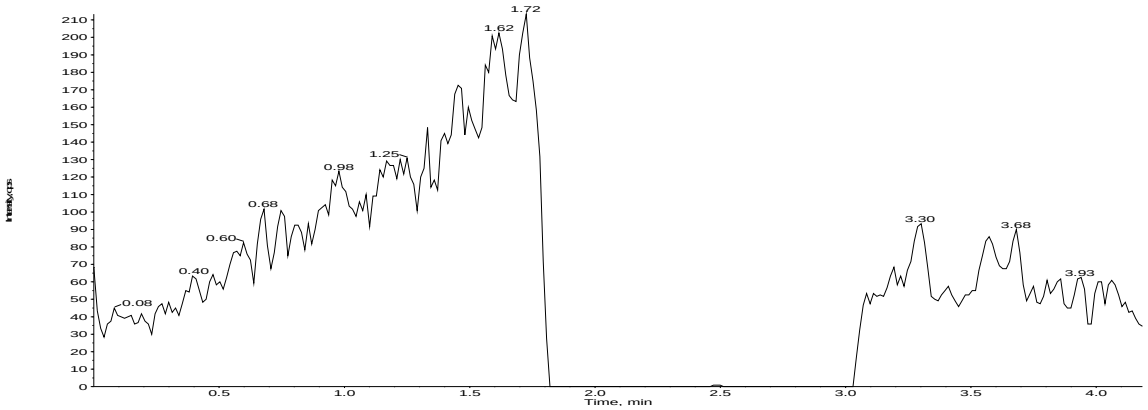


Figure 48 Representative Chromatogram of a Field Fortified Low Painter's Hat Sample

463SET45-7

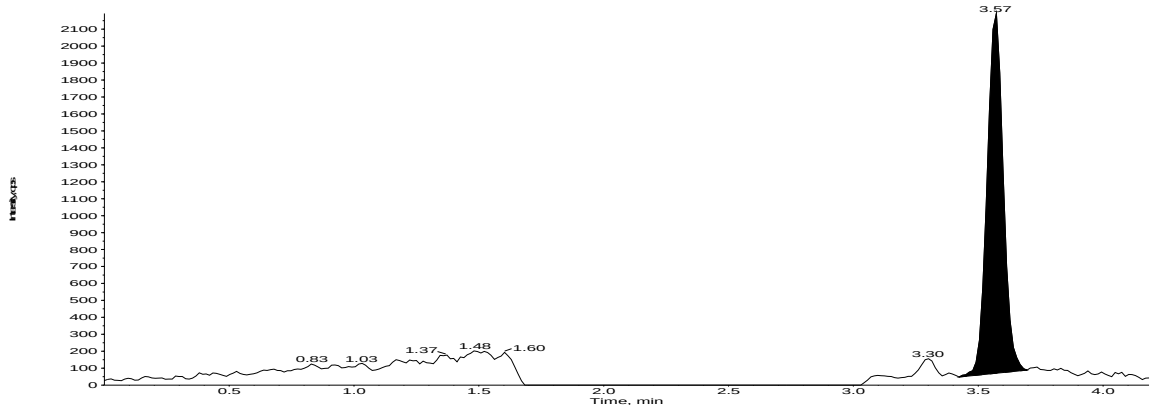


Figure 49 Representative Chromatogram of a Field Fortified High Painter's Hat Sample

463SET45-10

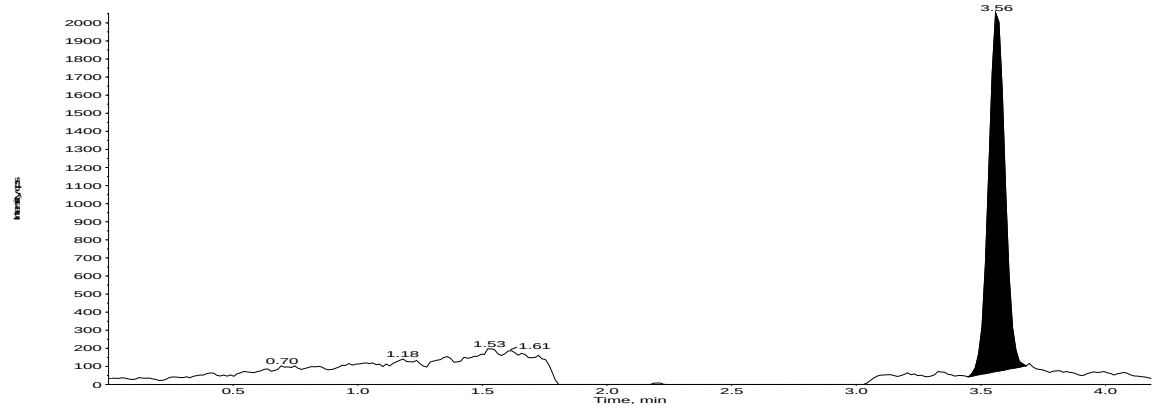


Figure 50 Representative Chromatogram of a Painter's Hat Field Sample

463SET45-4

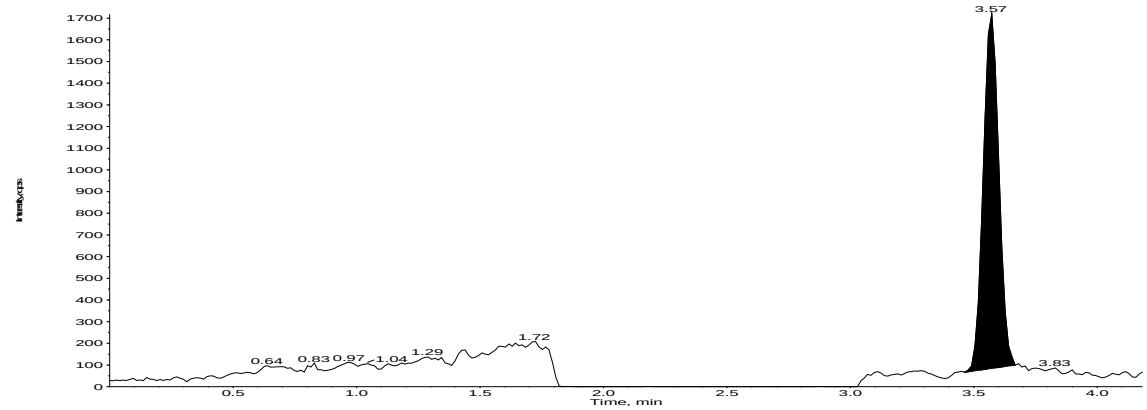


Figure 51 Representative Chromatogram of a Laboratory Control Outer Dosimeter Sample

463SET50-1

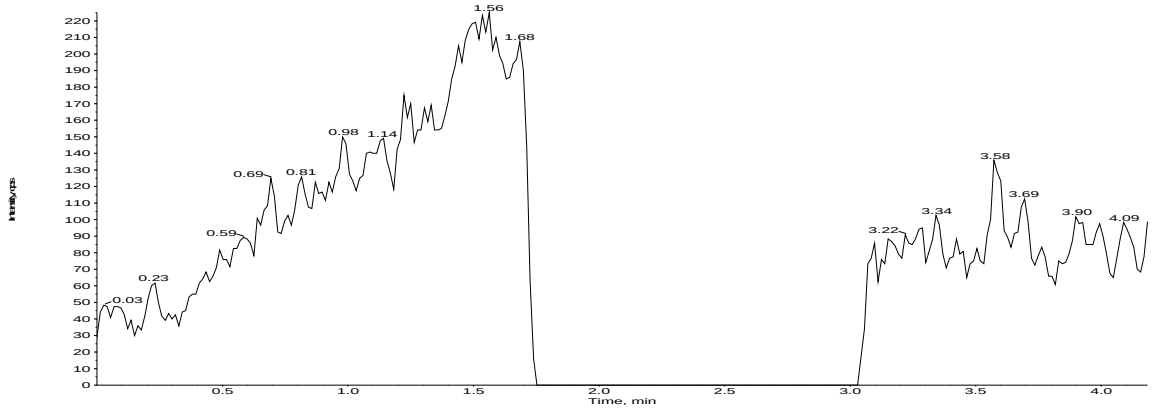


Figure 52 Representative Chromatogram of a Low Laboratory Fortification of an Outer Dosimeter Sample

463SET50-2

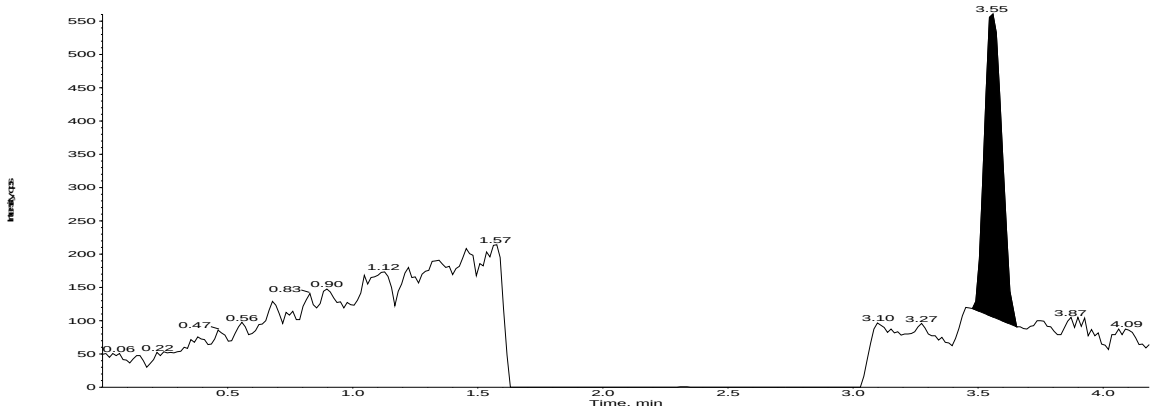


Figure 53 Representative Chromatogram of a High Laboratory Fortification of an Outer Dosimeter Sample

463SET50-3

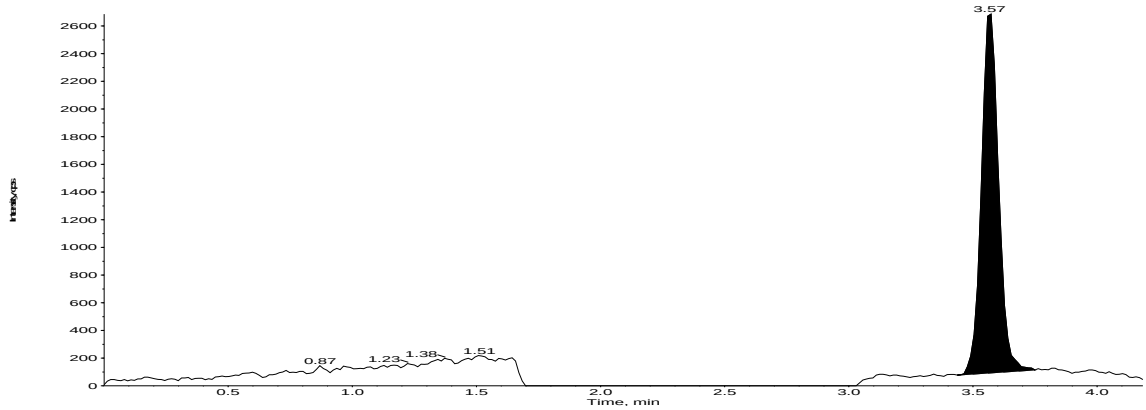


Figure 54 Representative Chromatogram of a Field Control Outer Dosimeter Sample

463SET50-16

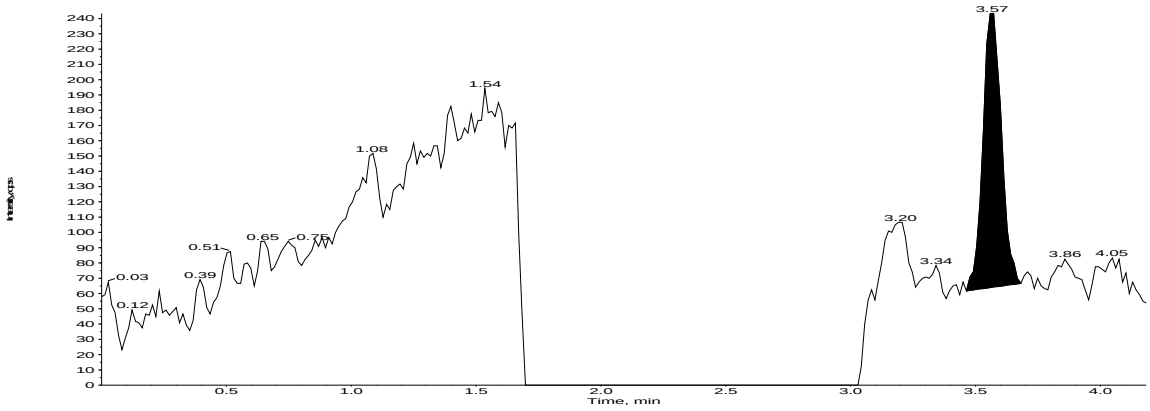


Figure 55 Representative Chromatogram of a Field Fortified Low Outer Dosimeter Sample

463SET50-18

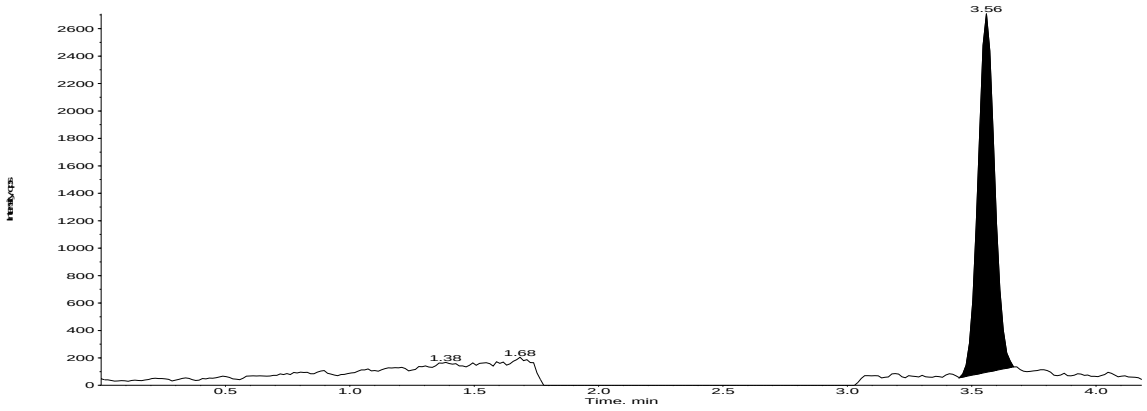


Figure 56 Representative Chromatogram of a Field Fortified High Outer Dosimeter Sample

463SET50-21

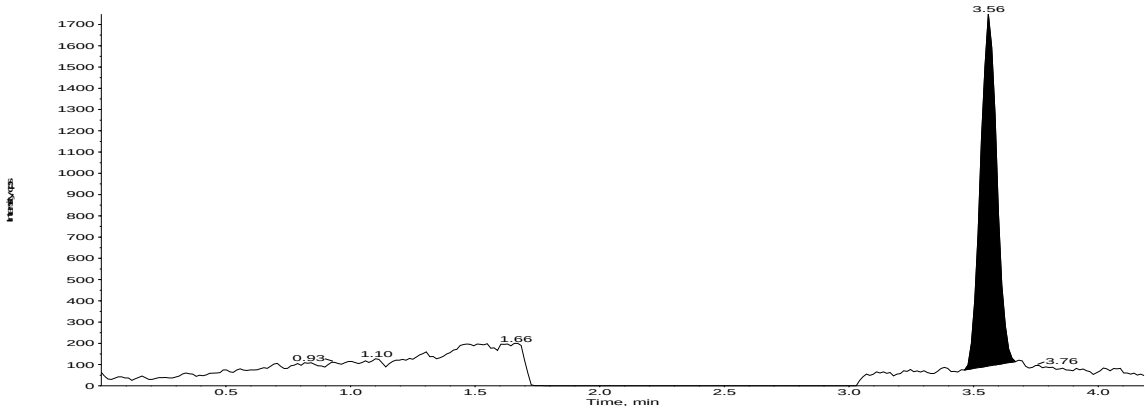


Figure 57 Representative Chromatogram of an Outer Dosimeter Field Sample

463SET50-4

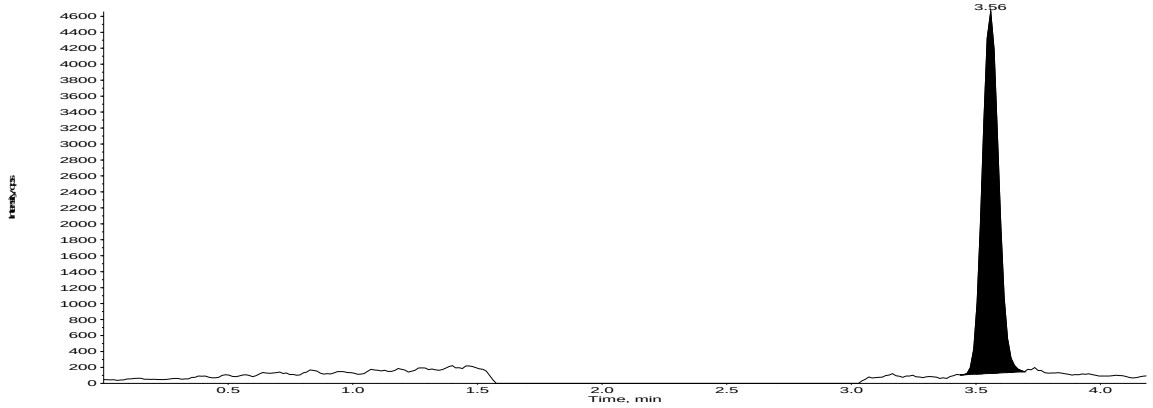


Figure 58 Representative Chromatogram of a Background Air Sampling Tube Sample

463SET36-4

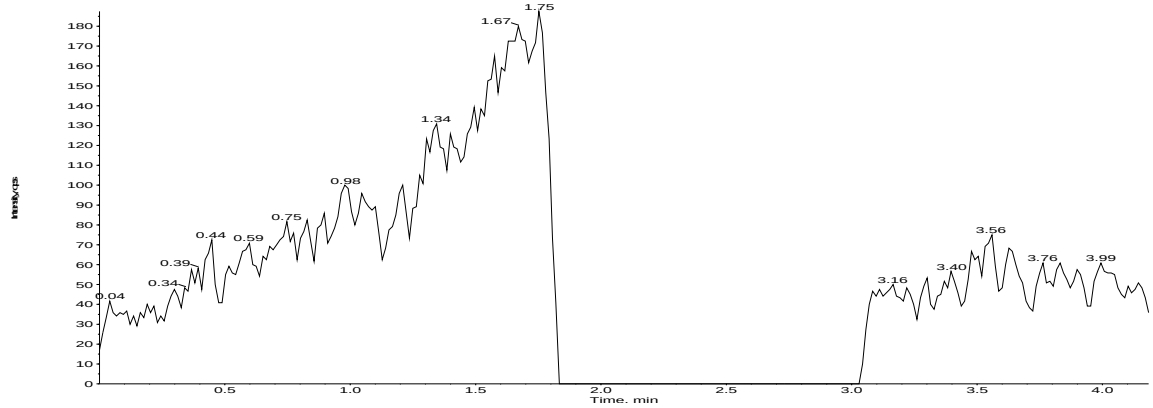
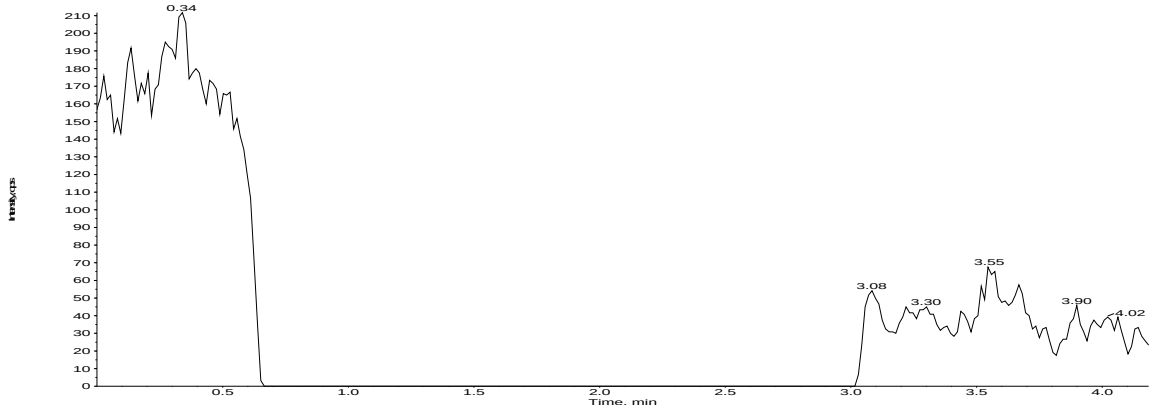


Figure 59 Representative Chromatogram of a Background Wall Wipe Sample

463SET75-4



APPENDIX K.

CERTIFICATES OF ANALYSIS

CERTIFICATE OF ANALYSIS FOR TEST MATERIAL

TITLE/OBJECTIVE: Characterization of 1,2-Benzisothiazolin-3-one (BIT) Lot A121028082 Under GLP

TEST MATERIAL:

COMMON NAME: BIT
CHEMICAL NAME: 1,2-Benzisothiazolin-3-one
LOT NO.: A121028082
CAS NO.: 2634-33-5
MOLECULAR FORMULA: C_7H_5NOS
MOLECULAR WEIGHT: 151.18

STUDY INITIATION DATE: April 22, 2016

METHODS USED:

PURITY: External-standard quantitation by high performance-liquid chromatography (HPLC) weight percent minus the average weight percent of water content by coulometric Karl Fischer (KF).
IDENTIFICATION: Liquid chromatography-mass spectrometry (LC-MS) and Fourier transform infrared Spectroscopy (FT-IR).

RESULTS AND CONCLUSIONS:

Structural confirmation of the test material was performed by LC-MS and FT-IR.

x PURITY DETERMINATION:
Result: 93.5% by external- standard quantitation HPLC after correcting for water determined by coulometric Karl Fischer titration.

x IDENTIFICATION:
LC-MS results were consistent with the expected mass spectra of 1,2-benzisothiazolin-3-one (BIT) and the FT-IR spectrum matched the FT-IR spectrum of a BIT reference sample

CALCULATIONS:

Area Percent: HPLC Internal Standard: N/A External Standard: HPLC
Other (explain): Karl Fischer titration

All original raw data and test material associated with this study were archived Quality Associates, Inc. 8161 Maple Lawn Blvd., 2nd Floor, Fulton, MD 20759. Only descriptive statistics were used unless otherwise noted in the results. This study was conducted in accordance with the Good Laboratory Practice Standard, 40 CFR Part 792, unless otherwise noted. Due to the short-term nature of the study, the stability of the test substance under storage conditions per 40 CFR Part 792.105(e) at the test site was not verified.

Recertification Date: April 22, 2018

D. N. Zuengler 6/3/2016

Dawn Zuengler, Study Director Date

Kerry Pacholke, Quality Assurance Date

STUDY DIRECTOR AND TEST FACILITY ADDRESS:
Impact Analytical 1940 N. Stark Rd. Midland, MI 48642

IMPACT ANALYTICAL

1940 H. Stark Road ▪ Midland, MI 48642 ▪ USA
Phone: (855) 427-6583 ▪ Fax: (989) 486-9429 ▪ www.impactanalytical.com
A Michigan Molecular Institute Center of Excellence

CERTIFICATE OF ANALYSIS FOR TEST SUBSTANCES

TITLE/OBJECTIVE: Characterization of 1,2-Benzisothiazolin-3-one (BIT) Under GLP

TEST MATERIAL:

COMMON NAME: BIT
CHEMICAL NAME: 1,2-Benzisothiazolin-3-one
LOT NO.: A121028082
CAS NO.: 2634-33-5
MOLECULAR FORMULA: C_7H_5NOS
MOLECULAR WEIGHT: 151.19

STUDY INITIATION DATE: 18 December 2013

METHODS USED:

PURITY: External standard quantitation HPLC weight percent minus the average weight percent of water content by coulometric Karl Fischer.
IDENTIFICATION: Liquid Chromatography-Mass Spectrometry and Fourier Transform-Infrared (FT-IR) Spectroscopy.

RESULTS AND CONCLUSIONS:

Structural confirmation of the test material was performed by LC-MS and FT-IR.

x PURITY DETERMINATION:
Result: 94.2% (94 ± 3% at 95% confidence limit) by external standard quantitation HPLC after correcting for water determined by coulometric Karl Fischer titration.

x IDENTIFICATION:
LC-MS results are consistent with the expected mass spectra of 1,2-Benzisothiazolin-3-one (BIT) and the FT-IR spectrum matched the FT-IR spectrum of a BIT reference sample

CALCULATIONS:

Area Percent: HPLC Internal Standard: N/A External Standard: HPLC
Other (explain): Karl Fischer titration

All original raw data and test material associated with this study were archived Quality Associates, Inc. 8161 Maple Lawn Blvd., 2nd Floor, Fulton, MD 20759. Only descriptive statistics were used unless otherwise noted in the results. This study was conducted in accordance with the Good Laboratory Practice Standard, 40 CFR Part 792, unless otherwise noted. The LC–MS, used to acquire the reference material spectra, was not re-qualified after maintenance. Due to the short-term nature of the study, the stability of the test substance under storage conditions per 40 CFR Part 792.105(e) at the test site was not verified.

Recertification Date: 18 December 2015

Arthur Ferruzzi, Ph.D., Study Director — 14 March 2014 — Date

John MacLauchlan, Quality Assurance — 14 March 2014 — Date

STUDY DIRECTOR AND TEST FACILITY ADDRESS:
Impact Analytical 1940 N. Stark Rd. Midland, MI 48642

CERTIFICATE OF ANALYSIS

Toronto Research Chemicals Inc.
2 Brisbane Road, North York, ON. M3J 2J8 Canada Tel: (416) 665-9696 Fax: (416) 665-4439
E-mail: orders@trc-canada.com Website: www.trc-canada.com

Bringing you products for innovative research.

dentification

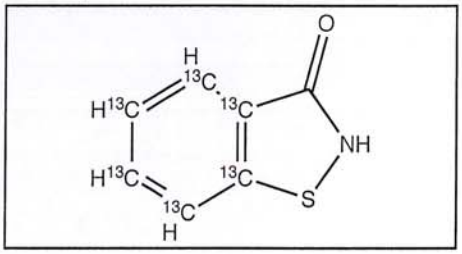
CAS Number:

Catalogue Number:
B204037

Product:
Benzoisothiazol-3-one-$^{13}C_6$

Synonyms:
1,2-Benzisothiazol-3(2H)-one-$^{13}C_6$; 3-Hydroxy-1,2-benzisothiazole-$^{13}C_6$; Acticide BIT-$^{13}C_6$; Apizas AP-DS-$^{13}C_6$; BIT -$^{13}C_6$; Benzisothiazolone-$^{13}C_6$; Benzo[d]isothiazol -3(2H)-one-$^{13}C_6$; Benzocil-$^{13}C_6$; Bestcide 200K-$^{13}C_6$; Bioban BIT 20DPG; Canguard BIT; Canguard BIT 20DPG; Proxel

Structure:



Molecular Formula:
$C^{13}C_6H_5NOS$

Molecular Weight:
157.14

Source of Product:
Synthetic

2. Analytical Information

Lot Number:
3-MGG-87-2

Melting Point:
135-138°C

Boiling Point:
N/A

Atmosphere:
Air

Appearance of Product:
Brown Solid

Solubility
DMSO, Methanol

Method for Determining Identity:
^1H NMR (DMSO-d_6 & CD_3OD), ^{13}C NMR (DMSO-d_6)
Spectroscopic and Mass Spectrometric Analysis

Stability
Not determined

Purity:
Chemical purity: 98%
Isotopic purity: 99.2%

Long Term Storage Condition:
-20°C Freezer

Additional Information:
TLC Conditions: SiO_2; Dichloromethane : Methanol = 9 : 1; Visualized with UV and AMCS; Single spot; Rf= 0.5.
^1H NMR, ^{13}C NMR and mass spectra conform to structure.
Normalized Intensity: $^{13}C_0$= 0.03%, $^{13}C_1$= 0.28%, $^{13}C_2$= 0.05%, $^{13}C_3$= 0.01%, $^{13}C_4$= 0.05%, $^{13}C_5$= 2.67%, $^{13}C_6$= 96.92%
Elemental Analysis: %C: 53.74, %H: 3.21, %N: 8.73

Philip Chan, Head of Quality Assurance

QC Test Date
September 21, 2012

Retest Date
September 21, 2015

APPENDIX L.

ANALYTICAL METHOD

Golden Pacific
LABORATORIES

Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters

GPL-MTH-081 (Revision 2)
Effective June 10, 2014

Reason for revision 1: Correct errors in extraction solvent for air sampling tubes and paint and to make minor editorial corrections.

Reason for revision 2: Clarification of expiration date for stock solutions prepared from reference substance.

Prepared by: _____ 01/30/18
Kimon P. Acedo, B.S. Date
Senior Chemist
Golden Pacific Laboratories, LLC

Reviewed by: _____ 01/30/18
Robert J. Testman, MBA Date
President
Golden Pacific Laboratories, LLC

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1.0 INTRODUCTION

Benzisothiazolinone (BIT) is a common additive to latex paint for control of microbes. An analytical method was developed for the determination of residues of BIT on various matrices, namely paint, dressing sponges wetted with isopropyl alcohol (IPA)/ water (50:50, v/v) [face wipes], an isopropyl alcohol (IPA)/ water (50:50, v/v) solution containing a dressing sponge [hand washes], cotton inner dosimeters, cotton outer dosimeters, air sampling tubes (OVS, XAD-2), painter's hats, and fiberglass filters.

The target limits of quantitation (LOQ) for the method (GPL-MTH-081) are summarized in the table below:

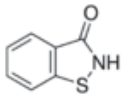
Matrix	LOQ
Face Wipes (Dressing Sponges)	100 ng/sample
Hand Washes	1 ng/mL
Outer Dosimeters	3 µg/sample
Inner Dosimeters	3 µg/sample
Painter's Hats	3 µg/sample
Air Sampling Tubes	10 ng/sample
Fiberglass Filters	10 ng/sample

2.0 REFERENCE SUBSTANCES

The reference substance is Benzisothiazolinone (BIT) available from Lonza, Carboquat (DDA as a carbonate/bicarbonate salt) available from Eurofins/Product Safety Labs, and isotopic Benzoisothiazol-3-one-($^{13}C_6$), available from Toronto Research Chemicals. These reference substances are used to prepare calibration and fortification solutions, and to determine procedural recoveries.

2.1 Reference Substance

Name: Benzisothiazolinone (BIT)
a.k.a 1,2-Benzisothiazolin-3-one



CAS No.: 2634-33-5
Source: Troy Chemical (Newark, NJ)
Date Received: October 2, 2013
Lot #: A121028082
Purity: 94.2%
Expiration Date: December 18, 2015
Storage: Ambient

2.2 Internal Standard

Name:	Benzoisothiazol-3-one-$^{13}C_6$
CAS No.:	Not available
Source:	Toronto Research Chemicals, Inc (Ontario, Canada)
Date Received:	September 27, 2012
Lot #:	3-MGG-87-2
Purity:	98.0%
Expiration Date:	September 15, 2015
Storage:	Frozen (≤ -10ºC)

3.0 PRINCIPLE OF THE METHOD

BIT residues are extracted from dressing sponges (face wipes), inner dosimeters, outer dosimeters, painter's hats, and fiberglass filters with methanol/ water/ formic acid (70: 30: 0.016, v/v/v) also referred to as MWF diluent. BIT residues are extracted from air sampling tubes with acetonitrile/ water/ formic acid (70: 30: 0.016, v/v/v). Internal standard in MWF diluent is added to an aliquot of the final extract and analyzed using HPLC/MS/MS for BIT residues

Aliquots of the hand washes are diluted with MWF diluent. Internal standard (IS) in MWF diluent is added to an aliquot of the diluted extract and analyzed using HPLC/MS/MS for BIT residues.

BIT residues are extracted from paint by diluting with methanol/ water (10:90, v/v), shaking then centrifuging to form a supernatant. The supernatant is then filtered, diluted into range, and analyzed on HPLC/MS/MS.

At least five concentrations of the reference substances in MWF diluent are used for standards. Calibration plots are drawn for peak area ratios of BIT/IS versus concentration ratio of BIT/IS and are used for quantitation purposes.

4.0 EQUIPMENT

Unless otherwise indicated, the equipment listed below may be substituted with functionally equivalent equipment as may be available.

- Balance, Analytical: Mettler model AB 204-S (Columbus, OH, USA)
- Balance, Analytical: Mettler model PB3002-S
- Disposable Pasteur pipettes, glass
- Eberbach Variable Speed Shaker (Ann Arbor, MI, USA)
- Eberbach Two-Speed Shaker

- Jar, amber glass with Teflon lined cap: 30 and 120 mL
- Jar, glass with Teflon lined cap: 1L and 4L
- Test tube with Teflon lined cap, glass: 7 and 15 mL
- Culture tube, glass, 25 mL
- Micropipet Drummond Wiretrol 100 µL disposable micropipets (Broomall, PA, USA)
- Adjustable micropipette, 100 – 1000 µL, Rainin Pipet-LiteTM Single-Channel Pipette, Mettler-Toledo (Columbus OH, USA)
- Syringes: various sizes from 10 to 1000 µL, Hamilton (Reno, Nevada, USA)
- Volumetric flasks, glass: 10, 25, 50 and 100 mL
- Volumetric glass pipette: various sizes
- Graduated Cylinders: 10, 25, 50, 100, 250, 500, 1000 and 2000 mL
- HPLC vials, clear glass: 1.8 mL
- AB Sciex API4000 LC-MS/MS with Shimadzu LC-20AD HPLC Pumps, Shimadzu SCL-10A VP Controller, and Shimadzu SIL-20AC Autosampler or Shimadzu SIL-20AC HT Autosampler with Analyst Software

5.0 CHEMICALS/REAGENTS/SUPPLIES

Alternate suppliers of reagents having comparable specifications may be used.

- Acetonitrile, Fisher #A996-4 (Pittsburg, PA, USA)
- Water, Optima Grade, Fisher #W7-4 (Pittsburg, PA, USA)
- Isopropyl Alcohol, Fisher #A464-4 (Pittsburg, PA, USA)
- Formic Acid 88%, Fisher #A118P-500 (Pittsburg, PA, USA)
- Methanol, ACS Grade, VWR MKH08010 (Radnor, PA, USA)
- Dressing Sponges, Johnson & Johnson Mirasorb, 4”x4”, 4-ply (Arlington, TX, USA)
- Inner Dosimeters, Coldmaster, 100% Cotton Union Suit (Athens, AL, USA)
- Outer Dosimeter, Universal Overall, 100% Cotton (Chicago, IL, USA)
- Air Sampling Tubes, SKC OVS, XAD-2 with glass fiber filters (Fullerton, CA, USA)
- Fiberglass Filters, SKC, RespiCon, 37 mm (Fullerton, CA, USA)
- Painter’s Hats, Dalix, Cotton Twill (Amazon.com)

6.0 STANDARD SOLUTIONS

The BIT reference substance is used in the preparation of the calibration solutions and fortification solutions for air sampling tubes. Base paint is fortified with BIT to a concentration of approximately 600 ppm and used for fortification of matrices and as a stock to serially dilute for dilute fortification solutions.

6.1 BIT Fortification Solutions in Solvent

The BIT reference substance is first weighed directly into a 100 mL volumetric flask and brought to volume with methanol to give a solution with a concentration of approximately 400 µg/mL BIT (Solution A) after being corrected for purity.

An aliquot of solution A (5 mL) is diluted with methanol to a final volume of 50 mL, resulting in a solution containing 40.0 µg/mL of BIT (Solution B).

An aliquot of solution A (1 mL) is diluted with methanol to a final volume of 100 mL, resulting in a solution containing 4.00 µg/mL of BIT (Solution C).

An aliquot of solution A (0.1 mL) is diluted with methanol to a final volume of 100 mL, resulting in a solution containing 400 ng/mL of BIT (Solution D).

The stock solution prepared directly from neat reference substance is assigned an expiration date of 1 year. Solutions A, B, C, and D are fortification solutions used for fortifying air sampling tubes. The fortification solutions diluted from the stock are renewed every 3 months or as needed. All solutions are stored in a refrigerator in amber bottles.

6.2 BIT Calibration Solutions

Aliquots of solution D are taken with glass pipettes or Hamilton syringes to make calibration standards. Calibration standards are diluted with MWF. Typical concentrations of calibration standards prior to addition of IS are shown below:

Volume Used (mL)	Final Volume (mL)	Concentration (ng/mL)
0.1	80	0.500
0.1	40	1.00
0.5	100	2.00
1	80	5.00
2	40	20.0
5	40	50.0

All calibration solutions are stored in amber bottles in the refrigerator (4 ± 5°C). Solutions are prepared every three months or as required.

6.3 Diluted Paint BIT Fortification Solutions

Sherwin Williams latex paint containing approximately 120 ppm BIT will be fortified with a concentrated solution of BIT in dipropylene glycol to achieve 600 ppm BIT in paint [600 µg BIT/g paint] (Solution P1).

Aliquots of solution P1 will be diluted with water to achieve solutions of various concentrations. These solutions will be used to fortify matrices when the fortified paint cannot be used.

An aliquot of solution P1 (~16.5 g) is diluted with water to a final volume of 100 mL, resulting in a solution containing 100 µg/mL of BIT (Solution P2).

An aliquot of solution P1 (20 mL) is diluted with water to a final volume of 40 mL, resulting in a solution containing 50.0 µg/mL of BIT (Solution P3).

An aliquot of solution P1 (30 mL) is diluted with water to a final volume of 100 mL, resulting in a solution containing 30.0 µg/mL of BIT (Solution P4).

An aliquot of solution P3 (5 mL) is diluted with water to a final volume of 50 mL, resulting in a solution containing 5.00 µg/mL of BIT (Solution P5).

An aliquot of solution P3 (3 mL) is diluted with water to a final volume of 50 mL, resulting in a solution containing 3.00 µg/mL of BIT (Solution P6).

An aliquot of solution P3 (1 mL) is diluted with water to a final volume of 100 mL, resulting in a solution containing 500 ng/mL of BIT (Solution P7).

The above fortification solutions are used to fortify test matrices except for air sampling tubes. Solution P1, the fortified base paint, is stored in amber bottles at ambient temperature and renewed every 6 months or as needed. The remaining fortification solutions, water-diluted paint solutions, are stored in the refrigerator (4 ± 5°C) in amber bottles and renewed every 3 months or as needed.

6.4 Internal Standard Calibration Solutions (IS)

The isotopic ($^{13}C_6$)-Benzisothiazolin-3-one (BIT-IS) reference substance is weighed (~1 mg) into a 10 mL volumetric flask and made up to volume with acetonitrile to give a solution with a concentration of

approximately 100 µg/mL BIT-IS (Solution IS) after being corrected for purity.

An aliquot of solution IS (0.25 mL) is diluted with MWF solvent to a final volume of 510 mL, resulting in a solution containing 50 ng/mL of BIT-IS (Solution IS-1). Solution IS-1 is used in preparing the mixed BIT and BIT-IS standard solution.

All IS solutions are stored in amber bottles in the refrigerator (4 ± 5°C). All internal standard solutions are not assigned an expiration date.

6.5 Mixed BIT and BIT-IS Calibration Solutions

Using the BIT calibration solutions prepared at various levels and the BIT-IS calibration solution prepared at 50 ng/mL, mixed calibration solutions are prepared. Prepare mixed calibration solutions by mixing equal volume aliquots each of the BIT calibration solutions with an equal volume of the BIT-IS calibration solution. Typical concentrations of calibration standards are shown below:

BIT Concentration (ng/mL)	BIT-IS Concentration (ng/mL)	BIT/BIT-IS Concentration (ng/mL)
50.0	50.0	25.0/25.0
20.0	50.0	10.0/25.0
5.00	50.0	2.50/25.0
2.00	50.0	1.00/25.0
1.00	50.0	0.500/25.0
0.500	50.0	0.250/25.0

Mixed calibration solutions are prepared daily just prior to sample analysis. A typical calibration curve is shown in Figure 3.

7.0 ANALYTICAL PROCEDURE

7.1 Determination of the Potency of BIT Fortification Solutions

Prior to using the fortification solutions with the matrices, aliquots of each fortification solution are analyzed to verify concentration. Triplicate aliquots of each fortification solution are pipetted into appropriate volumetric flasks and brought to volume with MWF so that the response falls within the calibration range of the standards.

BIT-IS is added and the samples are analyzed using HPLC/MS/MS analysis.

7.2 Analytical Procedure for Paint

Base paint is aliquoted by weight into appropriate containers to prepare paint samples. The paint samples are fortified at one of two different concentration levels prior to extraction. The fortification is performed by adding a known amount of BIT in a minimal volume of dipropylene glycol. Each sample will be shaken for at least 30 minutes to disperse BIT into the paint homogeneously.

After dispersal of BIT into paint, each paint sample is aliquoted by weight (~1 g) into a separate 30-mL amber bottles. To each sample, 19 mL of methanol/ water (10:90, v/v) is added and then shaken on a reciprocal platform shaker set at >30 RPM for 30 minutes. The samples are then poured into a 250-mL mixing cylinder. Each sample is quantitatively transferred using several ~20-mL volumes of methanol/ water (10:90, v/v) and subsequently QS'd to 250 mL. The final sample is mixed in the cylinder to ensure homogeneity, then a small sample is syringe filtered with a PVDF filter. The filtrate is then diluted into range of the calibration curve using MWF, transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. A copy of the flowchart is shown in Appendix 1.

7.3 Fortification of the QC Samples

For the determination of method performance, quality control (QC) samples are analyzed with each analytical set. Control samples of dressing sponges, hand washes, inner and outer dosimeters, painter's hats, air sampling tubes, and fiberglass filters are fortified with the appropriate amount of BIT and taken through the procedure to determine procedural recoveries. Samples from the different matrices are fortified with fortification solutions using volumetric pipets, positive displacement pipets, or syringes as described below.

7.4 Analytical Procedure for Face Wipes

Face wipes are used as directed by the protocol or Study Director. Face wipe samples are prepared by moistening two dressing sponges each with 4 or 5 mL of IPA/water (50:50, v/v), placed in a wide mouth jar and fortified with a fortification solution.

A 200 µL aliquot of the appropriate fortification solution is used for

fortification of face wipes using a 200 µL micropipette for the low and mid fortification levels. A ~0.17 g aliquot of BIT-fortified paint is added by weight for the high fortification level. The targeted levels are 0.1 µg/sample, 10 µg/sample, and 100 µg/sample. The fortified samples are allowed to stand for approximately 1 minute to ensure absorption of the fortification solution into the wipes.

Each face wipe sample is extracted with 100-mL of MWF, for a total extraction volume of 108-110 mL. The samples are placed on a platform shaker for 15 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.5 Analytical Procedure for Hand Washes

The blank hand wash solution is prepared by diluting isopropyl alcohol (IPA) with water in a 1:1 ratio. For human exposure studies, hand washes are comprised of 500 mL IPA/ water (50:50, v/v) and a packet containing two dressing sponges. For method validation or freezer storage stability experiments, the sample may be scaled down to 250 mL IPA/ water (50:50, v/v) and one dressing sponge. The hand wash samples fortified with an aliquot of the appropriate fortification solution. The targeted levels are 1 ng/mL, 100 ng/mL and 1000 ng/mL.

A 500 µL aliquot of the appropriate fortification solution is used for fortification of hand washes using a 1.0 mL pipet for the low and mid fortification levels. A ~0.45 g aliquot of BIT-fortified paint is added by weight for the high fortification level.

The fortified samples are placed on a platform shaker for 15 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.6 Analytical Procedure for Inner Dosimeters

Whole inner dosimeters are cut into six pieces (2 arms, 2 legs, torso front, and torso back) and any buttons on the dosimetry are removed and discarded. Pieces of inner dosimeter are placed in a

1 L glass jar. The pieces are fortified with an aliquot of the appropriate fortification solution. The targeted levels are 3 µg/sample, 300 µg/sample, and 3000 µg/sample.

A 1 mL aliquot of the appropriate fortification solution is used for fortification of inner dosimeters using a 1.00 mL pipet for the low fortification level. For the mid and high fortification level, a 0.5 g and 5.0 g aliquot of paint is added by weight, respectively. A swatch of each sample to be fortified is cut away and fortified on a weigh boat using an analytical balance. The weight of paint added to the swatch is recorded, then returned to the sample in the extraction vessel and smeared onto the matrix. The samples are allowed to stand for approximately 15 minute to ensure absorption of the fortification solution or paint into the dosimeter.

Each inner dosimeter sample is extracted with 750 mL of MWF. The samples are placed on a platform shaker for 15 minutes. Samples are then allowed to settle for at least 4 hours or overnight, then shaken again on a platform shaker for 15 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.7 Analytical Procedure for Outer Dosimeters

Outer dosimeters, consisting of pants and shirts, are cut into six pieces (2 arms, 2 legs, torso front, and torso back) and any buttons on the dosimetry are removed and discarded. Whole dosimeters may be pre-washed in a washing machine with no detergent and hang dried prior to sectioning if background residues are present. Pieces of the outer dosimeter are placed in a 4 L glass jar. The pieces are fortified with an aliquot of the appropriate fortification solution. The targeted levels are 3 µg/sample, 300 µg/sample, and 3000 µg/sample.

A 1 mL aliquot of the appropriate fortification solution is used for fortification of outer dosimeters using a 1.00 mL pipet for the low fortification level. For the mid and high fortification level, a 0.5 g and 5.0 g aliquot of paint is added by weight, respectively. A swatch of each sample to be fortified is cut away and fortified on a weigh boat using an analytical balance. The weight of paint added to the swatch is recorded, then returned to the sample in the extraction vessel and smeared onto the matrix. The samples are allowed to stand for approximately 15 minute to ensure absorption of the

fortification solution or paint into the dosimeter.

Each outer dosimeter sample is extracted with 2000 mL of MWF. The samples are placed on a platform shaker for 15 minutes. Samples are then allowed to settle for at least 4 hours or overnight, then shaken again on a platform shaker for 15 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.8 Analytical Procedure for Painter's Hats

Painter's hats are placed in a 4 L glass jar and fortified with an aliquot of the appropriate fortification solution. The targeted levels are 3 µg/sample, 300 µg/sample, and 3000 µg/sample.

A 1 mL aliquot of the appropriate fortification solution is used for fortification of painter's hats using a 1.00 mL pipet for the low fortification level. For the mid and high fortification level, a 0.5 g and 5.0 g aliquot of paint is added by weight, respectively. A swatch of each sample to be fortified is cut away and fortified on a weigh boat using an analytical balance. The weight of paint added to the swatch is recorded, then returned to the sample in the extraction vessel and smeared onto the matrix. The samples are allowed to stand for approximately 15 minute to ensure absorption of the fortification solution or paint into the dosimeter.

Each painter's hat sample is extracted with 2000 mL of MWF. The samples are placed on a platform shaker for 15 minutes. Samples are then allowed to settle for at least 4 hours or overnight, then shaken again on a platform shaker for 15 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.9 Analytical Procedure for Air Sampling Tubes

Air sampling tubes are fortified with 25 µL of the appropriate fortification solution using a 25 µL syringe. The syringe is placed just below the filter, piercing the filter and the fortification solution is injected onto the XAD-2 resin bed. The targeted levels are 0.01 µg/sample, 1 µg/sample, and 10 µg/sample.

The contents of the air sampling tube are emptied into a 25-mL glass culture tube and extracted with 10-mL of acetonitrile/ water/ formic acid (70: 30: 0.016, v/v/v). The samples are placed on a platform shaker for 15 minutes and allowed to settle for at least 5 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

7.10 Analytical Procedure for Fiberglass Filters

Fiberglass filters are placed into 25-mL culture tubes and fortified with 20 µL of the appropriate fortification solution using a 20 µL pipet for the low and mid fortification levels. For the high fortification level, 200 µL of the fortification solution is added using a 1.0 mL pipet. The fortified samples are allowed to stand until the fortification solution absorbs into the matrix. The targeted levels are 0.01 µg/sample, 1 µg/sample, and 10 µg/sample.

Each fiberglass filter sample is extracted with 10 mL of MWF. The samples are placed on a platform shaker for 15 minutes and allowed to settle for 5 minutes. An aliquot is transferred to a chromatography vial, an equal amount of IS solution is added and analyzed by HPLC/MS/MS. Samples having higher residue levels are diluted to an appropriate final volume using MWF so that the response falls within the calibration range of the standards. A copy of the flowchart is shown in Appendix 1.

8.0 QUANTITATION

8.1 Instrumentation

A Sciex API4000 LC/MS/MS system is used to analyze samples. The HPLC consists of two Shimadzu LC-20AD HPLC Pumps, a Shimadzu SCL-10A VP Controller, and a Shimadzu SIL-20AC HT Autosampler. Data is acquired using Analyst software, version 1.5 or equivalent.

8.2 HPLC Conditions

Analytical Column:	Phenomenex, Luna 3 µm, C18(2), 100Å, 50 x 3.0 mm
Column Temperature:	Ambient

Mobile Phase: Gradient:

A% = 0.2% formic acid in acetonitrile
B% = 0.2% formic acid in water

Time (min)	A (%)	B (%)
0.0	10.0	90.0
4.0	60.0	40.0
4.1	10.0	90.0
5.1	10.0	90.0

Flow Rate: 300 µL/min
Injector: autosampler
Injection Volume: 10 µL
Approximate Retention Time: BIT: ~3.5 min, IS: ~3.5 min

8.3 Mass Spectrometer Parameters

Interface: TurboIonSpray® (ESI)
Polarity: Positive
Scan Type: MRM Monitoring with Unit resolution
Ions Monitored:

(BIT)	m/z 152.2 (Q1)
	m/z 105.0 (Q3)
(BIT confirmatory ion)	m/z 152.2 (Q1)
	m/z 108.8 (Q3)
(IS)	m/z 158.2 (Q1)
	m/z 111.0 (Q3)

8.4 HPLC/MS/MS Detector Response Calibration

The HPLC/MS/MS responses (peak areas) are determined for a series of calibration standards. Through the Analyst Software, the concentrations of the standards and IS injected and their corresponding peak responses are compiled. From this Analyst calculates a standard calibration curve using a 1/x weighted linear regression (see Equation 1) and a correlation coefficient (r) based on the standard and IS concentrations and their respective peak response ratios.

For each analytical set, the calibration data is used to perform a linear regression analysis. The analyte versus IS injected ratio (concentration analyte injected / concentration IS injected) is taken as the X-axis (concentrations in ng/mL). The detector response ratio (peak area analyte / peak area IS) is taken as the Y-axis to

give Equation 2.

$$y = mx + b \quad \text{[Eq. 1]}$$

where: y = peak area response ratio (peak area analyte / peak area IS) or (sample/standard)
m = slope of the regression line
x = analyte versus IS injected ratio (concentration analyte injected / concentration IS injected)
b = intercept of the regression line

$$\text{peak area ratio} = m(\text{analyte/IS ratio}) + b \quad \text{[Eq. 2]}$$

8.5 Sample Analysis

The peak area response ratios for BIT versus IS are computed using the Analyst software, version 1.5. For the standards, a curve using the peak area response ratio for BIT versus IS and the concentration ratios of the calibration standards for BIT versus IS is generated using Analyst 1.5 or Microsoft Excel. The amount of material is determined from the corresponding calibration plot. For samples, the amount found (ng/mL) of BIT may be calculated from the observed peak area ratio (BIT/IS), using Equation 3.

$$\text{ng BIT/mL} = \frac{[(\text{peak area BIT/peak area IS}) - b] * \text{ng IS/mL}}{m} \quad \text{[Eq. 3]}$$

Any apparent residues found in the control samples are subtracted as raw peak area from the fortified samples if the peak area is greater than 30% of the LOQ.

Both samples and standards must be analyzed under the same HPLC/MS/MS conditions and within the same analytical sequence.

9.0 CALCULATION OF RESIDUES

Taking the ng/mL from the standard calibration curve, BIT concentrations (ng/sample, ng/mL or ng/g) in unknown samples and BIT recovery from fortified samples are determined using the following equations:

$$\textit{ng/sample (ng/g, ng/mL)} = \frac{\textit{(ng/mL from curve) x (final vol in mL)}}{\textit{(1 sample)}} \quad \text{[Eq. 4]}$$

$$\textit{\% Recovery} = \frac{\textit{measured residues}}{\textit{fortification amount}} \textit{ x 100} \quad \text{[Eq. 5]}$$

10.0 QUALITY CONTROL PROCEDURES

10.1 HPLC/MS/MS Analysis

To verify the stability of the response, a standard plot is drawn for the levels of interest. Calibration standards are injected at the beginning and end of an analytical set. The lowest level analytical standard corresponds to 70% or less of the limit of quantitation. Residue results must not be determined by extrapolation outside of the concentration range of the calibration standards. Samples with area counts greater than the calibrated range must be diluted and re-injected, in a timely manner, so that they fall within the calibrated range.

The recovery of laboratory fortified controls should fall in the range of 70-120%. The analyte signal should be ≥ 3 times the background signal noise. The intra-laboratory reproducibility as indicated by the relative standard deviation (n >3) obtained from replicated analyses should fall within 20% (rel.) of the averaged result.

11.0 DETECTION LIMITS

The limits of quantitation (LOQ) for this method for each matrix are listed below:

Matrix	LOQ
Face Wipes	100 ng/sample
Hand Washes	1 ng/mL
Inner Dosimeters	3 µg/sample
Outer Dosimeters	3 µg/sample
Painter's Hats	3 µg/sample
Air Sampling Tubes	10 ng/sample
Fiberglass Filters	10 ng/sample

Typical chromatograms for calibration standards, IS and low fortification samples for dressing sponges, hand washes, inner and outer dosimeters, painter's hats, air sampling tubes, and fiberglass filters are shown in Appendix 2, Figures 1-11.

APPENDIX 1 METHOD FLOWCHARTS

Analysis of BIT in Paint

Prior to weighing sample, shake paint samples on platform shaker set at >30 RPM for 20 minutes

↓

Weigh approximately 1 g base paint into pre-labeled 30-ml amber bottle

↓

Add 19 mL of Methanol/ Water (10:90, v/v) to each sample and shake fortified paint on platform shaker set at >30 RPM for 30 minutes

↓

Qualitatively transfer paint and extractant into separately labeled 250-mL mixing cylinder using at least 3x ~20-mL aliquots of Methanol/ water (10:90, v/v)

↓

QS samples to 250 mL with Methanol/ Water (10:90, v/v) and shake to mix

↓

Syringe filter an aliquot through a 0.45-µm PVDF filter into a new glass sample vial

↓

For samples that require a dilution - dilute with Methanol/ Water/ Formic Acid (70:30:0.016, v/v/v) and then transfer aliquot to HPLC vial and add an equal amount of IS

Analysis of BIT in/on Dressing Sponges

Moisten two (2) wipes (1 package) each with 4 mL of IPA/ water (50:50, v/v) in a 125-mL widemouth amber bottle

↓

Fortify at the appropriate levels.
Note: When using paint to fortify, mix paint by placing on shaker set at >30 RPM for at least 20 minutes prior to fortification.

↓

Allow fortified samples to sit for at least 15 minutes at ambient temperature to ensure absorption of fortification solution or paint into matrix.

↓

Add 100 mL Methanol/ Water/ Formic Acid (70:30:0.016, v/v/v) (MWF) to each sample

↓

Shake 15 minutes on platform shaker set at >30RPM

↓

Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

For Samples that require a dilution-dilute with MWF and then transfer aliquot to HPLC Vial and add an equal amount of IS:

Analysis of BIT in Hand Washes

Place one (1) gauze wipe and 250 mL of Isopropyl alcohol/ water (50:50, v/v) in a 500-mL widemouth glass jars

↓

Fortify at the appropriate levels.
Note: When using paint to fortify, mix paint by placing on shaker set at >30 RPM for at least 20 minutes prior to fortification.

↓

Shake 15 minutes on platform shaker set at >30RPM

↓

Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

For Samples that require a dilution-dilute with Methanol/ Water/ Formic Acid (70:30:0.016, v/v/v) and then transfer aliquot to HPLC Vial and add an equal amount of IS:

Analysis of BIT on Inner Dosimeters

Place inner dosimeter (ID) pieces into 1-L glass jar

↓

Fortify at the appropriate levels.
Note: When using paint to fortify, mix paint by placing on shaker set at >30 RPM for at least 20 minutes prior to fortification.
Note: For ID samples requiring fortification with paint, a swatch of fabric is cut from the ID and paint is added to swatch, the weight is recorded, and the swatch is smeared onto remaining ID sample in extraction vessel.

↓

Allowed fortified samples to sit for at least 15 minutes at ambient temperature to ensure absorption of fortification solution or paint into matrix.

↓

Add 750 mL of Methanol/ Water/ Formic Acid (70: 30: 0.016, v/v/v) (MWF) to each sample

↓

Shake 15 minutes, allow samples to sit at ambient temperature for at least 4 hours

↓

Shake 15 minutes

↓

Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

For Samples that require a dilution-dilute with MWF and then transfer aliquot to HPLC Vial and add an equal amount of IS:

Analysis of BIT in/on Outer Dosimeters

Place outer dosimeter (OD) pieces into 4-L glass jar

↓

Fortify at the appropriate levels.
Note: When using paint to fortify, mix paint by placing on shaker set at >30 RPM for at least 20 minutes prior to fortification.
Note: For OD samples requiring fortification with paint, a swatch of fabric is cut from the OD and paint is added to swatch, the weight is recorded, and the swatch is smeared onto remaining OD sample in extraction vessel.

↓

Allowed fortified samples to sit for at least 15 minutes at ambient temperature to ensure absorption of fortification solution or paint into matrix.

↓

Add 2000 mL of Methanol/ Water/ Formic Acid (70: 30: 0.016, v/v/v) (MWF) to each sample

↓

Shake 15 minutes, allow samples to sit at ambient temperature for at least 4 hours

↓

Shake 15 minutes

↓

Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

For Samples that require a dilution-dilute with MWF and then transfer aliquot to HPLC Vial and add an equal amount of IS:

Note: An ~10-mL aliquot of sample extract is transferred to a 25 mL liquid scintillation vial and stored frozen. The remaining bulk sample is stored at ambient temperature.

Analysis of BIT in/on Painter's Hats

Place one painter's hat (PH) into 4-L glass jar

↓

Fortify at the appropriate levels.
Note: When using paint to fortify, mix paint by placing on shaker set at >30 RPM for at least 20 minutes prior to fortification.
Note: For PH samples requiring fortification with paint, a swatch of fabric is cut from the PH and paint is added to swatch, the weight is recorded, and the swatch is smeared onto remaining PH sample in extraction vessel.

↓

Allowed fortified samples to sit for at least 15 minutes at ambient temperature to ensure absorption of fortification solution or paint into matrix.

↓

Add 2000 mL of Methanol/ Water/ Formic Acid (70: 30: 0.016, v/v/v) (MWF) to each sample

↓

Shake 15 minutes, allow samples to sit at ambient temperature for at least 4 hours

↓

Shake 15 minutes

↓

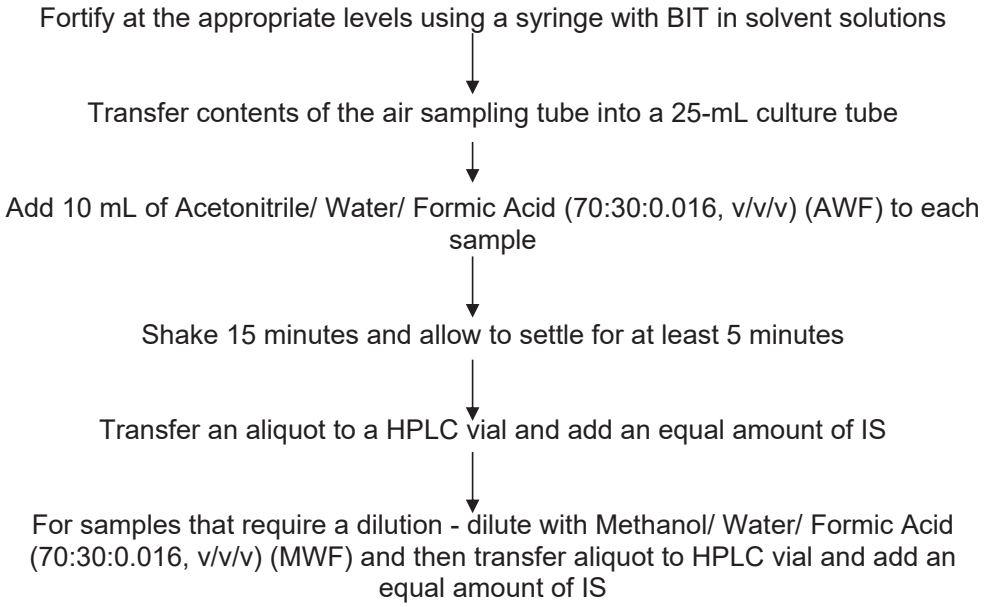
Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

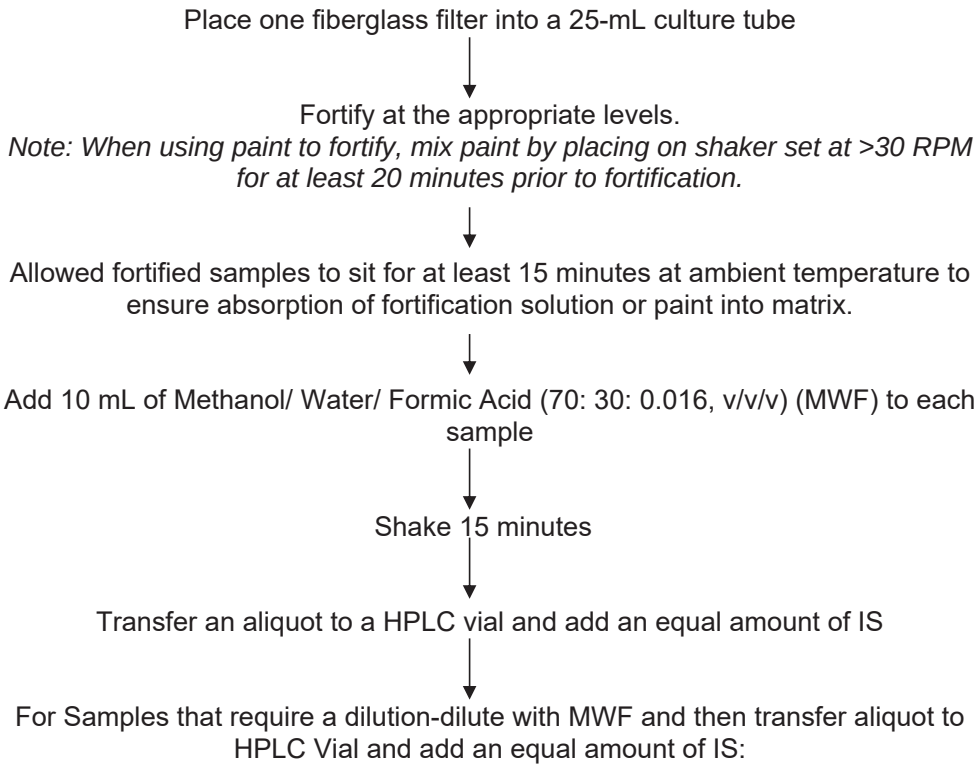
For Samples that require a dilution-dilute with MWF and then transfer aliquot to HPLC Vial and add an equal amount of IS:

Note: An ~10-mL aliquot of sample extract is transferred to a 25 mL liquid scintillation vial and stored frozen. The remaining bulk sample is stored at ambient temperature.

Analysis of BIT in/on Air Sampling Tubes



Analysis of BIT in/on Fiberglass Filters



APPENDIX 2 CALIBRATION CURVE AND CHROMATOGRAMS

FIGURE 1

Example Chromatogram of a 0.250 ng/mL BIT LC-MS/MS Standard

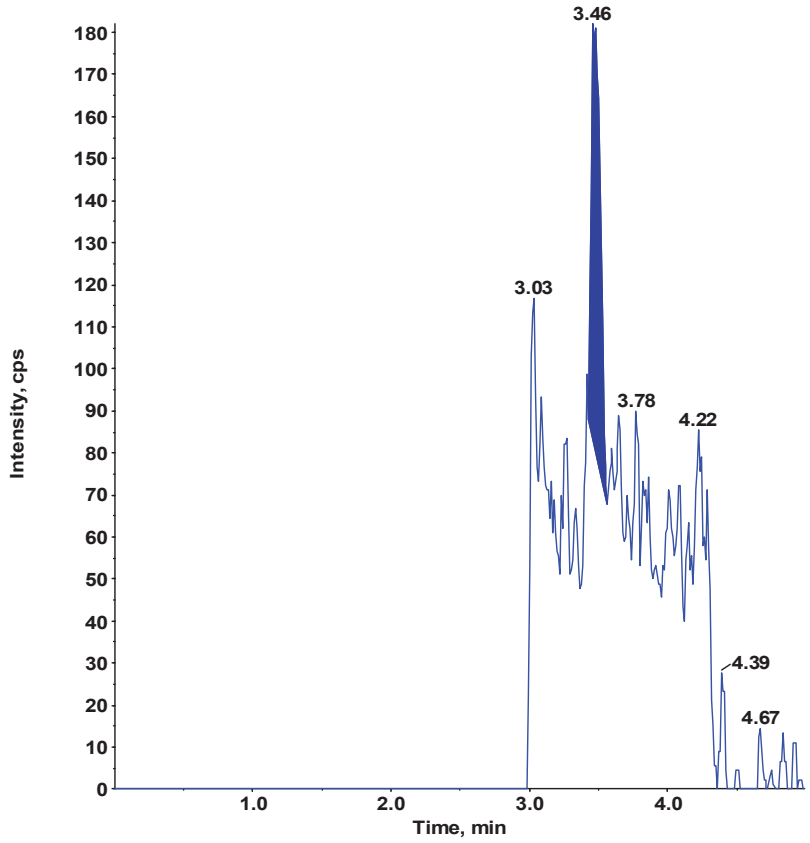


FIGURE 2

Example Chromatogram of a 25.0 ng/mL BIT Internal Standard LC-MS/MS Standard

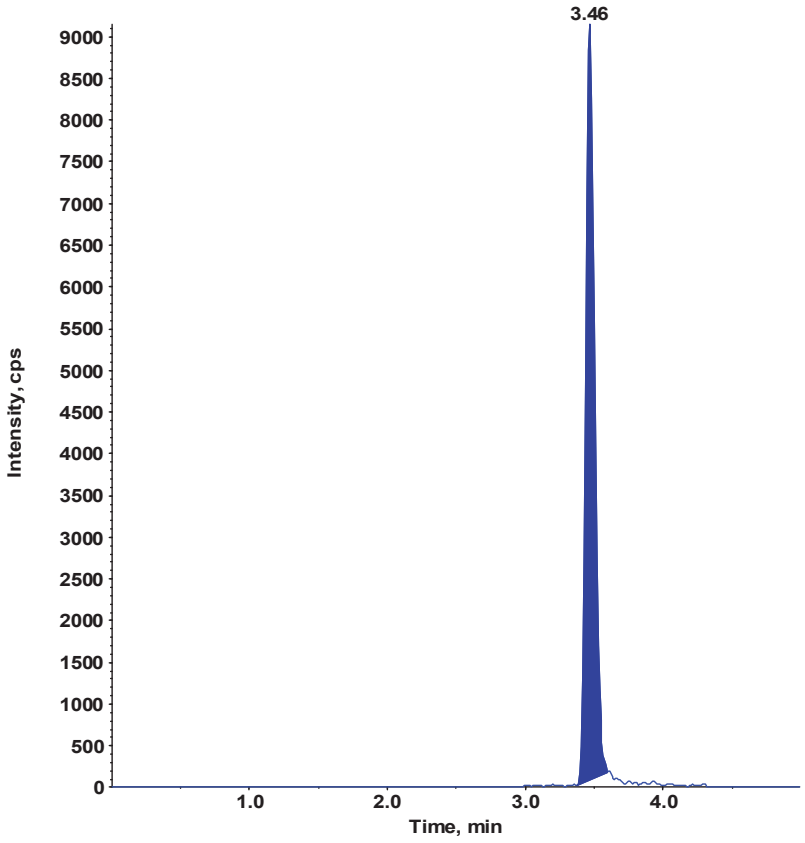


FIGURE 3

Example BIT Calibration Curve

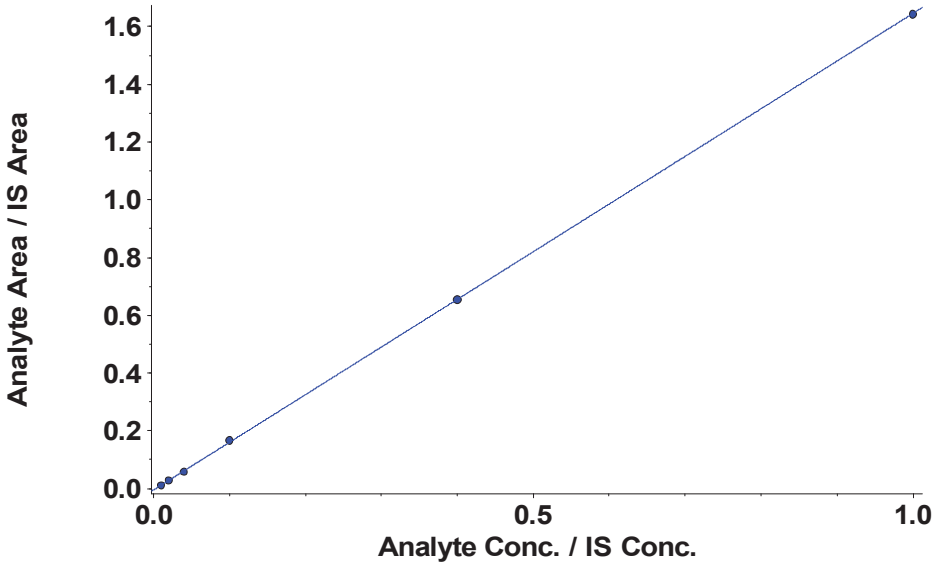


FIGURE 4

Example Chromatogram of Base Paint Fortified with an additional 300 ppm of BIT

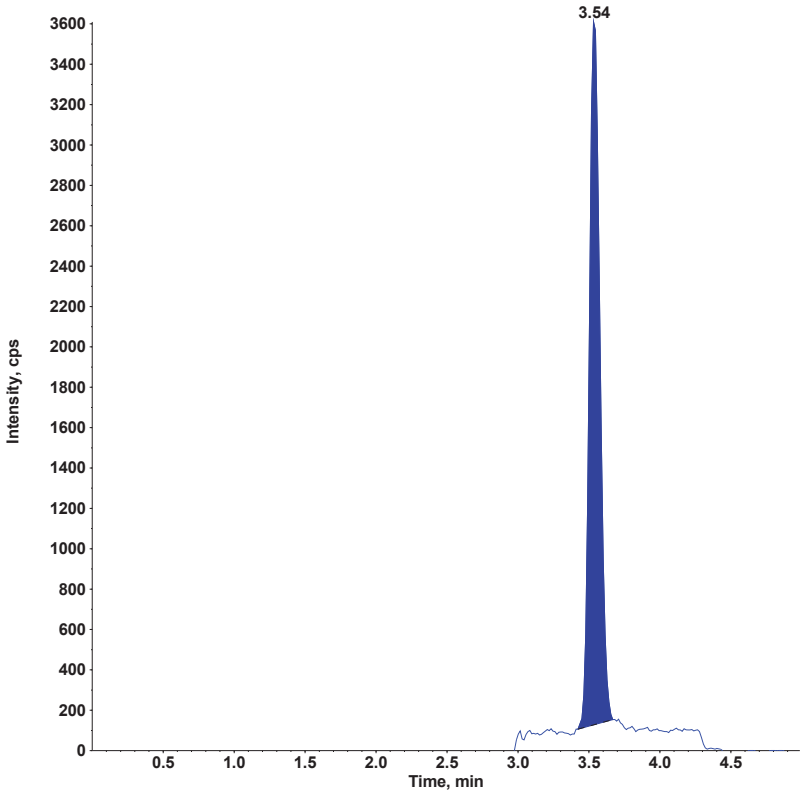


FIGURE 5

Example Chromatogram of a Dressing Sponge Sample Fortified with 0.100 µg/sample of BIT

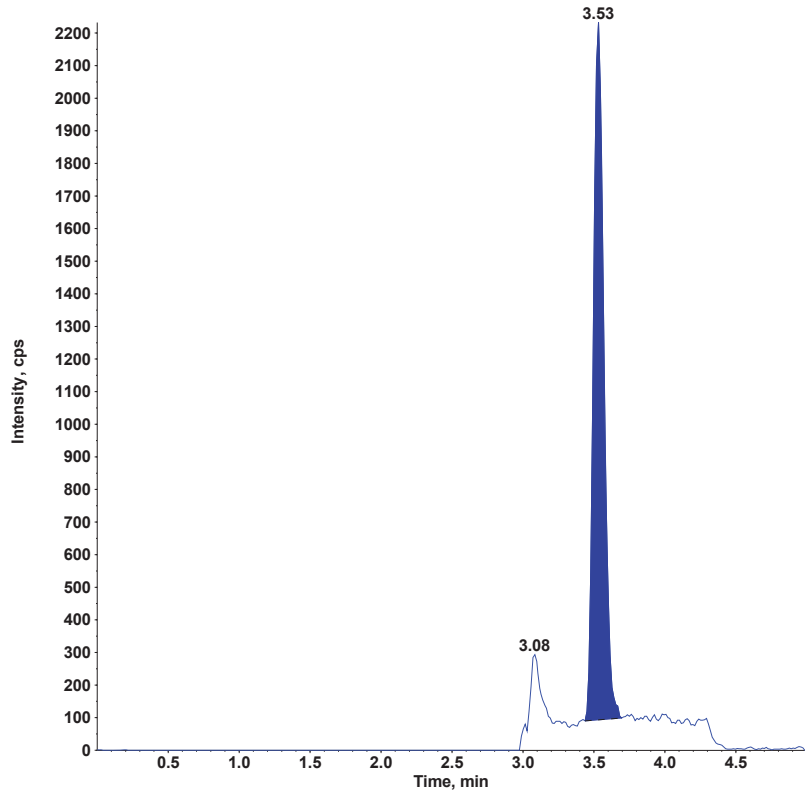


FIGURE 6

Example Chromatogram of a Hand Wash Sample Fortified with 1.00 ng/mL of BIT

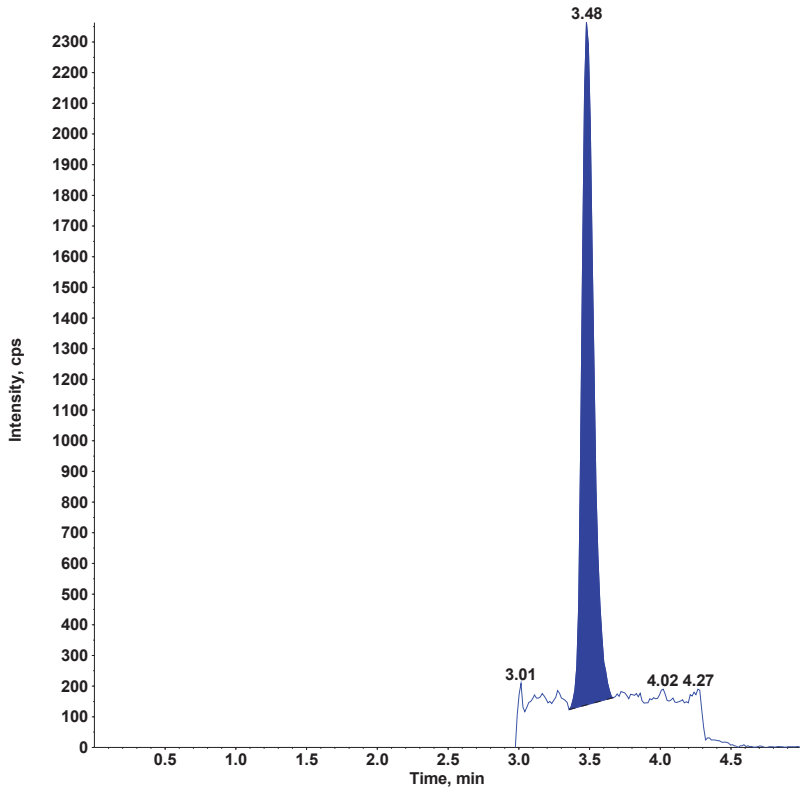


FIGURE 7

Example Chromatogram of an Inner Dosimeter Sample Fortified with 3.00 µg/sample of BIT

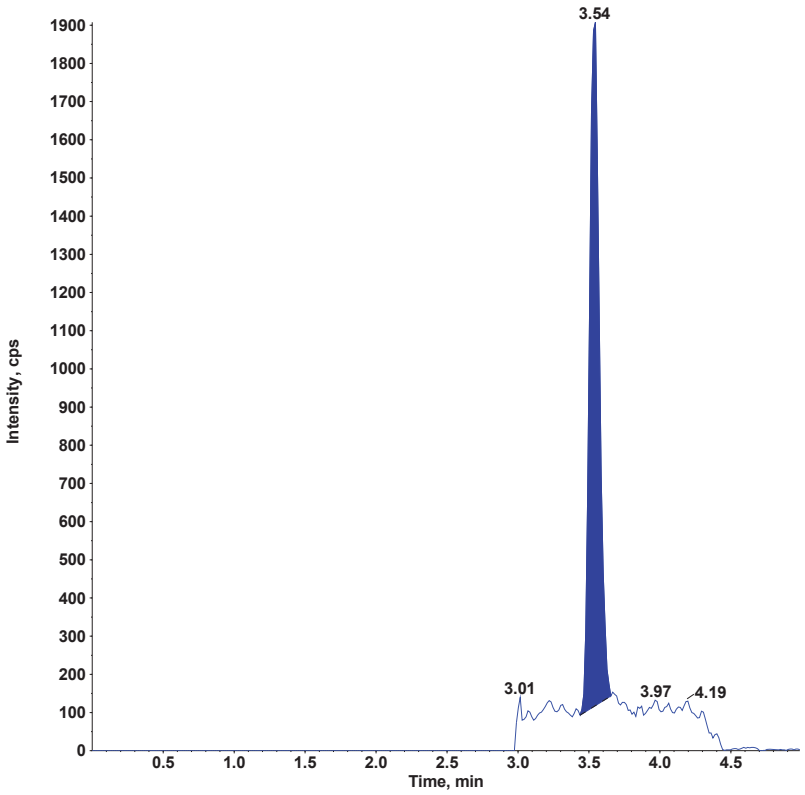


FIGURE 8

Example Chromatogram of an Outer Dosimeter Sample Fortified with 3.00 µg/sample of BIT

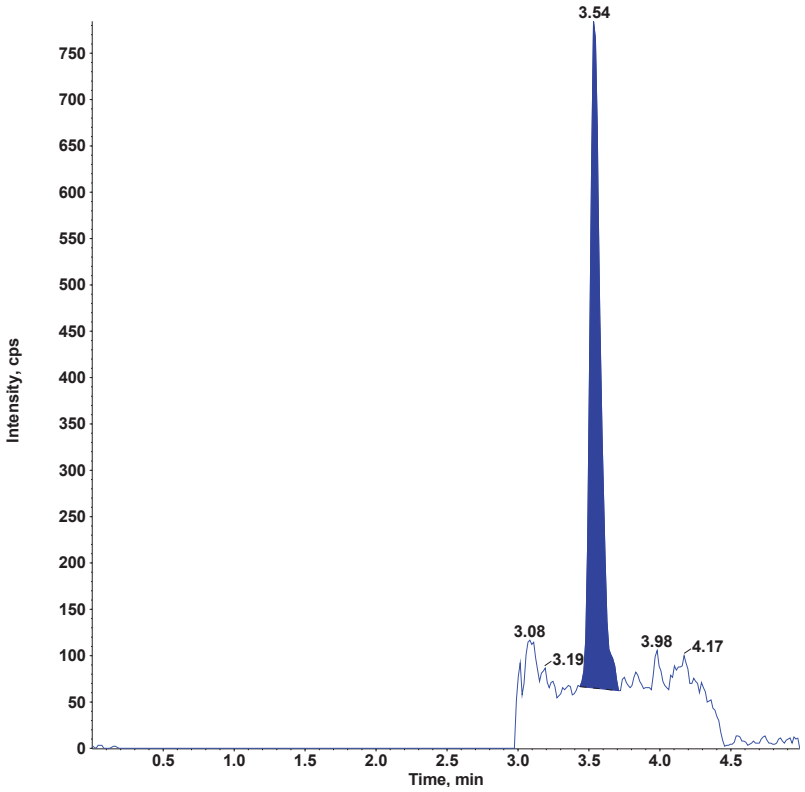


FIGURE 9

Example Chromatogram of a Painter's Hat Sample Fortified with 3.00 µg/sample of BIT

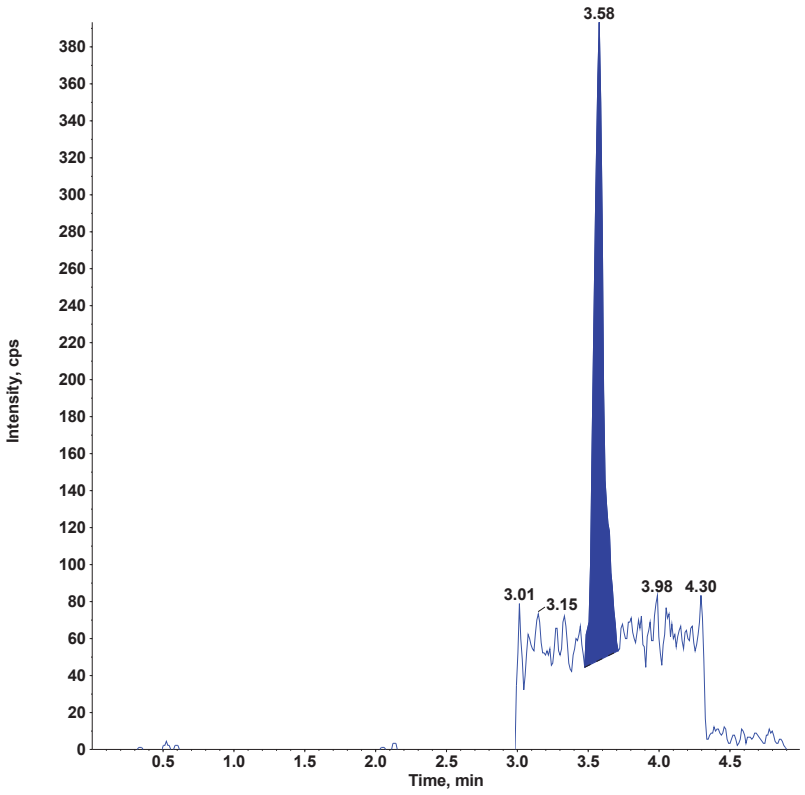


FIGURE 10

Example Chromatogram of an Air Sampling Tube Fortified with 0.0100 µg/sample of BIT

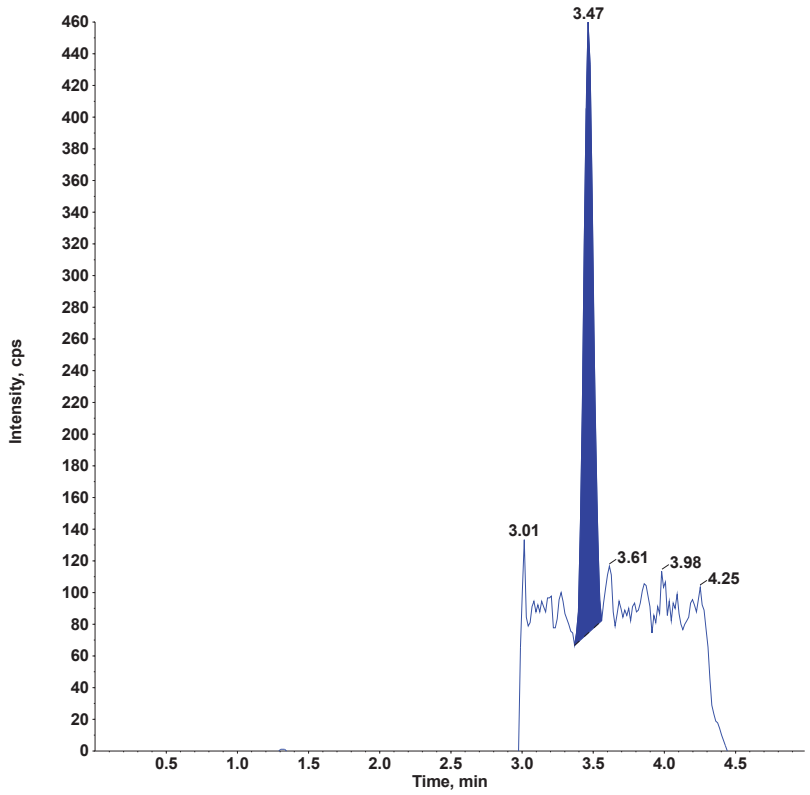
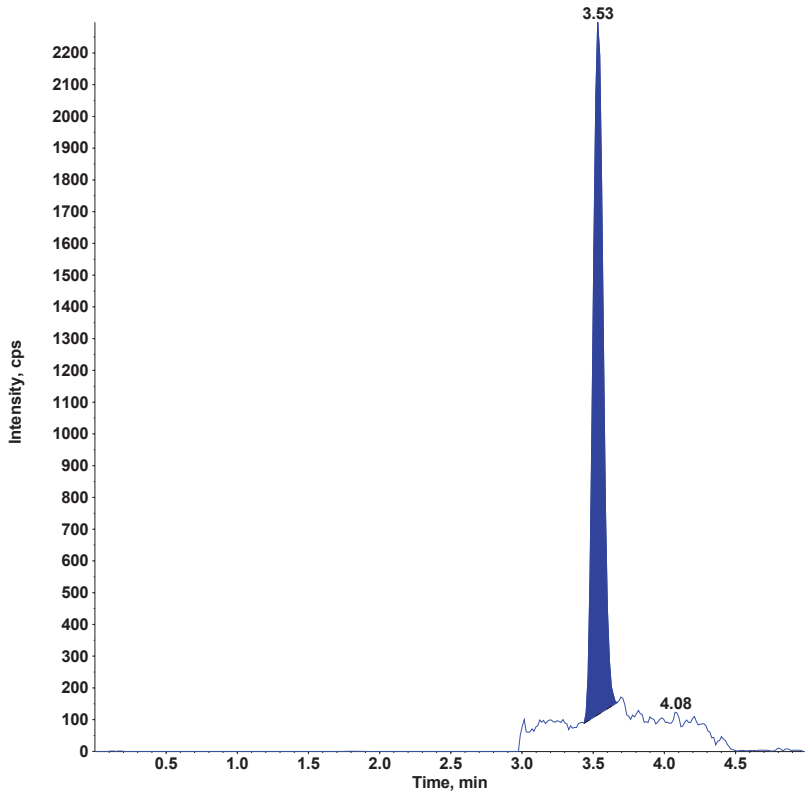


FIGURE 11

Example Chromatogram of a Fiberglass Filter Sample Fortified with 0.0100 µg/sample of BIT



APPENDIX M.

COORESPONDENCE FROM EPA REGARDING INTERNAL DOSIMETER CONTAMINATION

November 21, 2017

AEATF Brush/roller Painting Study

Subject: Determine clothing penetration factor (PF) for calculating unit exposures from brush/roller study.

Issue: BIT was used as the surrogate compound in the brush/roller study. As happenstance, 10 of the 18 WBDs were treated during the manufacturing process using BIT as the material preservative. The 10 BIT-treated WBDs were from two vendor's lot numbers. Thus, 10 MEs had their dermal inner WBDs "contaminated".

EPA Options to Salvage Study: Four options have been identified to move forward:

(1) Repeat the study;
(2) Use a mean study-derived penetration factor to replace contaminated WBDs
(3) Use the default penetration factor of 50% to replace the contaminated WBDs; or
(4) Use the upper bound of 100% penetration factor to replace the contaminated WBDs.

Results: Multiple methods are used to determine the mean PFs in Option 2 above. See Dr. Cohen's review (attached) for specific algorithms, confidence intervals, etc. In summary, a single PF is calculated for all of the individual body parts (n=48). Additionally, individual PFs are calculated for each of the body parts (i.e., front torso, lower arm, lower leg, rear torso, upper arm, and upper leg). The arithmetic means in Option 2 above are calculated as empirical arithmetic means and as arithmetic means from the lognormal model (i.e., exp(mu + V/2), where mu and V are the mean and variance of the logarithms of the ratios). Confidence intervals are also provided. Geometric means are also calculated for Option 2.

To determine the best option to move forward, the dermal unit exposures were calculated for options 2 through 4. The penetration factor (PF) was calculated as the ratios of inner dosimeters of BIT residues divided by the outer dosimeters of BIT residues for the same ME and body part using the MEs that did not have "contaminated" inner dosimeters (i.e., ME numbers 3, 5, 8, 9, 11, 14, 15, and 18). For the single arithmetic empirical mean, arithmetic lognormal mean, and geometric mean PFs (95%CI) are 12.3% (7.1, 22), 12.5% (7.5, 22), and 5.1% (3.5, 7.6), respectively. The table of PFs are provided in the attachment (i.e., Dr. Cohen's review memo Table 1).

Table 1 provides the dermal unit exposures from the brush/roller study using the single PFs of 5.1% (geo mean), 12.3% and 12.5% (arithmetic empirically and lognormally derived means), 50% (default), and 100% (upper bound). Table 1 also provides the previous dermal unit exposures from PHED. Finally, the percentage of the exposure contributed by the hands is provided. The calculation of this percentage in Table 1 uses the estimated arithmetic mean unit exposure for hands only divided by the estimated arithmetic mean unit exposure for each clothing scenario. An alternative approach is to use the arithmetic mean of the ratios of the hand exposure to total exposure, which gives hand contributions of 84% for commercial

painters, 65% for homeowner painters, and 49% of total dermal including all the inner and outer dosimeters (for a hypothetical naked painter), using the Mean-empirical option.

Table 1. Dermal Unit Exposures from AEATF Brush/Roller Paint Study Using Single PF.			
Option	Dermal Unit Exposure (mg/lb ai)		% Hand Contribution for AEATF Study*
	PHED	AEATF	
Commercial Painters (long pants, long-sleeved shirt, no gloves)			
5.1% (Geo)	180	115	95
12.3% (Mean-empirical)		117	94
12.5% (Mean-lognormal)		117	94
50% (Default)		127	86
100% (Max)		141	78
Homeowner Painters (short pants, short-sleeved shirts, no gloves)			
5.1% (Geo)	450	143	77
12.3% (Mean)		145	76
12.5% (Mean-lognormal)		145	76
50% (Default)		155	71
100% (Max)		169	65

PHED dermal unit exposures are as reported in the HED table for the commercial and HED SOPs for residential.

* Percentage from hands = Arithmetic Mean Unit Exposure for Hands Only / Arithmetic Mean Unit Exposure for Clothing

The dermal unit exposures have also been calculated using the PFs for individual body parts. The results of the individual body part PFs yield nearly identical dermal unit exposures as the single PF method. The results for the individual body part PFs dermal unit exposures are provided in the attachment (i.e., Dr. Cohen's review memo) in Table 2.

Discussion:

- Option 1: Repeat the study.

  The majority of the samples (i.e., all of the inhalation, all of the hands, 8 of the inner WBDs, and all of the outer WBDs) were not affected by the BIT-contaminated WBDs. Additionally, the majority of the dermal exposures are to the subject's hands. Therefore, EPA and PMRA do not believe it is warranted for the AEATF to repeat this intentional human study.

- Option 2: Use a mean study-derived penetration factor to replace contaminated WBDs.

  The PFs for the individual body parts were calculated separately because it was thought that there could be physical rationales for them to differ (e.g., billowing effects of sleeves, V-necks around chest, etc). However, the results of the overall dermal unit exposures are nearly identical when using the single PF versus individual body part PFs. Since these PFs are being solely used for the determination of the dermal unit exposures in this study, the simplicity of the single PF is selected. Next, as it reasonably captures the potential day-to-

day variability of clothing penetration, the arithmetic mean protection factor across all participants is utilized. Both a simple arithmetic mean and one assuming clothing penetration is lognormally distributed were calculated; no difference in the final dermal unit exposures was observed when rounded to 3 significant figures. Therefore, for simplicity purposes, EPA and PMRA select Option 2 using the simple arithmetic mean (i.e., 12.3%), and recommends that the AEATF completes the brush/roller study and submit the final report for review.

- Option 3: Use the default penetration factor of 50% to replace the contaminated WBDs

  Although the dermal unit exposures do not differ substantially using the data derived versus default PFs, we are data-driven, and have decided not to use the 50% default PF for a specific study.

- Option 4: Use the upper bound of 100% penetration factor to replace the contaminated WBDs.

  Although the dermal unit exposures do not differ substantially using the data derived versus maximum of 100% penetration (this is attributed to the fact that the majority of the exposure is to the hands), single layer of clothing does offer some protection, and we have decided not to use the outer dosimeters with no protection afforded by clothing.

Conclusion:

EPA and PMRA select Option 2 from above which is to use the simple arithmetic mean (i.e., 12.3%) penetration factor, and recommends that the AEATF completes the brush/roller study and submit the final report for review.

Attachment (Dr. Cohen's memo from 10/18/17)

MEMORANDUM

To:	Timothy Leighton, EPA; Timothy Dole, EPA; Diana Hsieh, EPA
From:	Jonathan Cohen, ICF
Date:	October 18, 2017
Re:	Statistical Analyses of the Brush and Roller Study Using Alternative Clothing Penetration Factors

The original version of this memorandum (August 15, 2017) has been revised to include separate estimates of penetration factors for each body part, estimates of arithmetic mean ratios based on a lognormal model, and confidence intervals for the estimated penetration factors.

Introduction and Summary

On August 14, 2017, AEATF II submitted the report "Brush and Roller Study, BIT Inner Dosimeter Residue Summary" giving initial data from their study "A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting. Revision 2." In this study, consumer painters used brushes and rollers to apply interior latex paint containing the antimicrobial pesticide 1-2-benzisothiazoline-3-one (BIT). Each of 18 volunteer subjects applied between 1.75 and 2.25 gallons of paint at one of three BIT concentrations. This gives 18 monitoring events (MEs). Paint concentrations of about 140, 400, or 600 mg/kg were applied by six subjects each. The potential total inhalation exposure for each subject was measured by analysis of residues of BIT collected with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute), using validated analytical methods. Dermal exposure was measured via analysis of inner and outer dosimeters, painter's hats, hand wash solutions, and face/neck wipes for residues of BIT using validated analytical methods.

AEATF II found that the BIT residues found in the inner dosimeters were higher than the BIT residues found in the outer dosimeters for ten MEs. In contrast, the BIT residues found in the inner dosimeters were about 10 to 20 percent of the BIT residues found in the outer dosimeters for the other eight MEs. As described in AEATF's report, these unexpected findings were determined to be due to BIT contamination of those inner dosimeters that came from two common vendor's lot numbers. The unusually high BIT concentrations were found on all of the inner dosimeter measurements from that lot and were not found on the inner dosimeters used for the other eight MEs. AEATF II proposed to replace the inner dosimeter BIT residues from the ten contaminated inner dosimeters by applying a study-specific clothing penetration factor to the corresponding outer dosimeter measurements. They estimated the clothing penetration factor to be 16%, by averaging the 48 ratios of inner dosimeter BIT residue divided by outer dosimeter BIT residue for the same ME and body part.

ICF was asked by EPA to calculate the clothing penetration factor using the five different approaches described below and then to calculate estimates and confidence intervals of the arithmetic mean and 95th percentiles of the normalized exposure based on the lognormal simple random sampling model for each dermal exposure route and clothing penetration factor. AEATF II provided the data in Excel spreadsheets as well as Word tables. Note that all the air sampling measurements were below the level of detection, and so the inhalation exposure estimates were not analyzed for this memorandum.

The five approaches for the clothing penetration factor were as follows:

1. Arithmetic Mean Empirical. Arithmetic mean of the 48 ratios of inner dosimeter BIT residue divided by outer dosimeter BIT residue for the same ME and body part. Empirical model. 12.3%.
2. Arithmetic Mean Lognormal. Estimated arithmetic mean of the 48 ratios of inner dosimeter BIT residue divided by outer dosimeter BIT residue for the same ME and body part. Lognormal model. 12.5%.
3. Geometric Mean. Geometric mean of the 48 ratios of inner dosimeter BIT residue divided by outer dosimeter BIT residue for the same ME and body part. 5.1%.
4. 50%. Default ratio. 50%.
5. 100%. Upper bound ratio. 100%.

For the Arithmetic Mean Empirical approach, the arithmetic mean is calculated assuming an empirical model as the simple average of the 48 ratios. For the Arithmetic Mean Lognormal, the arithmetic mean is estimated assuming that the ratios are lognormally distributed. Thus if the natural logarithms of the ratios have a mean of μ and a variance of σ^2, then the estimated arithmetic mean is $\exp(\mu + \sigma^2/2)$. The geometric mean of the ratios is $\exp(\mu)$. μ and σ^2 are estimated using the sample mean and sample variance of the logarithms of the ratios.

ICF calculated the arithmetic mean ratio from the empirical model as 12.3% rather than the 16% reported by AEATF II because there were 29 inner dosimeter values below the detection limit (LOQ or LOD) of 3 µg/sample (29/48 = 60.4% of the 48 measurements) and ICF substituted one half the detection limit (1.5 µg) for each non-detect instead of using the detection limit (3 µg). This approach is consistent

with the treatment of non-detects from previous AEATF II studies. The geometric mean ratio was also considered because the statistical models used for analyzing the residue data from the AEATF studies generally assume a log-normal model for the measured exposure, which suggests that the inner dosimeter values can be estimated by the geometric mean ratio multiplied by the outer dosimeter values.

The corresponding estimates of the arithmetic mean and 95th percentile of the normalized dermal exposure based on the lognormal simple random sampling model for each dermal exposure route are tabulated below in Table 2. The results show that the normalized dermal exposure is very similar when using the Arithmetic Mean Empirical, Arithmetic Mean Lognormal, and Geometric Mean clothing penetration factors, but the default and upper bound ratios lead to higher normalized dermal exposure estimates that may be unduly conservative. Since the Geometric Mean approach tends to lead to underestimates of the inner dosimeter values (see next section), the Arithmetic Mean Lognormal approach, with non-detects replaced by half the detection limit, can be recommended. Although the two alternative arithmetic mean estimates lead to almost the same results, the Arithmetic Mean Lognormal approach is preferred because it provides slightly more conservative (i.e., higher) estimates of dermal exposure and is consistent with the lognormal modeling approach that has generally been used for the statistical analyses of the AEATF studies.

As explained in the next section, ICF also calculated separate estimates of the penetration factors for each of the six body parts. The rationale for that alternative approach is that different body parts have different surface areas and shapes, leading to different penetration factors. For example, the outer dosimeter for the front torso has a V-neck and buttons which may allow a higher penetration than the upper arm. Since the estimates for each body part are based on 8 ratios rather than 48 ratios, the confidence intervals for the penetration factors by body part are wider. Furthermore, the resulting estimates and confidence intervals of the arithmetic mean and 95th percentiles of the normalized exposure are very close to the estimates using the overall penetration factors calculated from all 48 ratios. For these reasons, and also for simplicity, the approach of using the same penetration factor estimates for every body part is recommended over the approach of applying separate penetration factor estimates for each body part.

Clothing Penetration Factor

The eight MEs deemed not to have contaminated inner dosimeter values were ME numbers 3, 5, 8, 9, 11, 14, 15, and 18. Each of these ME's gave 6 inner dosimeter values and 6 outer dosimeter values: UA = Upper Arm, LA = Lower Arm, FT = Front Torso, RT = Rear Torso, UL = Upper Leg, LL = Lower Leg. This gives a total of 48 ratios, defined as inner dosimeter residue / outer dosimeter residue for the same ME and body part. The detection limit was 3 µg/sample. There were 29 inner dosimeter values below the detection limit (60.4% of the 48 inner dosimeter measurements). There was also 1 outer dosimeter values below the detection limit, which corresponded to an inner dosimeter value below the detection limit.

AEATF II estimated the clothing penetration factor as 16% (more exactly, 16.4%), by calculating the arithmetic mean ratio, using the detection limit to substitute for values below the detection limit. For consistency with previous AEATF study results, we recommend substituting one half the detection limit (1.5 μg) for values below the detection limit. (Using a censored maximum likelihood method seems unnecessarily complicated for these analyses).

ICF proposed two alternative calculations of the arithmetic mean ratio. The Arithmetic Mean Empirical is the simple arithmetic mean of the 48 ratios. The Arithmetic Mean Lognormal is the estimated arithmetic mean ratio assuming that the population of ratios is lognormally distributed, so that the natural logarithm of the ratio has a normal distribution with a mean of μ and a variance of σ^2. In that case the population of ratios has an arithmetic mean of $\exp(\mu + \sigma^2/2)$. The values of μ and σ^2 are estimated by the sample mean and sample variance of the logarithms of the ratios. (Thus $\exp(\mu)$ is estimated by the geometric mean ratio).

ICF also proposed to use the geometric mean of the ratios as an alternative estimate of the clothing penetration factor. This follows if we assume the statistical model in the last paragraph, which can be rewritten as

Log (Inner dosimeter residue) = μ + Log (Outer dosimeter residue) + Error,

where the errors are assumed to be independent, normally distributed, with a mean of zero and a constant variance σ^2. This gives:

Log (Ratio) = μ + Error

The parameter μ is therefore estimated by the mean of the logarithms of the ratios. The statistical model then implies that the inner dosimeter residue is the outer dosimeter residue multiplied by $\exp(\mu + \text{Error})$, which can be estimated by the geometric mean ratio. However, this approach will tend to underestimate the ratio because the expected value of exp(Error) is greater than 1.

EPA also asked ICF to consider alternative clothing penetration factor estimates of 50% and 100% (the maximum possible ratio assuming 100% penetration).

All these estimates are tabulated in Table 1. The rows for Body Part "All" use all 48 ratios. Also included in Table 1 for the different Body Part rows are separate calculations of the penetration factors for each body part based on their 8 measured ratios. The rationale for that alternative approach of calculating separate penetration factors for each body part is that different body parts have different surface areas and shapes, leading to different penetration factors. For example, the outer dosimeter for the front torso has a V-neck and buttons which may allow a higher penetration than the upper arm.[1] To evaluate

[1] From Table 2, this idea might seem to be contradicted by the fact that the estimated penetration factors using the arithmetic means are lower for the front torso than for the upper arm. However the estimates for the upper arm are quite uncertain because all the upper arm inner dosimeters were non-detects. The estimated penetration factors using the Arithmetic Mean Lognormal approach are higher for the front torso than for the upper arm, which is consistent with the physical theory.

whether the penetration factors differ by body part we used a one way analysis of variance. An analysis of the ratios showed that the mean ratios were not statistically significantly different at the 5% level between body parts (p-value = 0.18). Thus the arithmetic means of the ratios were not statistically significantly different. However, an analysis of the logarithms of the ratios showed that the means of the logarithms of the ratios were statistically significantly different at the 5% level between body parts (p-value = 0.03). Thus the geometric means were statistically significantly different.

Table 1 also includes 95% confidence intervals for each estimated penetration factor. For the Arithmetic Mean Empirical and Arithmetic Mean Lognormal scenarios, the confidence intervals were estimated using a parametric bootstrap assuming that the ratios are lognormally distributed.[2] For the Geometric Mean scenario an exact statistical calculation of the confidence interval was made using a t distribution, again assuming that the ratios are lognormally distributed.

Table 1. Clothing Penetration Factors

				95% Confidence Interval for Penetration Factor*		
Scenario	Body Part	N (Sample Size)	Percentage of Non-detects for IDs	Estimate	Lower Bound	Upper Bound
1. Arithmetic Mean Empirical	All	48	60.42%	12.30%	7.13%	22.13%
2. Arithmetic Mean Lognormal	All	48	60.42%	12.53%	7.48%	21.50%
3. Geometric Mean	All	48	60.42%	5.14%	3.49%	7.57%
4. 50%	All	48	60.42%	50.00%	50.00%	50.00%
5. 100%	All	48	60.42%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Front torso	8	50.00%	9.71%	3.48%	38.48%
2. Arithmetic Mean Lognormal	Front torso	8	50.00%	13.14%	3.87%	59.04%
3. Geometric Mean	Front torso	8	50.00%	5.20%	1.67%	16.24%
4. 50%	Front torso	8	50.00%	50.00%	50.00%	50.00%
5. 100%	Front torso	8	50.00%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Lower arm	8	12.50%	10.15%	5.66%	19.12%
2. Arithmetic Mean Lognormal	Lower arm	8	12.50%	10.70%	5.82%	20.42%
3. Geometric Mean	Lower arm	8	12.50%	7.92%	4.14%	15.14%
4. 50%	Lower arm	8	12.50%	50.00%	50.00%	50.00%
5. 100%	Lower arm	8	12.50%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Lower leg	8	87.50%	10.18%	1.55%	27.24%

[2] The parametric bootstrap was calculated as follows: Either 48 (for All body parts) or 8 (separate body parts) ratios were randomly generated from the corresponding fitted lognormal model 10,000 times each, and the penetration factor was estimated from each of the 10,000 simulations. The lower and upper bound are the 251th and 9751th highest of the 10,000 simulated penetration factors (e.g., counting the lowest simulated value as the 1th highest).

Scenario	Body Part	N (Sample Size)	Percentage of Non-detects for IDs	95% Confidence Interval for Penetration Factor*		
				Estimate	Lower Bound	Upper Bound
2. Arithmetic Mean Lognormal	Lower leg	8	87.50%	7.60%	1.74%	47.37%
3. Geometric Mean	Lower leg	8	87.50%	2.35%	0.65%	8.46%
4. 50%	Lower leg	8	87.50%	50.00%	50.00%	50.00%
5. 100%	Lower leg	8	87.50%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Rear torso	8	62.50%	27.44%	7.98%	110.52%
2. Arithmetic Mean Lognormal	Rear torso	8	62.50%	33.94%	8.98%	175.89%
3. Geometric Mean	Rear torso	8	62.50%	12.35%	3.76%	40.55%
4. 50%	Rear torso	8	62.50%	50.00%	50.00%	50.00%
5. 100%	Rear torso	8	62.50%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Upper arm	8	100.00%	13.93%	4.98%	51.12%
2. Arithmetic Mean Lognormal	Upper arm	8	100.00%	18.10%	5.53%	72.74%
3. Geometric Mean	Upper arm	8	100.00%	7.65%	2.55%	22.92%
4. 50%	Upper arm	8	100.00%	50.00%	50.00%	50.00%
5. 100%	Upper arm	8	100.00%	100.00%	100.00%	100.00%
1. Arithmetic Mean Empirical	Upper leg	8	50.00%	2.41%	1.49%	4.04%
2. Arithmetic Mean Lognormal	Upper leg	8	50.00%	2.52%	1.52%	4.25%
3. Geometric Mean	Upper leg	8	50.00%	2.02%	1.15%	3.53%
4. 50%	Upper leg	8	50.00%	50.00%	50.00%	50.00%
5. 100%	Upper leg	8	50.00%	100.00%	100.00%	100.00%

* Estimates and Confidence Intervals are calculated as follows:

1. Arithmetic Mean Empirical: Estimate = arithmetic mean ratio. Confidence Interval calculated using a parametric bootstrap assuming the ratios are lognormally distributed.

2. Arithmetic Mean Lognormal: Estimate = arithmetic mean ratio estimated from lognormal model = exp(mu + V/2), where mu and V are the mean and variance of the logarithms of the ratios. Confidence Interval calculated using a parametric bootstrap assuming the ratios are lognormally distributed.

3. Geometric Mean: Estimate = geometric mean ratio. Confidence interval calculated exactly assuming the ratios are lognormally distributed.

4. 50%: Estimate and Confidence Intervals calculated assuming all ratios are 50%.

5. 100%: Estimate and Confidence Intervals calculated assuming all ratios are 100%.

The attached Excel spreadsheet ratios.out.xlsx includes the 48 ratios (tab “Ratios”) and the results in Table 1 (tab “CI”).

For each approach, the inner dosimeter residue for each ME and body part with a (presumed) contaminated inner dosimeter is estimated by

Estimated inner dosimeter residue =

Measured outer dosimeter residue × Clothing Penetration Factor.

For the overall analyses, with the same penetration factor for every body part, the Clothing Penetration Factor is the value in the Estimate column for Body Part = "All". For the "By Part" analyses, with different penetration factors for each body part, the Clothing Penetration Factor is the value in the Estimate column for the corresponding Body Part row.

To consistently deal with values below the detection limit, the following approach is recommended. This approach was applied for calculating the normalized exposure estimates presented in the next section. If the measured outer dosimeter residue is at or below the detection limit (which occurred for the ME 2 right torso), it is replaced by half the detection limit, i.e., 1.5 µg. If the estimated inner dosimeter residue is less than or equal to 3 µg, it is replaced by half the detection limit, i.e., 1.5 µg. For example, the outer dosimeter residue for the upper arm on ME 1 was 9.39 µg, which gives an estimated inner dosimeter residue of 1.15 µg for the Arithmetic Mean Empirical approach with Body Part "All" using the above equation. This value is at or below 3 and so is replaced by 1.5 µg.

Arithmetic Mean and 95th Percentile of Normalized Dermal Exposure

The dermal exposure data were used to develop exposure measurements for the following dermal exposure routes:

- **Long Dermal**. This case represents the dermal exposure to a person wearing long pants and a long-sleeved shirt, without gloves. This is the sum of the mass from the six inner dosimeters, hand wash, painter's hats, and the face/neck wipes.
- **Short Dermal**. This case represents the dermal exposure to a person wearing short pants and a short-sleeved shirt, without gloves. This is the sum of the mass from the six inner dosimeters, the outer dosimeters for the lower leg and lower arm, hand wash, painter's hats, and the face/neck wipes.
- **Long Short Dermal**. This case represents the dermal exposure to a person wearing long pants and a short-sleeved shirt, without gloves. This is the sum of the mass from the six inner dosimeters, the outer dosimeters for the lower arm, hand wash, painter's hats, and the face/neck wipes.
- **Hands Only**. This case represents the dermal exposure to the hands only and is the mass from hand wash.

For the inner dosimeters, the mass for each body part equals the measured mass for the uncontaminated inner dosimeters, and equals the measured outer dosimeter mass multiplied by the clothing penetration factor for the contaminated inner dosimeters, as detailed in the previous section. The values for the hand wash and face/neck wipes were corrected by AEATF II for the mean dermal removal efficiency of 68.8%, presumably given by the hand wash removal efficiency study. The study data include two painter's hat residues, one marked "Painter's Hats" and one marked "ID - Painter's Hat." The painter's hat mass was calculated by summing these two measurements. If either

measurement is below the detection limit (3 µg) then that measurement is replaced by 1.5 µg. If the "Painter's Hats" residue is below the detection limit, then the ""ID - Painter's Hat" was reported as "NA," presumably because it was not measured in those cases; using the same approach used in previous AEATF studies, the "NA" values were assumed to be below the detection limit and were also replaced by 1.5 µg.

The statistical analyses of the normalized exposure in the final statistical review will use the following two alternative statistical models. However, only the results from the lognormal simple random sampling model are reported in this memorandum. Let X be the normalized exposure and X = exp(Y) so that Y = log (X), where log denotes the natural logarithm. LnGM is the log of the geometric mean. Let Z95 be the 95th percentile of a standard normal distribution, approximately 1.645.

- Empirical simple random sampling model. Code "s." Assumes that all the values of X were randomly drawn from an unspecified distribution.
  - Y = LnGM + Error. Error is independent and identically distributed with mean 0 and the same variance for every measurement.
  - AMs = Arithmetic mean of X values
  - GMs = Geometric mean of X values = exp(LnGM) (= GMu)
  - GSDs = Geometric standard deviation of X values (= GSDu)
  - P95s = 95th percentile of X values
- Lognormal simple random sampling model. Code "u." Assumes that all the values of X were randomly drawn from a lognormal distribution.
  - Y = LnGM + Error. Error is normally distributed with mean 0, variance Vu, and standard deviation Su = √Vu.
  - AMu = Modeled arithmetic mean of X values = exp(LnGM) exp(½ Vu)
  - GMu = Modeled geometric mean of X values = exp(LnGM)
  - GSDu = Modeled geometric standard deviation of X values = exp(Su)
  - P95u = Modeled 95th percentile of X values = exp(LnGM) exp(Z95×Su)

Table 2[3] presents the arithmetic mean and 95th percentile estimates from the lognormal simple random sampling model, together with 95% confidence intervals, for all the exposure routes and clothing penetration factors. These are the values of AMu and P95u. Estimates and confidence intervals for the other parameters are not reported in this memorandum. Results are given for the "Overall" case where

[3] The confidence intervals given in Table 2 of this version of the memorandum differ a little from the confidence intervals given in Table 2 of the August 15 version because different sequences of random numbers were generated.

all body parts are assigned the same penetration factor and for the "By Part" case where each body part is assigned its own penetration factor.

For each exposure route, the two statistical models were fitted to the observed data and the summary statistics listed above were calculated together with 95% confidence intervals. The 95% confidence intervals in Table 2 were computed using a parametric bootstrap. For these calculations, the parametric bootstrap simulations were all generated from the fitted lognormal simple random sampling model.

The algorithm used was as follows:

Step 1:
Assume that there are N subjects in a data subset. (N = 18 for the analyses reported in this memorandum.)
Simulate N random variables Y, X from the estimated lognormal distribution superimposed upon the observed sampling structure ---;

Y = LnGM + RanNor(Seed)×Sr

X = exp(Y)

where:

LnGM = natural logarithm of fitted geometric mean

Sr = natural logarithm of fitted geometric standard deviation

Step 2:
For Y:

Calculate GMs = exp(EAM)

Calculate GSDs = exp(Su)

Calculate AMu = GMs×exp(0.5×Su×Su)

Calculate P95u = GMs× exp(Z95×Su)

where:

EAM = sample arithmetic mean of Y = AMu

Su = standard deviation of Y

For X:

Calculate arithmetic mean AMs

Calculate 95th percentile P95s

Step 3: Repeat Steps 1 and 2 10,000 times.

Steps 1 to 3 result in 10,000 values each for each of GSDs, GMs, AMs, AMu, P95s, and P95u. 95% confidence intervals can be defined for each parameter by the 2.5th and 97.5th percentiles (lower and upper, respectively) of the bootstrap distribution of that corresponding parameter. Note that by definition, GSDs = GSDu and GMs = GMu.

The confidence intervals in Table 2 for the arithmetic mean and 95th percentiles of the normalized dermal exposure treat the clothing penetration factor as a known constant and thus do not account for the uncertainty of the clothing penetration factor. This uncertainty can be evaluated by comparing the confidence intervals in Table 2 between the different clothing penetration factors.

Also of interest is the fact that the "K-factors"(the 95th percentile fold relative accuracy) were all at most 2.2 for these statistics, meeting the study design benchmark of 3.

Table 2. Arithmetic mean and 95th percentile estimates from lognormal simple random sampling model for normalized dermal exposure (mg/lb AI)

Clothing	Clothing Penetration Factor	Overall or By Part*	Arithmetic Mean (95% Confidence Interval)	95th Percentile (95% Confidence Interval)	Percentage from Hands**
Long Dermal	1. Arithmetic Mean Empirical	Overall	117.0 (68.9, 204.2)	359.7 (177.1, 709.5)	94
	1. Arithmetic Mean Empirical	By Part	116.9 (68.2, 204.2)	360.8 (175.9, 707.1)	94
	2. Arithmetic Mean Lognormal	Overall	117.1 (69.4, 207.1)	359.8 (179.0, 711.3)	94
	2. Arithmetic Mean Lognormal	By Part	117.4 (68.3, 208.9)	361.7 (175.5, 724.8)	94
	3. Geometric Mean	Overall	115.2 (67.4, 204.8)	357.1 (174.9, 717.9)	95
	3. Geometric Mean	By Part	115.5 (67.3, 206.8)	358.2 (176.0, 722.0)	95
	4. Default Ratio (50%)	Overall	127.0 (78.3, 211.2)	373.7 (194.4, 706.1)	86
	5. Upper Bound Ratio (100%)	Overall	141.1 (88.5, 232.7)	402.8 (214.2, 763.6)	78
Short Dermal	1. Arithmetic Mean Empirical	Overall	145.2 (89.7, 240.3)	423.7 (220.1, 794.3)	76
	1. Arithmetic Mean Empirical	By Part	145.1 (89.1, 239.0)	424.6 (218.7, 790.7)	76
	2. Arithmetic Mean Lognormal	Overall	145.3 (90.4, 242.7)	423.8 (222.2, 796.1)	76

Clothing	Clothing Penetration Factor	Overall or By Part*	Arithmetic Mean (95% Confidence Interval)	95th Percentile (95% Confidence Interval)	Percentage from Hands**
	2. Arithmetic Mean Lognormal	By Part	145.5 (89.2, 245.1)	425.5 (218.1, 808.8)	75
	3. Geometric Mean	Overall	143.4 (88.3, 239.9)	421.3 (218.1, 802.3)	77
	3. Geometric Mean	By Part	143.7 (88.4, 242.1)	422.3 (219.3, 806.2)	76
	4. Default Ratio (50%)	Overall	155.0 (99.2, 246.0)	435.5 (236.5, 789.1)	71
	5. Upper Bound Ratio (100%)	Overall	168.5 (109.7, 265.7)	459.1 (254.7, 834.2)	65
Long Short Dermal	1. Arithmetic Mean Empirical	Overall	132.2 (80.1, 224.0)	394.7 (200.4, 755.9)	83
	1. Arithmetic Mean Empirical	By Part	132.1 (79.4, 222.9)	395.8 (199.2, 753.2)	83
	2. Arithmetic Mean Lognormal	Overall	132.3 (80.7, 226.4)	394.8 (202.4, 757.6)	83
	2. Arithmetic Mean Lognormal	By Part	132.5 (79.6, 228.8)	396.5 (198.6, 770.7)	83
	3. Geometric Mean	Overall	130.5 (78.6, 224.1)	392.8 (198.5, 765.9)	84
	3. Geometric Mean	By Part	130.9 (78.5, 226.6)	393.9 (199.7, 770.1)	84
	4. Default Ratio (50%)	Overall	141.7 (89.5, 228.7)	405.0 (216.6, 745.1)	77
	5. Upper Bound Ratio (100%)	Overall	155.1 (99.9, 248.1)	429.1 (234.9, 789.8)	71
Hands Only***	1. Arithmetic Mean Empirical	Overall	109.8 (59.4, 210.7)	362.3 (164.1, 774.0)	
	1. Arithmetic Mean Empirical	By Part	109.8 (58.9, 209.9)	362.3 (163.1, 765.4)	

Clothing	Clothing Penetration Factor	Overall or By Part*	Arithmetic Mean (95% Confidence Interval)	95th Percentile (95% Confidence Interval)	Percentage from Hands**
	2. Arithmetic Mean Lognormal	Overall	109.8 (59.9, 213.4)	362.3 (165.9, 776.4)	
	2. Arithmetic Mean Lognormal	By Part	109.8 (58.7, 215.2)	362.3 (161.9, 785.5)	
	3. Geometric Mean	Overall	109.8 (59.4, 212.4)	362.3 (164.8, 783.0)	
	3. Geometric Mean	By Part	109.8 (59.7, 213.9)	362.3 (165.4, 785.2)	
	4. Default Ratio (50%)	Overall	109.8 (59.6, 212.6)	362.3 (166.1, 774.5)	
	5. Upper Bound Ratio (100%)	Overall	109.8 (59.3, 219.9)	362.3 (164.7, 805.1)	

*"Overall" = same penetration factor for all body parts. "By Part" = different penetration factors for each body part.
**Percentage from hands = Arithmetic Mean Normalized Exposure for Hands Only / Arithmetic Mean Normalized Exposure for Clothing.
***For the hands only clothing, the estimates are the same for all clothing penetration factors since the inner dosimeter data are not used. However, the confidence intervals are slightly different because different sets of random bootstrap simulations are selected

The percentage from hands is given in the last column of Table 2. This is the estimated arithmetic mean normalized exposure for hands only divided by the estimated arithmetic mean normalized exposure for a specific clothing scenario. The ratios depend upon the clothing penetration factor and clothing scenario. They range from 78-95% for Long Dermal, 65-77% for Short Dermal, and 71-84% for Long Short Dermal. Thus at least 65% of the dermal exposure from brush and roller painting is to the hands.

The results in Table 2 for Body Part = "All" show that the normalized dermal exposure is very similar when using the Arithmetic Mean Empirical, Arithmetic Mean Lognormal, and Geometric Mean clothing penetration factors, but the default and upper bound ratios lead to higher normalized dermal exposure estimates that may be unduly conservative. Since the geometric mean approach tends to lead to underestimates of the inner dosimeter values (see section 2), the Arithmetic Mean Lognormal approach, with non-detects replaced by half the detection limit, can be recommended. Although the two alternative arithmetic mean estimates lead to almost the same results, the Arithmetic Mean Lognormal approach is preferred because it provides slightly more conservative (i.e., higher) estimates of dermal exposure and is consistent with the lognormal modeling approach that has generally been used for the statistical analyses of the AEATF studies.

The results in Table 2 for the models with different penetration factors for each body part show that the estimates and confidence intervals of the arithmetic mean and 95th percentiles of the normalized exposure are very close to the estimates using the overall penetration factors calculated from all 48 ratios. For that reason, and also for simplicity, the approach of using the same penetration factor for all body parts is recommended over the approach of applying separate penetration factor estimates for each body part.

APPENDIX N.

CORRESPONDENCE WITH IRB AND IRB MEETING MINUTES

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Date	Page Range	Document(s)
8 Nov 13	555-566	RTestman→SAIRB transmittal of Single Site Study Submission Form dated 08 November 2013
8 Nov 13	567-568	RTestman→JAtlas forward e-mail from Schulman Technical Support→RTestman confirming receipt of eSubmission and inquiring on how to submit all documents needed to support Single Site Study Submission Form
8 Nov 13	569-570	JAtlas→RTestman instructing to send documents to him and he will get them attached to the submission
8 Nov 13	571-572	RTestman→JAtlas transmittal of Protocol 120463 dated 04 November 2013, Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design dated October 25, 2013, Informed Consent Form, NIH Certificate for SD
	573-696	Protocol 120463 dated 04 November 2013
	697-710	Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design dated October 25, 2013
	711-721	Informed Consent Form
	722	NIH Certificate for R. Testmen
8 Nov 13	723-725	RTestman→JAtlas transmittal of CVs and EPA Inspection Audits
	726-734	CVs – R. Testman, M. Boatwright, N. Chavez, T. Moate
	735-738	EPA Inspection Audits
8 Nov 13	739-744	RTestman↔JAtlas exchange of information regarding the study number of the last study submitted and acknowledgement
13 Nov 13	745-746	RTestman↔DGuzman responding to findings from initial screening of submission prior to IRB review
13 Nov 13	747-749	RTestman↔DGuzman responding to request for NIH Certificate and Nursing License for W. Harkey
	750	NIH Certificate for W Harkey
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13 Nov 13	752-754	DGuzman→RTestman acknowledging receipt and informing that new license is not needed but CV for W Harkey is needed
14 Nov 13	755-757	JAtlas→RTestman transmittal of outcome of review by board and Study Status Notification document with findings
	758-759	Study Status Notification – Conditionally Approved
20 Nov 13	760-763	RTestman→JAtlas addressed SAIRB question regarding pregnancy testing
20 Nov 13	764-767	JAtlas→RTestman confirmating internal review of response
04 Dec 13	768-771	JAtlas→RTestman transmittal of Study Status Notification II document removing finding regarding pregnancy test but conferring remaining condition to be met

Date	Page Range	Document(s)
	772	Study Status Notification II – Conditionally Approved
04 Dec 13	773-777	RTestman↔JAtlas pointing out that sponsor name is wrong on the SNN II and the IRB correcting and reissuing the SSN II
	778	Study Status Notification II – Conditionally Approved
20 Jan 14	779	MBoatwright→JAtlas requesting meeting minutes and roster from SAIRB in which study 120463 was discussed
22 Jan 14	780-781	JAtlas→MBoatwright transmittal of minutes and direction on how to obtain the roster
	782-783	SAIRB Meeting Minutes
22 Jan 14	784	MBoatwright→SAIRB request confirmation from website for member roster
22 Jan 14	785	alertreply→MBoatwright e-mail summary of request
22 Jan 14	786	BBayne→MBoatwright transmittal of Board Membership Roster
	787-788	Board Membership Roster
27 Jan 14	789	MBoatwright→JAtlas requesting help with Check List Item 6 for EPA submission for HSRB review
	790	Check List
3 Feb 14	791-792	JAtlas→MBoatwright updating on status of Item 6 on Check List
4 Feb 14	793-794	JAtlas→MBoatwright responding to Item 6 of Check List with Letter from Operations Manager as an attachment
	795	Letter from Operations Manager
11 Mar 14	796	JAtlas→MBoatwright inquiring of progress of study
11 Mar 14	797	RTestman→JAtlas responding with schedule for HSRB meeting on April 8 and expected timelines for process
17 June 14	798-801	JAtlas↔RTestman exchanging request and response of status of EPA/HSRB review and final written approval
4 Sept 14	802-804	JAtlas→RTestman informing that if full approval is not obtained by renew date of Nov 13, 2014, a 6 month continue review could be granted and providing the form to submit
	805-808	Single Site Study Periodic and Continuing Review Report From Version: September 2013
13 Oct 14	809-811	JAtlas→RTestman reminding re-approval is approaching and requesting status update and timeframe for submitting the final protocol to SAIRB for full approval
3 Nov 14	812	JAtlas→RTestman reminding of expiration date and providing form to be completed for continued review
	813-816	Single Site Study Periodic and Continuing Review Report From Version: September 2013
6 Nov 14	817-818	JAtlas→RTestman reminding of timeline to get form submitted and again providing form

Date	Page Range	Document(s)
	819-822	Single Site Study Periodic and Continuing Review Report From Version: September 2013
6 Nov 14	823-824	RTestman→JAtlas transmittal of Single Site Study Periodic and Continuing Review Report Form and letter from PI explaining delay in providing final protocol
	825	Letter from PI
	826-829	Single Site Study Periodic and Continuing Review Report From
11 Nov 14	830-840	DMartz↔MBoatwright exchanging request and response of CV for W Harkey, RN
	836	CV for W Harkey
	837	Nurses License
17 Nov 14	841	Schulman Technical Support→RTestman informing of Re-Approval Letter available via SiteAccess
	842	Re-approval Letter Dated November 13, 2014
9 Dec 14	843	Memorandum notifying of language mistakes in Re-Approval Letter issued November 13, 2014 and issue of corrected letter
	844	Corrected letter dated 12/09/14
9 Mar 15	845	JAtlas→RTestman inquiring of progress of study and timeline for submission of final protocol
27 Mar 15	846	JAtlas→MBoatwright inquiring of progress of study and proposed timeline for submission
27 Mar 15	847-849	RTestman↔JAtlas providing response and timeline
15 Oct 15	850-851	Schulman Technical Support→RTestman acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report
21 Oct 15	852	DCorrea→RTestman asking for new explanation letter of why protocol had not yet been finalized and submitted for approval
	853	Original Explanation Letter
23 Oct 15	854	DCorrea→RTestman asking for new rational letter
23 Oct 15	855	RTestman→DCorrea submitting letter
	856	Letter
10 Nov 15	857	Schulman Technical Support→RTestman informing of Re-Approval Letter available via SiteAccess
	858	Re-approval Letter Dated November 10, 2015
19 Feb 16	859	RTestman→JAtlas transmittal of final Protocol 120463 dated 05 January 2016 and Informed Consent Form also asking for Spanish translations of Informed Consent Form
	860-871	Inform Consent Form
	872-1018	Protocol 120463 dated 05 January 2016
22 Feb 16	1019	DGuzman→RTestman acknowledging receipt of protocol but requesting reviews and approvals from CDPR and HSRB

Date	Page Range	Document(s)
22 Feb 16	1020-1021	RTestman→DGuzman transmittal of HSRB meeting report and CDPR review with GPL response
	1022-1080	HSRB Meeting Report
	1081-1089	Letter to CDPR with GPL Responses to CDPR Review
	1090	E-mail exchange between RTestman and CDPR corresponding the review letter from the CDPR and the responses by GPL of the CDPR findings
	1091-1097	CDPR Review Letter
22 Feb 16	1098-1099	DGuzman→RTestman confirming receipt
26 Feb 16	1100-1101	DGuzman→RTestman requesting a signed letter summarizing HSRB and EPA recommendations and how GPL addressed each in the final version of the protocol
29 Feb 16	1102-1104	RTestman→DGuzman providing a signed letter with requested summary of recommendations and actions
	1105-1109	Letter with GPL Responses to HSRB/EPA Review
1 Mar 16	1110-1112	DGuzman→RTestman confirming receipt
3 Mar 16	1113-1115	DGuzman→RTestman transmittal of Study Status Notification III document removing conditionally from the approval since all findings have been resolved satisfactory
	1116	Study Status Notification III
3 Mar 16	1117-1120	DGuzman→RTestman transmittal of draft Informed Consent Form with IRB comments
	1121-1132	Informed Consent Form in tracked change (dated 03/03/2016)
3 Mar 16	1133-1136	RTestman→DGuzman confirming receipt
3 Mar 16	1137-1140	RTestman→DGuzman transmittal of revised Informed Consent Form
	1141-1152	Informed Consent Form in tracked change (dated 03/03/2016)
4 Mar 16	1153-1157	DGuzman→RTestman transmittal of approval for Informed Consent Form requesting approval from PI of final draft
	1158-1169	Final Draft of Informed Consent Form
4 Mar 16	1170-1174	RTestman→DGuzman approval of Informed Consent Form for finalization
4 Mar 16	1175-1180	DGuzman→RTestman acknowledgement of approval and communication of transfer from DGuzman to JAtlas as SAIRB Coordinator
7 Mar 16	1181	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess - Initial Approval
	1182-1183	Initial Approval Documents dated March 4, 2016
	1184	Memo clarifying why the word version and final PDF of the Informed Consent are available in the zipped file
	1185-1195	Informed Consent Form (English) SCHULMAN APPROVED, IRB # 201307318, Date: March 4, 2016 (PDF File

Date	Page Range	Document(s)
	1196-1206	Informed Consent Form (English) SCHULMAN APPROVED, IRB # 201307318, Date: March 4, 2016 (Word file)
	1207-1223	Informed Consent Form (English) in tracked changes
8 Mar 16	1224	RTestman→JAtlas request for Informed Consent Form, Subject Self-reporting Form, Newspaper Ad, and Subject Initiation to Participate to be translated into Spanish
9 Mar 16	1225	JAtlas→RTestman confirming submission of Informed Consent Form for translation and assurance that the other documents will also be submitted
10 Mar 16	1226	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess – Initial ICD Packet Translation
	1227	Initial Translated Approval Documents dated March 10, 2016
	1228-1240	Spanish Informed Consent Form dated 03/04/16 with Certification of Translation
14 Mar 16	1241	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess – Recruitment/Study-Related Material Translation
	1242	Translated Recruitment/Study Related Materials dated March 14, 2016 – Subject Information Sheet
	1243-1245	Appendix D: Spanish Subject Self-Reporting Demographic Form with Certification of Translation (PDF File)
	1246-1247	Appendix D: Spanish Subject Self-Reporting Demographic Form (word file)
	1248	Translated Recruitment/Study Related Materials dated March 14, 2016 – Ad Print
	1249-1251	Appendix F: Spanish Newspaper Advertisement with Certification of Translation (PDF file)
	1252-1253	Appendix F: Spanish Newspaper Advertisement (word file)
	1254	Translated Recruitment/Study Related Materials dated March 14, 2016 – Phone Screen
	1255-1257	Appendix G: Spanish Subject Invitation to Participate Script with Certification of Translation (PDF file)
	1258-1259	Appendix G: Spanish Subject Invitation to Participate Script (word file)
3 May 16	1260	RTestman→JAtlas transmittal of Protocol Amendment 1
	1261-1262	Protocol Amendment 1
4 May 16	1263-1264	AHelmes↔RTestman acknowledgement of receipt and request to complete appropriate form which in return was completed and sent back by PI
	1265-1266	Protocol/Informed Consent Change Submission Form

Date	Page Range	Document(s)
4 May 16	1267-1269	AHelmes→RTestman acknowledging receipt and that everything needed is present and the submission has been sent for preliminary review
9 May 16	1270	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess – Amended Approval Letter
	1271	Letter dated May 6, 2016 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 1
13 June 16	1272	RTestman→AHelmes transmittal of Protocol/Informed Consent Change Submission Form and Protocol Amendment 2
	1273-1274	Protocol/Informed Consent Change Submission Form dated May 5, 2016
	1275-1276	Protocol Amendment 2
13 June 16	1277	AHelmes→RTestman acknowledging receipt and submission to the correct team for processing
16 June 16	1278	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess – Amended Approval Letter
	1279	Letter dated June 15, 2106 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 2
27 Oct 16	1280-1284	Single Site Study Periodic and Continuing Review Report (submitted via eSubmission portal)
27 Oct 16	1285	Schulman Technical Support→RTestman acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report and supporting material
7 Nov 16	1286	Schulman Technical Support→RTestman notification of IRB documents available via SAIRB SiteAccess – Re-Approval Letter
	1287	Re-Approval Letter dated November 7, 2016
11 Sept 17	1288-1289	Site Reminder→RTestman 1st notification a periodic review is due by November 3, 2017
16 Oct 17	1290	Site Reminder→RTestman final notification a periodic review is due by November 3, 2017
17 Oct 17	1291-1292	CarterM→Rtestman reminding that a periodic review is due by November 3, 2017
27 Oct 17	1293-1294	Noncompliance Issue/Deviation Submission Acknowledgement Form (submitted via eSubmission portal)
27 Oct 17	1295-1296	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
27 Oct 17	1297-1298	Rtestman→CarterM transmittal of Protocol Deviation 1

Date	Page Range	Document(s)
	1299-1301	Protocol Deviation 1
30 Oct 17	1302-1304	Single Site Study Final Report Form (submitted via eSubmission portal)
30 Oct 17	1305	Schulman Technical Support→RTestman acknowledged receipt of Single Site Study Final Report dated October 30, 2017 (submitted via eSubmission portal)
30 Oct 17	1306-1307	CarterM→Rtestman requesting a Noncompliance Issue/Deviation Submission Acknowledgement Form be submitted for each deviation item.
30 Oct 17	1308-1321	Seven Noncompliance Issue/Deviation Submission Acknowledgement Forms (submitted via eSubmission portal) per request of SAIRB
30 Oct 17	1322	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1323	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1324	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1325	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1326	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1327	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1328	Schulman Technical Support→RTestman acknowledgement of receipt of Noncompliance Issue/Deviation Submission Acknowledgement
30 Oct 17	1329	Schulman Technical Support→ RTestman informing that Study Closure Letter dated October 30, 2017 was posted and available via Schulman IRB SiteAccess.
	1330	Study Closure Letter dated October 30, 2017

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Single Site Study Submission Form

SECTION 1.0: Submission Requirements & Instructions

1. Standard single site study submission requirements:

- Completed *Single Site Study Submission Form*
- Protocol ☒ Check box to request review of a DRAFT protocol
- Informed Consent(s) in Microsoft Word Format
- Investigator's Brochure / Package Insert(s) / Device Information / Product Information (if applicable)
- *Curriculum vitae* (CV) of the Principal/ Qualified Investigator (PI/QI) and each Sub-Investigator (Sub-I), if not already on file
- Clinical Research Budget Template (Canada sites only) TCPS 2 Article 11.11
- Copy of the PI/QI's current medical/professional license (Canada, Mississippi and Puerto Rico sites only)

NOTE: Please visit www.sairb.com for submission requirements for Non-Interventional, Federally Funded/FWA and Transfer of IRB Oversight studies.

2. Submission instructions: Submit via Secure eSubmission or email to Submissions@sairb.com

SECTION 2.0: General Information

1. Sponsor: AEATF II **2. Protocol Number:** 120463 **3. Acronym:** ____ **4. Indication:** ____

5. This study is classified as: ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☒ N/A

6. Qualifying studies will be reviewed in an expedited manner by Minimal Risk Review (MRR) rather than by the full Board. If this study qualifies, may Schulman review by MRR? ☒ No ☐ Yes

7. Please provide the protocol number(s) of any similar/related protocols previously reviewed by Schulman: 070270b

8. Investigator and Primary Site Information: Enter information as it should appear on all IRB correspondence, including the Informed Consent (IC)

PI/QI Name (including degree & credentials): Robert Testman, M.B.A.
Office Phone Number to appear on IC (Optional): 559-275-9091
24-Hour Phone Number to appear on IC (Required): 949-939-3585

Site Name: Golden Pacific Labs Address: 4720 W. Jennifer Ave #105 City: Fresno
State/Province: CA Zip/Postal Code: 93722 Country: USA
Site Phone: 559-275-9091 Fax: 559-275-1810 Email: rtestman@gplabs.com

9. Will this study be conducted at additional locations under the same PI/QI listed above?

☐ No
☒ Yes **>>> a.** Please provide the names and addresses of these additional locations (attach additional sheets if necessary): study to be performed at an unoccupied commercial building in Fresno County, CA - see protocol and rationale for details.
b. Please specify which of these additional locations are to be listed on the Informed Consent (attach additional sheets if necessary): above is listed on informed consent

NOTE: Schulman is **not** able to review/approve research in: Alberta, Saskatchewan and Newfoundland and Labrador. Schulman will only review research in Québec that involves adults with capacity to consent.

10. Is this research site under the jurisdiction of the Capital District Health Authority of Nova Scotia?

☒ No
☐ Yes **>>>** Schulman is not able to review research located in the 'Capital District Health Authority'.

11. Will this study be conducted through an institution that has a contract for Schulman review services?

Institutions" include academic medical centers, colleges, universities, hospital systems, community hospitals, nursing facilities, public health clinics, and other centers that may or may not have local IRBs. Please visit the Institution portion of the Schulman website for more information.

☒ No
☐ Yes **>>>** Please provide the name of the institution identified on the contract or agreement: ____

SECTION 3.0: Site Contact Information

1. Site Contact Information: ☒ **Check here if same as Primary Site Information listed in Section 2.0.**

Name: ____ Title: ____ Email: ____
Phone: ____ Fax: ____ Mailstop: ____
Company: ____ Address: ____ City: ____
State/Province: ____ Zip/Postal Code: ____ Country: ____

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Single Site Study Submission Form

2. Site Correspondence Information: ☒ **Check here if same as Site Contact Information listed above.**

Name:	_____	Title:	_____	Email:	_____
Phone:	_____	Fax:	_____	Mailstop:	_____
Company:	_____	Address:	_____	City:	_____
State/Province:	_____	Zip/Postal Code:	_____	Country:	_____

3. Institution Contact Information (only if applicable):

Name:	_____	Title:	_____	Email:	_____
Phone:	_____	Fax:	_____	Mailstop:	_____
Company:	_____	Address:	_____	City:	_____
State/Province:	_____	Zip/Postal Code:	_____	Country:	_____

NOTE: Site contacts listed on this form will receive SiteAccess 1.0 to review study status information and receive IRB documents. Please visit the SiteAccess 1.0 login page to request access for an additional user.

SECTION 4.0: Study Contact & Billing Information

1. Sponsor Contact Information: ☐ Study Contact ☐ Copy on Communications

Name:	Has Shah, Ph.D.	Title:	_____	Email:	has_shah@americanchemistry.com
Phone:	202-249-6724	Fax:	_____	Mailstop:	_____
Company:	AEATF II / ACC	Address:	700 2nd st. NE	City:	Washington
State/Province:	DC	Zip/Postal Code:	20002	Country:	USA

2. CRO Contact Information: ☒ Study Contact ☐ Copy on Communications

Name:	_____	Title:	_____	Email:	_____
Phone:	_____	Fax:	_____	Mailstop:	_____
Company:	_____	Address:	_____	City:	_____
State/Province:	_____	Zip/Postal Code:	_____	Country:	_____

3. The party responsible for Schulman service fees:

Name:	Robert Testman	Title:	President	Email:	rtestman@gplabs.com
Phone:	559-275-9091	Fax:	559-275-1810	Mailstop:	Suite 105
Company:	Golden Pacific Labs	Address:	4720 W. Jennifer Ave	City:	Fresno
State/Province:	CA	Zip/Postal Code:	93722	Country:	USA

4. Please send invoices via: ☒ Email OR ☐ Hard Copy **5. Purchase Order Number (if applicable):** _____

SECTION 5.0: Study Information

1. What is the source of funding for this study? Check all that apply:

☐ Drug or Medical Device Company

☐ Not-for-Profit Sponsor

☐ US Government >>> Please specify the funding agency: _____

☒ Other: Antimicrobial Exposure Task Force II / American Chemistry Council

2. Does this study involve an investigational new drug or biologic OR the investigational use of a marketed drug or biologic?

☒ No

☐ Yes >>> Please complete **a.** through **c.** for US studies or **d.** and **e.** for Canadian studies:

US study: a. What is the IND number? _____

b. If this is a Phase 1 or 2 study, please provide the date of the IND submission to the FDA: _____

☐ By checking here the sponsor/CRO/site agrees to comply with FDA guidelines and control release of the study drug so it is not available to study sites until day 31 after the IND submission or release by the FDA and any questions from the FDA have been answered (if applicable). The sponsor/CRO/site further agrees not to screen or obtain informed consent for the specific study until the IND is in effect.

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c. Does this study include an off-label use of an FDA approved drug?

☐ No

☐ Yes **>>>** Please indicate whether the off-label use is subject to the IND regulations or whether it is exempt from the IND regulations because such use satisfies all criteria of 21 CFR 312.2. Please provide copies of all relevant FDA documentation.

Canadian study: d. What is the CTA Control Number? _____

e. If this is a Phase 1, 2 or 3 study, please provide:

☐ A copy of the No Objection Letter (NOL) **OR** ☐ The date of submission to Health Canada: _____

NOTE: Approval cannot be granted by Schulman Associates IRB unless the NOL letter is provided.

3. Is this study under the jurisdiction of the Environmental Protection Agency (EPA)?

☐ No

☒ Yes **>>>** Please complete **a.**:

a. Does this study require review by the Human Studies Review Board (HSRB)? ☐ No ☒ Yes

4. Does this study involve the use of an investigational device?

☒ No

☐ Yes **>>>** Please attach one of the following:

☐ FDA letter granting an Investigational Device Exemption (IDE) for the proposed use;

☐ Letter from the Sponsor stating that the test article is a non-significant risk device; or

☐ *Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2 (c).

*This letter must be provided for your study to qualify for expedited (MRR) review.

5. Does this study involve the dispensing of a controlled substance which comes under the jurisdiction of federal/state laws regulating its manufacture, sale, distribution, use, and disposal?

☒ No

☐ Yes **>>>** Please complete **a.** through **c.** for US studies or **d.** and **e.** for Canadian studies:

US study: a. What is the generic name of the controlled substance? _____

b. The controlled substance is Class: _____

c. ☐ Attached is a copy of the DEA registration or controlled substance license for each investigator prescribing and/or dispensing the controlled substance.

Canadian study: d. What is the generic name of the controlled substance? _____

e. ☐ Attached are copies of the Letter of Exemption under the Controlled Drugs and Substances Act and Regulations and Letter of Authorization permitting the controlled substance to be shipped to the QI.

6. Does this study involve the use of a placebo control?

☒ No

☐ Yes **>>>** Please complete **a.** through **d.**:

a. Is there standard treatment for the indication(s) being studied?	☐ No	☐ Yes
b. Is the targeted population refractory to standard treatment AND there exists no standard second-line treatment for this targeted population?	☐ No	☐ Yes
c. Is the study testing add-on treatment to standard therapy such that all subjects will receive all treatments that would normally be prescribed?	☐ No	☐ Yes
d. Does the informed consent (IC) fully inform subjects of the reasons why a placebo-controlled study design is necessary?	☐ No	☐ Yes

NOTE: Your responses must be substantiated by your protocol text and, where applicable, your informed consent text.

7. Does this study involve a sub-study or additional optional research activities that subjects may "opt-in"?

☒ No

☐ Yes **>>>** Please complete **a.** through **c.**:

a. ☐ Submit the *Sub-Study/Additional Research Submission Form* to describe *each* sub-study

b. ☐ Submit the protocol supplement detailing the sub-study and/or additional research **OR** ☐ Confirm the sub-study and/or additional research is detailed in protocol section(s): _____

c. ☐ Submit the sub-study and/or additional research IC and sub-study specific HIPAA Authorization (as applicable) **OR** ☐ Confirm the sub-study is described in the main IC/Compound HIPAA Authorization (under Final Omnibus Rule)

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8. Does this study involve a Data Safety Monitoring Board or Committee?

☒ No

☐ Yes >>> Please complete **a.** and **b.**:

a. Please attach the data monitoring plan or indicate the protocol section(s) where this information is located:

☐ Data monitoring plan attached **OR** ☐ This information is located in protocol section(s): _____

b. ☐ By checking here, the site agrees to submit to Schulman routine data and safety monitoring reports within ten (10) days of availability and urgent data and safety monitoring reports within twenty-four (24) hours of availability.

9. Will this study be registered on clinicaltrials.gov?

☒ No

☐ Yes

SECTION 6.0: FWA & Previous Review

1. Is this study being conducted under a Federalwide Assurance (FWA)?

☒ No

☐ Yes >>> Please provide the FWA number: _____

NOTE: Please refer to Federally Funded/FWA Site for additional submission requirements.

2. Was this site previously submitted to another IRB/REB for this protocol?

☒ No

☐ Yes >>> Please complete **a.** and **b.**:

a. Was it disapproved or withdrawn?

☐ No

☐ Yes >>> Please attach a detailed explanation.

b. Are you requesting transfer of IRB oversight?

☐ No

☐ Yes >>> Please refer to Transfer of IRB Oversight Site for additional submission requirements.

SECTION 7.0: Research Site Information

1. Where will the study be conducted? Check all that apply:

☐ Research Facility	☐ Private Practice	☐ Public Health Clinic
☐ Hospital or Hospital System	☐ Surgery Center	☐ Free-standing Psychiatric Facility
☐ University/Academic Medical Center	☐ Nursing Care Facility	☐ Facility owned by or affiliated with a hospital or university
☐ Hospice	☒ Other: Unoccupied commercial building in Fresno County, CA	

2. Will any part of this study be conducted in a facility under the jurisdiction of or is affiliated with another IRB?

☒ No

☐ Yes >>> Please submit a **Letter of Deferral** from that institution, signed by the CEO of the institution or Board Chairperson, authorizing Schulman to be the reviewing IRB/REB. Please reference the Letter of Deferral. If you will use an outside hospital to perform a study-related procedure, but no subjects will be consented and no study drug will be administered at the hospital, please reference the Hospital Procedure Letter as a template for composing a hospital procedure letter to be included with your submission.

3. Approximately how many research studies have been conducted at this site during the last calendar year? 1

4. Please describe the attitudes in your community (*e.g., religious, ethical, ethnic or economic*) that affect the conduct of research at your site as:

☒ Positive ☐ Neutral ☐ Negative >>> Please attach an explanation.

5. What precautions are used to maintain confidentiality and security of study records at your site? Check all that apply:

☒ Paper-based records will be kept in a secure location and will be accessible only to personnel involved in this study;

☒ Computer-based files will be available only to personnel involved in the study through the use of access privileges and passwords;

☐ Prior to accessing any study-related information, site personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information;

☒ Whenever feasible, identifiers will be removed from study-related information; and/or

☒ Other (specify): subjects names only on enrollment documents and kept in locked archive

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Single Site Study Submission Form

6. What precautions are used to maintain the privacy of subjects at your site? Check all that apply:

☐ A private room for discussion of health-related information

☐ Working knowledge of and adherence to the HIPAA Privacy Rule / Final Omnibus Rule (US) or PIPEDA (Canada);

☐ Consideration of parental inclusion in the visit if the study involves children;

☐ Consideration of parental absence in the visit if the study involves teens; and/or

☒ Other (specify): private interview area and dressing areas during study

7. Are there any state, provincial or local laws that govern the conduct of research (*e.g., California Experimental Subjects' Bill of Rights*) at your site?

☐ No

☒ Yes **>>>** Please attach an explanation.

NOTE: If unsure, please contact a healthcare attorney or your local, state or provincial government.

8. What resources are available at your site for a subject in need of emergency care? Check all that apply:

☐ ACLS trained personnel and crash cart with emergency medications

☐ Automatic external defibrillator

☐ On-site paramedics

☒ Other (specify): On-site RN will be present

☒ Access to 911

☐ CPR certified staff

☐ N/A

9. Please provide the travel time between the research site and the nearest hospital: approx. 10 minutes

10. Do you plan to enroll subjects through a legally authorized representative (LAR)?

☒ No

☐ *Yes **>>>** Please complete **a.** through **c.**:

*An LAR may consent on behalf of a subject ONLY if the Board has determined that an LAR is appropriate for the study.

a. Which individuals will you allow to give consent/permission? For example, durable power of attorney for health care, spouse, guardian etc.: _____

b. How will you verify who constitutes an LAR in your state/province? Check all that apply:

☐ Legal Counsel ☐ Sponsor/CRO ☐ Other: _____

NOTE: Who can serve as a legally authorized representative (LAR) is determined on a state-by-state/province-by-province basis. When a study requires consent to be provided by an LAR, Schulman requests that the PI/QI confirm with a regulatory attorney or with the sponsor/CRO who may serve as an LAR for their particular state/province. The sponsor is responsible for ensuring proper monitoring of investigators under 21 CFR Part 312.50 or Part C Division 5 of the Canadian Food and Drug Regulations C.05.0100, which includes confirming that a legally effective consent process was performed. The monitor should verify that the person signing as LAR has the authority to provide consent on the subject's behalf; otherwise the consent may not be legally effective.

c. Briefly describe the plan to assess the subject's ability to be able to provide consent and/or assent (attach additional sheets if necessary): _____

11. Massachusetts sites conducting investigational drug studies ONLY: Are you registered with the Massachusetts Department of Public Health to dispense investigational drugs?

☐ No **>>>** Please obtain the appropriate registration in order to conduct research in the state of Massachusetts.

☐ Yes **>>>** Please attach a copy of your current registration document.

NOTE: You may contact the Massachusetts Department of Public Health.

12. Is this research site a "covered entity" under the HIPAA Privacy Rule/Final Omnibus Rule (US only)?

☒ No

☐ Yes

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Single Site Study Submission Form

SECTION 8.0: Research Experience, Education & Training

1. Please list the PI/QI and all Sub-Is for this study and indicate the clinical research experience (in years) and human research subject protection education and training for each:

Name (First Last) Degree	Experience	Education & Training
PI/QI: Robert Testman MBA	15 years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☒ Received training on human subject protection provided by the sponsor/CRO/SMO ☒ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: Megan Boatwright, BS	10 years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☒ Received training on human subject protection provided by the sponsor/CRO/SMO ☒ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: Thomas Moate, MS	10 years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☒ Received training on human subject protection provided by the sponsor/CRO/SMO ☒ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: Natan Chavez	5 years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☒ Received training on human subject protection provided by the sponsor/CRO/SMO ☒ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: _____	___ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: _____	___ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____
Sub-I: _____	___ years	☐ Reviewed FDA Information Sheets, TCPS Tutorial(CAN), GCP Guidelines and the Belmont Report ☐ Attended educational seminar(s) related to human subject protection ☐ Received training on human subject protection provided by the sponsor/CRO/SMO ☐ Completed formal education/training in human subject protection via web-based or published modules ☐ Other: _____

NOTE: Please attach additional sheets if necessary to list all Sub-Is.

SECTION 9.0: Informed Consent

1. Will compensation for study participation or reimbursement for expenses be provided?

☐ No

☒ Yes **>>>** Please detail the compensation/reimbursement plan to be included in the IC by completing **a.** through **c.**:

a. Who will receive compensation/reimbursement? Check all that apply:

☒ Adult Subjects ☐ Minor Subjects ☐ Parents/Guardians of Minor Subjects ☐ Caregivers ☐ Other: _____

b. Please attach the established visit payment schedule or list the payment amount for each visit in the spaces provided below. To avoid delays in processing, please refer to the visit schedule in the study protocol to ensure all visits are addressed:

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Payment of $20 for screening / enrollment visit
Payment of $100 for study participation / alternate visit
Payment of $_____ for _____ visit
Payment of $_____ for _____ visit
Payment of $_____ for _____ visit

Examples of visit types that should be addressed:
- Screening
- Completed
- Inpatient/Confinement
- Subjects serving as alternates
- Unscheduled
- Optional
- Sub-study
- Telephone

>>Please list all visits for which subjects will **NOT** be compensated or reimbursed:
none

>>Would you like the payment total to be listed on the Informed Consent?
☐ No
☒ Yes >>> Please provide the **Total** payment of up to $120 for **completing** all study visits.

c. When will compensation/reimbursement for expenses be provided? Choose one:

☒ after each visit
☐ weekly
☐ bi-weekly (every 2 weeks)
☐ monthly
☐ annually
☐ at the time participation in the study ends*
☐ at the end of the study*
☐ other: _____

* **NOTE:** Compensation/reimbursement must be prorated across study visits and provided at least annually for participation lasting longer than one year.

2. Do you plan to consent/enroll non-English speaking subjects?

☐ No
☒ Yes >>> Please complete **a.** through **b.**:

a. Who will be responsible for obtaining translations? Choose one:

☐ Site or Sponsor/CRO >>> Please reference the *Translations Guidance*.
☒ Schulman >>> What language(s) are authorized? Spanish

b. Is there someone at your site fluent in the language(s) of the non-English speaking subject(s) who is capable of explaining the study and answering questions during the consent process and throughout the participation in the study (i.e. employee, member of the study staff, professional [impartial] translator)?

☐ No >>> Please attach an explanation
☒ Yes

NOTE: Translated study documents may be used only if enrollment of non-English speaking subjects is permitted by the protocol and authorized by the sponsor/CRO. All translations of study documents and materials approved in English must be approved by Schulman. You must comply with the safeguards pertaining to enrollment of subjects from the vulnerable group of non-English speaking subjects. For further information, please refer to the *Translations Guidance*.

3. It is Schulman's expectation that the PI/QI will be aware of and comply with state/provincial laws and/or regulations regarding HIV testing when HIV testing is explicitly required by the protocol or when the protocol allows for HIV testing at the investigator's discretion. Please confirm the PI/QI's agreement to follow this expectation:

☐ By checking here, you confirm that the PI/QI agrees that this site will comply with state/provincial laws and/or regulations pertaining to HIV testing, which may include, but may not be limited to obtaining informed consent, providing HIV counseling, and reporting positive HIV test results to public health authorities.

NOTE: Schulman recommends that Canadian sites consult with their provinces' health officials and/or legal counsel to assist in determining the provinces' laws and/or regulations pertaining to HIV testing. Schulman recommends that US sites consult with their states' departments of health and/or legal counsel to assist in determining the states' laws and/or regulations pertaining to HIV testing.

4. Which individuals at your site are authorized to conduct the informed consent discussion with subjects?

☒ PI/QI ☒ Sub-Is ☐ Research Coordinator/Study Nurse ☐ Other: _____

5. What education related to informed consent discussion has been provided to these individuals?

☐ Job Orientation ☒ In-house education ☐ Education provided by a professional association
☐ Role Play ☒ Education provided by sponsor/CRO ☒ Knowledge of protocol
☒ Other: NIH web training / Experience on prior studies

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Single Site Study Submission Form

6. Please confirm the following regarding the informed consent process that will be followed for this study by checking the boxes below:

☒ Informed consent discussions with subjects will take place in a private area.

☒ Potential subjects will be allowed as long as needed to review the IC to decide study participation, including at home or overnight.

☒ The PI/QI will be available to answer subject questions during the informed consent process.

☒ A copy of the signed IC will be provided to the subjects.

☒ Information during the consent process will be provided in a language understandable to the subjects.

☐ Subjects will be informed of alternative treatments, therapies, or procedures prior to participation in this research study.

☒ No information will be presented to a subject that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the organization, or its agents from liability for negligence.

☒ Subject understanding of the study will be assessed following the consenting process and before being enrolled into the study.

☒ Coercion and undue influence will be minimized by: not allowing bonuses for study staff that are directly based on enrollment; providing compensation for participation/reimbursement for expenses that is based only on time and inconvenience to subjects; equitably prorating compensation for participation; thoroughly explaining the IC and allowing for subjects to ask questions; and implementing appropriate safeguards for vulnerable subjects.

NOTE: If any of the above are not true for the consenting process at your site, please attach a written explanation. alternative treatments are n/a

SECTION 10.0: Subject Recruitment Information

1. From what groups may subjects for this study be recruited? ☐ N/A – Extension Study

a. Gender:	☒ Male	☒ Female	
b. Economic Status:	☒ Upper Income	☒ Middle Income	☒ Lower Income
c. Ethnic Background:	☒ Caucasian	☒ African	☒ Asian
	☒ Hispanic	☒ Native American/Aboriginal	☐ Other: _____

2. Will recruitment methods and materials be used for this study?

☐ No

☒ Yes **>>>** Please submit all recruitment materials for review using the *Recruitment/Study-Related Material Submission Form*.

NOTE: All recruitment material(s) not incorporated in the protocol must be submitted for review. Approval of your recruitment material will be sent to you under separate cover and will not appear in your initial study approval letter.

US SITES NOTE: For HIPAA Privacy Rule compliance, your site may need subject authorization or a Partial Waiver of Authorizationbefore your site can use or disclose protected health information for research screening or recruitment purposes.

3. Will study-related materials be used for this study?

☐ No

☒ Yes **>>>** Please submit all study-related materials for review using the *Recruitment/Study-Related Material Submission Form*.

NOTE: All study-related material(s) not incorporated in the protocol must be submitted for review. Approval of your study-related materials will be sent to you under separate cover and will not appear in your initial study approval letter.

4. If a potential subject is eligible for multiple research studies being conducted at your site, it is Schulman's expectation that both the PI/QI and the potential subject will collaborate to decide in which study the subject will enroll. Please check the appropriate response:

☐ By checking here, you confirm that the PI/QI agrees that the potential subject and study doctor will be involved in the decision.

☒ N/A; our research site does not perform competing research studies.

5. It is Schulman's expectation that referral fees (finders' fees) will not be paid to physicians/healthcare providers or others for referrals of research subjects in this study. Please confirm the PI/QI's agreement to follow this expectation:

☒ By checking here, you confirm that the PI/QI agrees that this site will not pay referral fees (finders' fees) for referrals of research subjects to this study without Board approval.

NOTE: Schulman agrees with the American Medical Association Code of Ethics – Section 6.03 and Canadian Medical Association – Policy #13.

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Single Site Study Submission Form

SECTION 11.0: Vulnerable Groups

1. If your site plans to recruit or enroll subjects into this study from vulnerable groups, please check all applicable vulnerable groups below and review the provided safeguards:	
Vulnerable Group	**Safeguards**
☐ **None**	We have no plans to recruit or enroll vulnerable subjects.
☐ **Children**	Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. A child's parent or legal guardian must accompany a child during the informed consent process. A written assent should be prepared for children 7 years or older unless assent is waived by the Board. The child should be given an opportunity to decide, independently, whether or not to participate in the study. If the child agrees, his/her signature (or printed name) indicates assent. In Alabama, Nebraska, British Columbia, New Brunswick, Northwest Territories, Nova Scotia, Nunavut, and Yukon, persons younger than **19** are considered children. In Puerto Rico, persons younger than **21** are considered children. Schulman does not review studies that target wards of the state/province.
☐ **Economically Disadvantaged**	The site must ensure that the compensation is not presented in a manner that may be coercive to this population. Payment must not be contingent upon completion of the entire study. There must be a plan to pro-rate payments. Any compensation or bonus for completion must be reasonable and not so large as to induce subjects to enroll or stay in the study.
☐ **Educationally Disadvantaged**	For an individual who may have trouble comprehending the written IC, the person conducting the consent discussion must review each section of the IC with the potential subject and pose questions after each section to ensure an adequate understanding. For an illiterate subject, an independent witness must also be present during the presentation of and signing of the IC. An independent witness must not be an employee of the investigator or research site.
☐ **Employees**	Measures must be taken to ensure the confidentiality of an employee's study-related medical records. Additionally, no action can be taken with an employee based on information to which an employer would not otherwise be entitled but obtains because of an employee's participation in a study. An employee who participates in a research study must be treated as other subjects and must be able to decide not to participate or to discontinue study participation without any impact on his/her employment status. The Board requires that each employee sign a non-coercion addendum prior to the subject's participation in the study. "Employee" refers to either an employee or an employee's family member who is participating in a study.
☐ **Physically Impaired**	An individual with a physical impairment(s) (e.g., visual, hearing, speech) that would prevent normal communication, and who is unable to read and/or sign the IC, must have an independent witness present during the presentation and signing of the IC. The independent witness must also sign the IC. An independent witness must not be an employee of the investigator or research site.
☐ **Life-Threatening Condition/ Seriously Debilitating Illness**	For an individual with a life-threatening condition, the investigator must fully explain alternative treatments and that participation in a research study may not benefit his/her present medical condition. The investigator must confirm that the subject understands this information.
☐ **Mentally Disabled/ Cognitively Impaired**	An individual who is not competent to understand verbal and written information and provide informed consent must have an LAR. The law of the state/province where the site is located defines who may act as an LAR. The LAR must sign the IC on behalf of the subject. If checked, please attach, on a separate page, justification for inclusion into the study and explain how lack of capacity to consent will be determined. Please consult your state/province law regarding informed consent and LAR. **NOTE Canadian sites:** Schulman will only review research in Québec that involves adults with capacity to consent.
☒ **Non-English Speaking Subjects**	If the site consents a non-English speaking subject, it must use an IRB approved translated informed consent. The site must also provide someone (i.e.: Employee, member of the study staff, or impartial translator) who is capable of explaining the study and answering questions in the language of the non-English speaking subject throughout the subjects participation in the study. This person cannot be a family member or friend of the subject.
☐ **Nursing Home Residents**	Each state/province has a "Nursing Home Bill of Rights" of which the PI/QI, study staff, subject and LAR, if appropriate, must be fully aware.

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Single Site Study Submission Form

☐ **Pregnant Women**	A pregnant woman must be fully informed regarding the foreseeable impact of the research on the fetus or resultant child. In addition, the individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy and will have no part in determining the viability of the fetus. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
Prisoners	Schulman does not review studies in which prisoners are the targeted population.

NOTE: Please attach: 1) a description of any additional safeguard(s) used at your site; and/or 2) a description of any additional vulnerable groups from which you plan to recruit and enroll and any additional safeguard(s) used to protect them.

SECTION 12.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research**.**.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. During the past calendar year, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of $5,000 when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?;
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the investigator that have a monetary value of more than $5,000 exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☒ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

SECTION 13.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Health Products and Food Branch Inspectorate (HPFB), or Environmental Protection Agency (EPA) within the last five (5) years?

☐ No

☒ Yes **>>>** Please complete **a.** and **b.**:

a. Please provide the name of the agency (FDA, OHRP, HPFB, EPA), name of each physician/investigator who was audited, and the date(s) of the audit(s):

Agency: EPA Physician/Investigator: site audit Date: 9/18/12

Agency: EPA Physician/Investigator: site audit Date: 12/7/10-12/8/10

b. Schulman must be in receipt of all audit-related correspondence including, but not limited to, the FDA Form 483, the Establishment Inspection Report (EIR), HPFB Inspection Letter and the response, if any, to all of the audits listed, unless previously submitted.

☒ Attached ☐ Previously submitted ☒ Will submit when available

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Single Site Study Submission Form

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

3. Since your last submission to Schulman, or if this is your first submission to Schulman, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, or EPA (US sites) or HPFB (Canadian sites) terminate a study?
- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g., suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Please explain: _____

SECTION 14.0: WebPortal™ 3D Access & Site Document Distribution

1. Sponsor/CRO contacts listed on this form will receive WebPortal™ 3D, access to review status information and IRB documents. Please visit www.sairb.com/requestaccess to add or remove sponsor/CRO WebPortal 3D access later.

2. Site contacts listed on this form will receive IRB documents via SiteAccess™ 1.0 only (paperless document distribution). Please contact Schulman if other document distribution arrangements may be necessary.

SECTION 15.0: Investigator Certification & Signature

On behalf of all the investigators involved in this study, and under penalty of law, I certify that:

1. My signature below indicates that I will fulfill my responsibilities as Principal/Qualified Investigator as defined by the applicable federal, state, provincial and local law, ICH GCP guidelines and any additional responsibilities that may be imposed by Schulman;
2. I will report to Schulman all Unanticipated Problems Involving Risks to Human Subjects or Others ("Unanticipated Problems") and all Unanticipated Adverse Device Effects (UADEs) that occur within ten (10) business days of discovery, and within twenty-four 24 hours of discovery if the Unanticipated Problem or UADE involves a death;
3. If applicable, I will report to Schulman all noncompliance issues that have an adverse effect on the safety or welfare of the study subject(s), and/or on the data collected and/or are related to a breach of confidentiality within ten (10) business days of discovery;
4. I will not make any changes in the research prior to receiving approval of Schulman unless an immediate change is necessary to eliminate an apparent hazard to the subjects and I agree to report to the Board within ten (10) business days any change to research that is necessary for subject safety that was implemented without Board approval;
5. I will report to the sponsor and Schulman any change of the location at which the study is conducted;
6. I will report to the sponsor and Schulman any proposed transfer of subject(s);
7. I, or someone under my supervision, will verbally explain the elements of informed consent to each potential subject or, if applicable, the subject's legally authorized representative before obtaining his/her signature on the informed consent;
8. The selection of subjects for this study will be equitable;
9. I am aware of my investigator responsibilities as set forth on the Schulman website (www.sairb.com);
10. Responses to the conflict of interest questions are accurate and complete and constitute a full disclosure of any conflicting interests and activities of any investigator or clinical research coordinator involved in this research at this site. I have discussed with these individuals the requirements to disclose any potential conflict of interest. I will disclose to Schulman any conflicts of interest that arise during the course of the study;
11. I have reviewed the information regarding safeguards for vulnerable group(s) and, for categories indicated in this form, I agree to the appropriate safeguards;
12. All study personnel have been made aware of the information provided to Schulman in this form;
13. No subject related study activities will occur prior to receiving the approval letter and informed consent document from Schulman;

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Single Site Study Submission Form

14. I will maintain a list of appropriately qualified persons to whom I have delegated significant clinical trial-related duties;

15. I will ensure adequate control of investigational drugs and devices, or products so that they are used only in approved research protocols and under the direction of approved researchers;

16. The protocol, clinical trial agreement or other contract with the sponsor/CRO of this study states: the responsible party who will provide medical care in case of study-related injury and who will pay for the care (e.g., sponsor, site, subject, insurance provider); the sponsor/CRO is required to promptly report to me any findings of study monitors that could affect the safety of participants or influence the conduct of the study, and I will promptly forward this information to Schulman; the sponsor/CRO is required to send routine and urgent data and safety monitoring reports to me, and I will promptly forward this information to Schulman; and the sponsor/CRO is required to report to me any study results uncovered within two (2) years of study closure that could directly affect subject safety, and I will promptly forward this information to Schulman; and

17. I have reviewed all responses provided in this *Single Site Study Submission Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the submission form and agrees this information is true and accurate

Robert J. Testman

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature

11/08/13

Signature Date (mm/dd/yyyy)

Robert J. Testman, P.I.

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

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Megan Boatwright

From: Robert Testman
Sent: Friday, November 08, 2013 10:46 AM
To: Megan Boatwright
Subject: FW: eSubmission System - Document Submission Confirmation

Importance: High

From: Robert Testman
Sent: Friday, November 8, 2013 8:42 AM
To: 'Jeffrey Atlas'
Subject: FW: eSubmission System - Document Submission Confirmation
Importance: High

Hi Jeff,

I had a problem submitting a new study. I attached the site submission document but did not get the other documents attached. Not sure how I was supposed to go back and get more documents. Hitting Browse Files then submitted the study. How do I submit the remaining documents?

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Friday, November 8, 2013 8:39 AM
To: Robert Testman
Subject: eSubmission System - Document Submission Confirmation
Importance: High

Robert,

The following documents have been successfully submitted via Schulman IRB **eSubmission** system:

Submission Type: Initial Submission - New Study (Single-Site)

Document Types Checked:
Site Submission Form
CVs (PI/QI and Sub-Investigators)
Protocol
Informed Consent (Unlocked Word Version)
Additional documents

Additional Document Types Listed: Study Design Rationale
Additional Instructions: For the Florida review board

List of Uploaded Files
(1) submission form.docx (101.8 KB)

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
Phone 559-275-9091
Email: rtestman@gplabs.com

SCHULMAN Associates IRB, Inc.
www.sairb.com

Megan Boatwright

From: Robert Testman
Sent: Friday, November 08, 2013 10:46 AM
To: Megan Boatwright
Subject: FW: eSubmission System - Document Submission Confirmation

---

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, November 8, 2013 8:43 AM
To: Robert Testman
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Robert,

No problem. Feel free to send them as an attachment in your response to this email. I will be sure they get included with the entire study submission.

Thanks.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, November 08, 2013 11:42 AM
To: Jeffrey Atlas
Subject: FW: eSubmission System - Document Submission Confirmation
Importance: High

Hi Jeff,

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Additional Document Types Listed:	Study Design Rationale
Additional Instructions:	For the Florida review board

List of Uploaded Files
(1) submission form.docx (101.8 KB)

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone	559-275-9091
Email:	rtestman@gplabs.com

SCHULMAN Associates IRB, Inc.
www.sairb.com

Megan Boatwright

From: Robert Testman
Sent: Friday, November 08, 2013 10:46 AM
To: Megan Boatwright
Subject: FW: eSubmission System - Document Submission Confirmation
Attachments: AEATF Brush Roller Draft Protocol 04Nov2013.docx; AEATF Brush Roller Scenario Design Document 25Oct2013.doc; 120463 ICF 07Nov2013 Draft.docx; R Testman CITI cert.pdf

---

From: Robert Testman
Sent: Friday, November 8, 2013 8:47 AM
To: 'Jeffrey Atlas'
Subject: RE: eSubmission System - Document Submission Confirmation

OK, thanks. I will send in two emails to keep size reasonable. Attached is the first set of documents.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, November 8, 2013 8:43 AM
To: Robert Testman
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Robert,

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Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
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Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone	559-275-9091
Email:	rtestman@gplabs.com

SCHULMAN Associates IRB, Inc.
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***DRAFT* PROTOCOL**

04 November 2013

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Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

May 2014

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEA09

GPL Study Number

120463

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No: AEA09
GPL Study No: 120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date: May 2014

Proposed Experimental Termination Date: August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
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Reviewing IRB:	Schulman Associates IRB, Inc. 1550 Sawgrass Corporate Parkway Suite 120 Sunrise, FL 33323 Phone: (954) 327-0778 Website: www.sairb.com

2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 400 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 400 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all personal protective equipment (PPE, i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable,

thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as

outlined in section 4 of the scenario design document. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is little incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: (*954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its

risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish.

Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California Department of Pesticide Review (DPR) and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity

profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations, and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data available to EPA from the PHED the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or isopropyl alcohol (IPA) will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own sex. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that

apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low (Bartels, 2013), and the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 400 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 400 ppm and 600 ppm.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study.

A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantitation of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint types. The table below lists the proposed limit of quantitation (LOQ) for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube

Matrix	LOQ
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample
Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue. Subjects will be provided dry cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at ambient room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary the amount of active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for

MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).

Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 8 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 10 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The AiAH will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Applicators to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates. At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24 initially selected are required, randomized subject 25 will be contacted

followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate applicators (or 'workers') for the MEs. This includes the planned 18 surrogate painters needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire about the health of the subject. The investigator will answer any questions. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well

as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate when at the end of the 4 week recruitment time period a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form . If fewer than 24 subjects have been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in

7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and Subject Self-Reporting Demographic Form

- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies to latex paint, soaps or isopropyl alcohol
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential applicators of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study

sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of six will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the

Principal Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink.

The on-site health professional will immediately be contacted for further medical management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an

approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same sex. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer

dosimeter shirt will be tucked into the pants. A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation, and the subject will retain the key during their ME.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections. Ceiling ventilation fans will be turned off while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME.

Following each application cycle, the subject will be provided additional test substance until they have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks. Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same sex. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

   a. The researcher will help subjects take off the painter's hat

and save it for analysis.

b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse with the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

f. The researcher will help subjects take off the long underwear, and save it for analysis.

g. When all samples have been collected, subjects will dress again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat will be removed with the assistance of a researcher (study team member) of the same sex, placed in a pre-labeled glass jar and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing, sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™

filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same sex and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in "gross violation" or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.
5. Prepare field fortification samples.

6. Monitor temperature and humidity, ensure room vent fans are off during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site (e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at $\leq$ -10° C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	TBA
Purity:	TBA
Date Received:	TBA
Expiration Date:	TBA

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS methods will be validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits. The limit of quantification (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the remaining samples. Any sample not bracketed by the standard curve concentrations will be re-diluted and re-analyzed unless it is below the LOQ when at the minimum method dilution.

Each analytical set will include two laboratory fortified matrix samples, a solvent blank and an unfortified matrix control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantitation

Chromatographic quantitation (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);

12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be kept in a separate location and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts (Appendix H), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H).

Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the quality assurance unit (QAU). The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Principal Investigator and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.

9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.
13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with California DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing

to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

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E-mail: rtestman@gplabs.com

B. Quality Assurance Unit

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ASK GLP Consulting
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Clovis, California 93619
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*A.K. Kang will report directly to the GPL Board of Directors, i.e., independent of any involvement of the Study Director or other investigators.

C. Field Coordinators

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D. Analytical Coordinator

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19. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Robert J. Testman, M.B.A. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Megan T. Boatwright, B.S. Date
Field Coordinator (English)
Golden Pacific Laboratories, LLC

Kimon P. Acedo, B.S. Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Anantdeep K. Kang, M.S. Date
Quality Assurance
ASK GLP Consulting

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

Bartels, 2013. Personal Communication. Abstract of Determination of The In-Vitro Dermal Absorption of 1,2-Benzisothiazolin-3-one.

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol.* Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012, Complies with:			
OTC	Yes	LEED®09 CI	Yes
SCAQMD	Yes	LEED®09 NC	Yes
CARB	Yes	LEED®09 CS	Yes
CARB SCM 2007	Yes	LEED®09 H	Yes
MPI #	53	NGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer

Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry

Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent

Flash Point: N/A

Finish: 0-5 units @ 85°

Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic

A86W00151

VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12

Volume Solids: 43 ± 2%

Weight Solids: 61 ± 2%

Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

continued on back

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE. Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
HOTW 03/25/2013 A86W00151 09 47

The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet.

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or, absorbed through skin. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles or face shield) long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

FIRST AID	
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latices, Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Car Care Products Including Car Washes, Car Waxes, And Silicone Emulsions, Home Care Cleaning Products Including Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	**5383-121**
EPA Establishment Number	**5383-NJ-1**

ACTIVE INGREDIENT:	**% Weight**
1,2-Benzisothiazolin-3(2H)-One	**19.18%**
INERT INGREDIENTS	**80.82%**
TOTAL	**100.0%**

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:
[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

®MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

APPLICATION RATE: Mergal® BIT 20 is an effective preservative for most aqueous applications. Mergal® BIT 20 is suggested for use in aqueous or water-containing products and systems, including industrial and institutional products to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% wt/wt of Mergal® BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below.

FOR FOOD-CONTACT PAPER AND PAPERBOARD COATINGS: Follow the FDA clearances cited below. Use of Mergal® BIT 20 must not exceed 0.21 mg/in^2 (0.0326 mg/cm^2) of finished paper and paperboard intended for contact with dry foods and 0.11 mg/in^2 (0.0168 mg/cm^2) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal® BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 -	Components for Adhesives
21 CFR 176.170 –	Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 –	Components of Paper and Paperboard in contact with dry food
21 CFR 176-300 –	Slimicides (in the manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 –	Rubber articles intended for repeated use: follow instructions in paragraph (c)(4)(1X)

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polymer and micellar/polymer waterfloods: Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or paint products; if you have psoriasis, eczema, sores or open cuts on your skin; if you have severe diabetes; if you have a suppressed immune system such as with an organ transplant or active chemotherapy; or if you have heart or breathing problems.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, or the laboratory General Manager, Thomas Moate, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long

johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The research will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates Independent Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of each informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Schulman Associates Independent Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA09: Interior Latex Paint Application with Brush and Roller Scenario

Part I: *Interview questions*			**Q/NQ**
1. Do you have any skin conditions on your hands (psoriasis, eczema, etc.)? ☐Yes ☐No			
2. Do you have difficulty breathing? Moderate or severe asthma or emphysema? ☐Yes ☐No			
3. Do you have Cardiovascular disease? Have you ever had a myocardial infarct, stroke, or congestive heart failure? Do you have uncontrolled high blood pressure? ☐Yes ☐No			
4. Do you have severe diabetes? ☐Yes ☐No			
5. Are you immunologically suppressed? Have you ever had a transplant? Chemotherapy? ☐Yes ☐No			
6. Are you employed by or married to an employee of an AEATF company, GPL, a paint manufacturer or the ACC (interviewer to explain initials of various entities)? ☐Yes ☐No			
Part II: *To be filled out by candidate*			
7. Name		10. Weight: lbs	
8. Address		11. Height: ft in	
		12. Shirt size: ☐ **S** ☐ **M** ☐ **L** ☐ **XL** ☐ **XXL** ☐ **XXXL**	
9. City, ST, Zip		13. Waist: ☐ 24-28 in ☐ 28-32 in ☐ 32-36 in ☐ 36-40 in ☐ 40-44 in ☐ 44-50 in	
14. Telephone(s)			
15. Age in years =	16. DOB:	17. Sex ☐ M ☐ F	
18. Resident in Fresno County? ☐ Yes ☐ No		19. Have you painted with a brush and roller in the past 5 years? ☐Yes ☐No	
		20. Have you worked as a professional painter in the past 10 years? ☐Yes ☐No	
21. Preferred Language: ☐ English ☐ Spanish		22. Reads: ☐ English ☐ Spanish	
23. Are you pregnant? ☐ NA ☐Yes ☐ No		24. Are you nursing a baby? ☐ NA ☐Yes ☐ No	
25. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No			
26. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐No			
27. Are you bothered by rubbing alcohol or soap on your skin more than family or friends? ☐Yes ☐No			
Interviewer ID age verification: ☐Yes ☐No _____ _____ Subject Signature Date			
Language of interview: : ☐ English ☐ Spanish	Interviewer Name:		
Interview date:	Interviewer Signature:		

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
*for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	Cristoballite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	Calcium Carbonate		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	Titanium Dioxide		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.
EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.
SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

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SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

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SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable
CONDITIONS TO AVOID
None known.
INCOMPATIBILITY
None known.
HAZARDOUS DECOMPOSITION PRODUCTS
By fire: Carbon Dioxide, Carbon Monoxide
HAZARDOUS POLYMERIZATION
Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS
Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.
IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD
Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.
Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

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SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

Spanish advertisement here after translation of approved English version

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.

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Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:
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1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA09-BRS-01-PH	Brush and Roller Worker Sample, ME 01, Painter's Hat
AEA09-BRS-01-AR	Brush and Roller Worker Sample, ME 01, Air Sampling Tube
AEA09-BRS-01-RES-01	Brush and Roller Worker Sample, ME 01, RespiCon™ 100 µm
AEA09-BRS-01-RES-02	Brush and Roller Worker Sample, ME 01, RespiCon™ 10 µm
AEA09-BRS-01-RES-03	Brush and Roller Worker Sample, ME 01, RespiCon™ 2.5 µm
AEA09-BRS-01-HW-01	Brush and Roller Worker Sample, ME 01, Hand Wash
AEA09-BRS-01-FW-01	Brush and Roller Worker Sample, ME 01, Face and Neck Wipe
AEA09-BRS-01-ID-UA	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Upper Arm
AEA09-BRS-01-ID-LA	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Lower Arm
AEA09-BRS-01-ID-FT	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Front Torso
AEA09-BRS-01-ID-RT	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Rear Torso
AEA09-BRS-01-ID-UL	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Upper Leg
AEA09-BRS-01-ID-LL	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Lower Leg
AEA09-BRS-01-OD-UA	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Upper Arm
AEA09-BRS-01-OD-LA	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Lower Arm
AEA09-BRS-01-OD-FT	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Front Torso
AEA09-BRS-01-OD-RT	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Rear Torso
AEA09-BRS-01-OD-UL	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Upper Leg
AEA09-BRS-01-OD-LL	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Lower Leg
AEA09-BRS-02-PH	Brush and Roller Worker Sample, ME 02, Painter's Hat
AEA09-BRS-02-AR	Brush and Roller Worker Sample, ME 02, Air Sampling Tube
AEA09-BRS-02-RES-01	Brush and Roller Worker Sample, ME 02, RespiCon™ 100 µm
AEA09-BRS-02-RES-02	Brush and Roller Worker Sample, ME 02, RespiCon™ 10 µm
AEA09-BRS-02-RES-03	Brush and Roller Worker Sample, ME 02, RespiCon™ 2.5 µm
AEA09-BRS-02-HW-01	Brush and Roller Worker Sample, ME 02, Hand Wash
AEA09-BRS-02-FW-01	Brush and Roller Worker Sample, ME 02, Face and Neck Wipe
AEA09-BRS-02-ID-UA	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Upper Arm
AEA09-BRS-02-ID-LA	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Lower Arm
AEA09-BRS-02-ID-FT	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Front Torso
AEA09-BRS-02-ID-RT	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-02-ID-UL	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Upper Leg
AEA09-BRS-02-ID-LL	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Lower Leg
AEA09-BRS-02-OD-UA	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Upper Arm
AEA09-BRS-02-OD-LA	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Lower Arm
AEA09-BRS-02-OD-FT	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Front Torso
AEA09-BRS-02-OD-RT	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Rear Torso
AEA09-BRS-02-OD-UL	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Upper Leg
AEA09-BRS-02-OD-LL	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Lower Leg
AEA09-BRS-03-PH	Brush and Roller Worker Sample, ME 03, Painter's Hat
AEA09-BRS-03-AR	Brush and Roller Worker Sample, ME 03, Air Sampling Tube
AEA09-BRS-03-RES-01	Brush and Roller Worker Sample, ME 03, RespiCon™ 100 µm
AEA09-BRS-03-RES-02	Brush and Roller Worker Sample, ME 03, RespiCon™ 10 µm
AEA09-BRS-03-RES-03	Brush and Roller Worker Sample, ME 03, RespiCon™ 2.5 µm
AEA09-BRS-03-HW-01	Brush and Roller Worker Sample, ME 03, Hand Wash
AEA09-BRS-03-FW-01	Brush and Roller Worker Sample, ME 03, Face and Neck Wipe
AEA09-BRS-03-ID-UA	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Upper Arm
AEA09-BRS-03-ID-LA	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Lower Arm
AEA09-BRS-03-ID-FT	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Front Torso
AEA09-BRS-03-ID-RT	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Rear Torso
AEA09-BRS-03-ID-UL	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Upper Leg
AEA09-BRS-03-ID-LL	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Lower Leg
AEA09-BRS-03-OD-UA	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Upper Arm
AEA09-BRS-03-OD-LA	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Lower Arm
AEA09-BRS-03-OD-FT	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Front Torso
AEA09-BRS-03-OD-RT	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Rear Torso
AEA09-BRS-03-OD-UL	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Upper Leg
AEA09-BRS-03-OD-LL	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-04-PH	Brush and Roller Worker Sample, ME 04, Painter's Hat
AEA09-BRS-04-AR	Brush and Roller Worker Sample, ME 04, Air Sampling Tube
AEA09-BRS-04-RES-01	Brush and Roller Worker Sample, ME 04, RespiCon™ 100 µm
AEA09-BRS-04-RES-02	Brush and Roller Worker Sample, ME 04, RespiCon™ 10 µm
AEA09-BRS-04-RES-03	Brush and Roller Worker Sample, ME 04, RespiCon™ 2.5 µm
AEA09-BRS-04-HW-01	Brush and Roller Worker Sample, ME 04, Hand Wash
AEA09-BRS-04-FW-01	Brush and Roller Worker Sample, ME 04, Face and Neck Wipe
AEA09-BRS-04-ID-UA	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Upper Arm
AEA09-BRS-04-ID-LA	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Lower Arm
AEA09-BRS-04-ID-FT	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Front Torso
AEA09-BRS-04-ID-RT	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Rear Torso
AEA09-BRS-04-ID-UL	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Upper Leg
AEA09-BRS-04-ID-LL	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Lower Leg
AEA09-BRS-04-OD-UA	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Upper Arm
AEA09-BRS-04-OD-LA	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Lower Arm
AEA09-BRS-04-OD-FT	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Front Torso
AEA09-BRS-04-OD-RT	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Rear Torso
AEA09-BRS-04-OD-UL	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Upper Leg
AEA09-BRS-04-OD-LL	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Lower Leg
AEA09-BRS-05-PH	Brush and Roller Worker Sample, ME 05, Painter's Hat
AEA09-BRS-05-AR	Brush and Roller Worker Sample, ME 05, Air Sampling Tube
AEA09-BRS-05-RES-01	Brush and Roller Worker Sample, ME 05, RespiCon™ 100 µm
AEA09-BRS-05-RES-02	Brush and Roller Worker Sample, ME 05, RespiCon™ 10 µm
AEA09-BRS-05-RES-03	Brush and Roller Worker Sample, ME 05, RespiCon™ 2.5 µm
AEA09-BRS-05-HW-01	Brush and Roller Worker Sample, ME 05, Hand Wash
AEA09-BRS-05-FW-01	Brush and Roller Worker Sample, ME 05, Face and Neck Wipe
AEA09-BRS-05-ID-UA	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Upper Arm
AEA09-BRS-05-ID-LA	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Lower Arm
AEA09-BRS-05-ID-FT	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Front Torso
AEA09-BRS-05-ID-RT	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-05-ID-UL	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Upper Leg
AEA09-BRS-05-ID-LL	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Lower Leg
AEA09-BRS-05-OD-UA	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Upper Arm
AEA09-BRS-05-OD-LA	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Lower Arm
AEA09-BRS-05-OD-FT	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Front Torso
AEA09-BRS-05-OD-RT	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Rear Torso
AEA09-BRS-05-OD-UL	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Upper Leg
AEA09-BRS-05-OD-LL	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Lower Leg
AEA09-BRS-06-PH	Brush and Roller Worker Sample, ME 06, Painter's Hat
AEA09-BRS-06-AR	Brush and Roller Worker Sample, ME 06, Air Sampling Tube
AEA09-BRS-06-RES-01	Brush and Roller Worker Sample, ME 06, RespiCon™ 100 µm
AEA09-BRS-06-RES-02	Brush and Roller Worker Sample, ME 06, RespiCon™ 10 µm
AEA09-BRS-06-RES-03	Brush and Roller Worker Sample, ME 06, RespiCon™ 2.5 µm
AEA09-BRS-06-HW-01	Brush and Roller Worker Sample, ME 06, Hand Wash
AEA09-BRS-06-FW-01	Brush and Roller Worker Sample, ME 06, Face and Neck Wipe
AEA09-BRS-06-ID-UA	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Upper Arm
AEA09-BRS-06-ID-LA	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Lower Arm
AEA09-BRS-06-ID-FT	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Front Torso
AEA09-BRS-06-ID-RT	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Rear Torso
AEA09-BRS-06-ID-UL	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Upper Leg
AEA09-BRS-06-ID-LL	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Lower Leg
AEA09-BRS-06-OD-UA	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Upper Arm
AEA09-BRS-06-OD-LA	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Lower Arm
AEA09-BRS-06-OD-FT	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Front Torso
AEA09-BRS-06-OD-RT	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Rear Torso
AEA09-BRS-06-OD-UL	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Upper Leg
AEA09-BRS-06-OD-LL	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-07-PH	Brush and Roller Worker Sample, ME 07, Painter's Hat
AEA09-BRS-07-AR	Brush and Roller Worker Sample, ME 07, Air Sampling Tube
AEA09-BRS-07-RES-01	Brush and Roller Worker Sample, ME 07, RespiCon™ 100 µm
AEA09-BRS-07-RES-02	Brush and Roller Worker Sample, ME 07, RespiCon™ 10 µm
AEA09-BRS-07-RES-03	Brush and Roller Worker Sample, ME 07, RespiCon™ 2.5 µm
AEA09-BRS-07-HW-01	Brush and Roller Worker Sample, ME 07, Hand Wash
AEA09-BRS-07-FW-01	Brush and Roller Worker Sample, ME 07, Face and Neck Wipe
AEA09-BRS-07-ID-UA	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Upper Arm
AEA09-BRS-07-ID-LA	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Lower Arm
AEA09-BRS-07-ID-FT	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Front Torso
AEA09-BRS-07-ID-RT	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Rear Torso
AEA09-BRS-07-ID-UL	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Upper Leg
AEA09-BRS-07-ID-LL	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Lower Leg
AEA09-BRS-07-OD-UA	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Upper Arm
AEA09-BRS-07-OD-LA	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Lower Arm
AEA09-BRS-07-OD-FT	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Front Torso
AEA09-BRS-07-OD-RT	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Rear Torso
AEA09-BRS-07-OD-UL	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Upper Leg
AEA09-BRS-07-OD-LL	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Lower Leg
AEA09-BRS-08-PH	Brush and Roller Worker Sample, ME 08, Painter's Hat
AEA09-BRS-08-AR	Brush and Roller Worker Sample, ME 08, Air Sampling Tube
AEA09-BRS-08-RES-01	Brush and Roller Worker Sample, ME 08, RespiCon™ 100 µm
AEA09-BRS-08-RES-02	Brush and Roller Worker Sample, ME 08, RespiCon™ 10 µm
AEA09-BRS-08-RES-03	Brush and Roller Worker Sample, ME 08, RespiCon™ 2.5 µm
AEA09-BRS-08-HW-01	Brush and Roller Worker Sample, ME 08, Hand Wash
AEA09-BRS-08-FW-01	Brush and Roller Worker Sample, ME 08, Face and Neck Wipe
AEA09-BRS-08-ID-UA	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Upper Arm
AEA09-BRS-08-ID-LA	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Lower Arm
AEA09-BRS-08-ID-FT	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Front Torso
AEA09-BRS-08-ID-RT	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-08-ID-UL	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Upper Leg
AEA09-BRS-08-ID-LL	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Lower Leg
AEA09-BRS-08-OD-UA	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Upper Arm
AEA09-BRS-08-OD-LA	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Lower Arm
AEA09-BRS-08-OD-FT	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Front Torso
AEA09-BRS-08-OD-RT	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Rear Torso
AEA09-BRS-08-OD-UL	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Upper Leg
AEA09-BRS-08-OD-LL	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Lower Leg
AEA09-BRS-09-PH	Brush and Roller Worker Sample, ME 09, Painter's Hat
AEA09-BRS-09-AR	Brush and Roller Worker Sample, ME 09, Air Sampling Tube
AEA09-BRS-09-RES-01	Brush and Roller Worker Sample, ME 09, RespiCon™ 100 µm
AEA09-BRS-09-RES-02	Brush and Roller Worker Sample, ME 09, RespiCon™ 10 µm
AEA09-BRS-09-RES-03	Brush and Roller Worker Sample, ME 09, RespiCon™ 2.5 µm
AEA09-BRS-09-HW-01	Brush and Roller Worker Sample, ME 09, Hand Wash
AEA09-BRS-09-FW-01	Brush and Roller Worker Sample, ME 09, Face and Neck Wipe
AEA09-BRS-09-ID-UA	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Upper Arm
AEA09-BRS-09-ID-LA	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Lower Arm
AEA09-BRS-09-ID-FT	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Front Torso
AEA09-BRS-09-ID-RT	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Rear Torso
AEA09-BRS-09-ID-UL	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Upper Leg
AEA09-BRS-09-ID-LL	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Lower Leg
AEA09-BRS-09-OD-UA	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Upper Arm
AEA09-BRS-09-OD-LA	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Lower Arm
AEA09-BRS-09-OD-FT	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Front Torso
AEA09-BRS-09-OD-RT	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Rear Torso
AEA09-BRS-09-OD-UL	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Upper Leg
AEA09-BRS-09-OD-LL	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-10-PH	Brush and Roller Worker Sample, ME 10, Painter's Hat
AEA09-BRS-10-AR	Brush and Roller Worker Sample, ME 10, Air Sampling Tube
AEA09-BRS-10-RES-01	Brush and Roller Worker Sample, ME 10, RespiCon™ 100 µm
AEA09-BRS-10-RES-02	Brush and Roller Worker Sample, ME 10, RespiCon™ 10 µm
AEA09-BRS-10-RES-03	Brush and Roller Worker Sample, ME 10, RespiCon™ 2.5 µm
AEA09-BRS-10-HW-01	Brush and Roller Worker Sample, ME 10, Hand Wash
AEA09-BRS-10-FW-01	Brush and Roller Worker Sample, ME 10, Face and Neck Wipe
AEA09-BRS-10-ID-UA	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Upper Arm
AEA09-BRS-10-ID-LA	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Lower Arm
AEA09-BRS-10-ID-FT	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Front Torso
AEA09-BRS-10-ID-RT	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Rear Torso
AEA09-BRS-10-ID-UL	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Upper Leg
AEA09-BRS-10-ID-LL	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Lower Leg
AEA09-BRS-10-OD-UA	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Upper Arm
AEA09-BRS-10-OD-LA	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Lower Arm
AEA09-BRS-10-OD-FT	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Front Torso
AEA09-BRS-10-OD-RT	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Rear Torso
AEA09-BRS-10-OD-UL	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Upper Leg
AEA09-BRS-10-OD-LL	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Lower Leg
AEA09-BRS-11-PH	Brush and Roller Worker Sample, ME 11, Painter's Hat
AEA09-BRS-11-AR	Brush and Roller Worker Sample, ME 11, Air Sampling Tube
AEA09-BRS-11-RES-01	Brush and Roller Worker Sample, ME 11, RespiCon™ 100 µm
AEA09-BRS-11-RES-02	Brush and Roller Worker Sample, ME 11, RespiCon™ 10 µm
AEA09-BRS-11-RES-03	Brush and Roller Worker Sample, ME 11, RespiCon™ 2.5 µm
AEA09-BRS-11-HW-01	Brush and Roller Worker Sample, ME 11, Hand Wash
AEA09-BRS-11-FW-01	Brush and Roller Worker Sample, ME 11, Face and Neck Wipe
AEA09-BRS-11-ID-UA	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Upper Arm
AEA09-BRS-11-ID-LA	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Lower Arm
AEA09-BRS-11-ID-FT	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Front Torso
AEA09-BRS-11-ID-RT	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-11-ID-UL	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Upper Leg
AEA09-BRS-11-ID-LL	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Lower Leg
AEA09-BRS-11-OD-UA	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Upper Arm
AEA09-BRS-11-OD-LA	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Lower Arm
AEA09-BRS-11-OD-FT	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Front Torso
AEA09-BRS-11-OD-RT	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Rear Torso
AEA09-BRS-11-OD-UL	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Upper Leg
AEA09-BRS-11-OD-LL	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Lower Leg
AEA09-BRS-12-PH	Brush and Roller Worker Sample, ME 12, Painter's Hat
AEA09-BRS-12-AR	Brush and Roller Worker Sample, ME 12, Air Sampling Tube
AEA09-BRS-12-RES-01	Brush and Roller Worker Sample, ME 12, RespiCon™ 100 µm
AEA09-BRS-12-RES-02	Brush and Roller Worker Sample, ME 12, RespiCon™ 10 µm
AEA09-BRS-12-RES-03	Brush and Roller Worker Sample, ME 12, RespiCon™ 2.5 µm
AEA09-BRS-12-HW-01	Brush and Roller Worker Sample, ME 12, Hand Wash
AEA09-BRS-12-FW-01	Brush and Roller Worker Sample, ME 12, Face and Neck Wipe
AEA09-BRS-12-ID-UA	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Upper Arm
AEA09-BRS-12-ID-LA	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Lower Arm
AEA09-BRS-12-ID-FT	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Front Torso
AEA09-BRS-12-ID-RT	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Rear Torso
AEA09-BRS-12-ID-UL	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Upper Leg
AEA09-BRS-12-ID-LL	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Lower Leg
AEA09-BRS-12-OD-UA	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Upper Arm
AEA09-BRS-12-OD-LA	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Lower Arm
AEA09-BRS-12-OD-FT	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Front Torso
AEA09-BRS-12-OD-RT	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Rear Torso
AEA09-BRS-12-OD-UL	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Upper Leg
AEA09-BRS-12-OD-LL	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-13-PH	Brush and Roller Worker Sample, ME 13, Painter's Hat
AEA09-BRS-13-AR	Brush and Roller Worker Sample, ME 13, Air Sampling Tube
AEA09-BRS-13-RES-01	Brush and Roller Worker Sample, ME 13, RespiCon™ 100 µm
AEA09-BRS-13-RES-02	Brush and Roller Worker Sample, ME 13, RespiCon™ 10 µm
AEA09-BRS-13-RES-03	Brush and Roller Worker Sample, ME 13, RespiCon™ 2.5 µm
AEA09-BRS-13-HW-01	Brush and Roller Worker Sample, ME 13, Hand Wash
AEA09-BRS-13-FW-01	Brush and Roller Worker Sample, ME 13, Face and Neck Wipe
AEA09-BRS-13-ID-UA	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Upper Arm
AEA09-BRS-13-ID-LA	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Lower Arm
AEA09-BRS-13-ID-FT	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Front Torso
AEA09-BRS-13-ID-RT	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Rear Torso
AEA09-BRS-13-ID-UL	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Upper Leg
AEA09-BRS-13-ID-LL	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Lower Leg
AEA09-BRS-13-OD-UA	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Upper Arm
AEA09-BRS-13-OD-LA	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Lower Arm
AEA09-BRS-13-OD-FT	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Front Torso
AEA09-BRS-13-OD-RT	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Rear Torso
AEA09-BRS-13-OD-UL	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Upper Leg
AEA09-BRS-13-OD-LL	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Lower Leg
AEA09-BRS-14-PH	Brush and Roller Worker Sample, ME 14, Painter's Hat
AEA09-BRS-14-AR	Brush and Roller Worker Sample, ME 14, Air Sampling Tube
AEA09-BRS-14-RES-01	Brush and Roller Worker Sample, ME 14, RespiCon™ 100 µm
AEA09-BRS-14-RES-02	Brush and Roller Worker Sample, ME 14, RespiCon™ 10 µm
AEA09-BRS-14-RES-03	Brush and Roller Worker Sample, ME 14, RespiCon™ 2.5 µm
AEA09-BRS-14-HW-01	Brush and Roller Worker Sample, ME 14, Hand Wash
AEA09-BRS-14-FW-01	Brush and Roller Worker Sample, ME 14, Face and Neck Wipe
AEA09-BRS-14-ID-UA	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Upper Arm
AEA09-BRS-14-ID-LA	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Lower Arm
AEA09-BRS-14-ID-FT	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Front Torso
AEA09-BRS-14-ID-RT	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-14-ID-UL	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Upper Leg
AEA09-BRS-14-ID-LL	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Lower Leg
AEA09-BRS-14-OD-UA	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Upper Arm
AEA09-BRS-14-OD-LA	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Lower Arm
AEA09-BRS-14-OD-FT	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Front Torso
AEA09-BRS-14-OD-RT	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Rear Torso
AEA09-BRS-14-OD-UL	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Upper Leg
AEA09-BRS-14-OD-LL	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Lower Leg
AEA09-BRS-15-PH	Brush and Roller Worker Sample, ME 15, Painter's Hat
AEA09-BRS-15-AR	Brush and Roller Worker Sample, ME 15, Air Sampling Tube
AEA09-BRS-15-RES-01	Brush and Roller Worker Sample, ME 15, RespiCon™ 100 µm
AEA09-BRS-15-RES-02	Brush and Roller Worker Sample, ME 15, RespiCon™ 10 µm
AEA09-BRS-15-RES-03	Brush and Roller Worker Sample, ME 15, RespiCon™ 2.5 µm
AEA09-BRS-15-HW-01	Brush and Roller Worker Sample, ME 15, Hand Wash
AEA09-BRS-15-FW-01	Brush and Roller Worker Sample, ME 15, Face and Neck Wipe
AEA09-BRS-15-ID-UA	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Upper Arm
AEA09-BRS-15-ID-LA	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Lower Arm
AEA09-BRS-15-ID-FT	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Front Torso
AEA09-BRS-15-ID-RT	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Rear Torso
AEA09-BRS-15-ID-UL	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Upper Leg
AEA09-BRS-15-ID-LL	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Lower Leg
AEA09-BRS-15-OD-UA	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Upper Arm
AEA09-BRS-15-OD-LA	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Lower Arm
AEA09-BRS-15-OD-FT	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Front Torso
AEA09-BRS-15-OD-RT	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Rear Torso
AEA09-BRS-15-OD-UL	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Upper Leg
AEA09-BRS-15-OD-LL	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-16-PH	Brush and Roller Worker Sample, ME 16, Painter's Hat
AEA09-BRS-16-AR	Brush and Roller Worker Sample, ME 16, Air Sampling Tube
AEA09-BRS-16-RES-01	Brush and Roller Worker Sample, ME 16, RespiCon™ 100 µm
AEA09-BRS-16-RES-02	Brush and Roller Worker Sample, ME 16, RespiCon™ 10 µm
AEA09-BRS-16-RES-03	Brush and Roller Worker Sample, ME 16, RespiCon™ 2.5 µm
AEA09-BRS-16-HW-01	Brush and Roller Worker Sample, ME 16, Hand Wash
AEA09-BRS-16-FW-01	Brush and Roller Worker Sample, ME 16, Face and Neck Wipe
AEA09-BRS-16-ID-UA	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Upper Arm
AEA09-BRS-16-ID-LA	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Lower Arm
AEA09-BRS-16-ID-FT	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Front Torso
AEA09-BRS-16-ID-RT	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Rear Torso
AEA09-BRS-16-ID-UL	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Upper Leg
AEA09-BRS-16-ID-LL	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Lower Leg
AEA09-BRS-16-OD-UA	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Upper Arm
AEA09-BRS-16-OD-LA	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Lower Arm
AEA09-BRS-16-OD-FT	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Front Torso
AEA09-BRS-16-OD-RT	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Rear Torso
AEA09-BRS-16-OD-UL	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Upper Leg
AEA09-BRS-16-OD-LL	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Lower Leg
AEA09-BRS-17-PH	Brush and Roller Worker Sample, ME 17, Painter's Hat
AEA09-BRS-17-AR	Brush and Roller Worker Sample, ME 17, Air Sampling Tube
AEA09-BRS-17-RES-01	Brush and Roller Worker Sample, ME 17, RespiCon™ 100 µm
AEA09-BRS-17-RES-02	Brush and Roller Worker Sample, ME 17, RespiCon™ 10 µm
AEA09-BRS-17-RES-03	Brush and Roller Worker Sample, ME 17, RespiCon™ 2.5 µm
AEA09-BRS-17-HW-01	Brush and Roller Worker Sample, ME 17, Hand Wash
AEA09-BRS-17-FW-01	Brush and Roller Worker Sample, ME 17, Face and Neck Wipe
AEA09-BRS-17-ID-UA	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Upper Arm
AEA09-BRS-17-ID-LA	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Lower Arm
AEA09-BRS-17-ID-FT	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Front Torso
AEA09-BRS-17-ID-RT	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-17-ID-UL	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Upper Leg
AEA09-BRS-17-ID-LL	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Lower Leg
AEA09-BRS-17-OD-UA	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Upper Arm
AEA09-BRS-17-OD-LA	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Lower Arm
AEA09-BRS-17-OD-FT	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Front Torso
AEA09-BRS-17-OD-RT	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Rear Torso
AEA09-BRS-17-OD-UL	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Upper Leg
AEA09-BRS-17-OD-LL	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Lower Leg
AEA09-BRS-18-PH	Brush and Roller Worker Sample, ME 18, Painter's Hat
AEA09-BRS-18-AR	Brush and Roller Worker Sample, ME 18, Air Sampling Tube
AEA09-BRS-18-RES-01	Brush and Roller Worker Sample, ME 18, RespiCon™ 100 µm
AEA09-BRS-18-RES-02	Brush and Roller Worker Sample, ME 18, RespiCon™ 10 µm
AEA09-BRS-18-RES-03	Brush and Roller Worker Sample, ME 18, RespiCon™ 2.5 µm
AEA09-BRS-18-HW-01	Brush and Roller Worker Sample, ME 18, Hand Wash
AEA09-BRS-18-FW-01	Brush and Roller Worker Sample, ME 18, Face and Neck Wipe
AEA09-BRS-18-ID-UA	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Upper Arm
AEA09-BRS-18-ID-LA	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Lower Arm
AEA09-BRS-18-ID-FT	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Front Torso
AEA09-BRS-18-ID-RT	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Rear Torso
AEA09-BRS-18-ID-UL	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Upper Leg
AEA09-BRS-18-ID-LL	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Lower Leg
AEA09-BRS-18-OD-UA	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Upper Arm
AEA09-BRS-18-OD-LA	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Lower Arm
AEA09-BRS-18-OD-FT	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Front Torso
AEA09-BRS-18-OD-RT	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Rear Torso
AEA09-BRS-18-OD-UL	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Upper Leg
AEA09-BRS-18-OD-LL	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-FF-01-PH-C1	Fortification Sample, ME 01, Painter's Hat, 1st Control
AEA09-FF-01-PH-C2	Fortification Sample, ME 01, Painter's Hat, 2nd Control
AEA09-FF-01-PH-L1	Fortification Sample, ME 01, Painter's Hat, 1st Low Level
AEA09-FF-01-PH-L2	Fortification Sample, ME 01, Painter's Hat, 2nd Low Level
AEA09-FF-01-PH-L3	Fortification Sample, ME 01, Painter's Hat, 3rd Low Level
AEA09-FF-01-PH-H1	Fortification Sample, ME 01, Painter's Hat, 1st High Level
AEA09-FF-01-PH-H2	Fortification Sample, ME 01, Painter's Hat, 2nd High Level
AEA09-FF-01-PH-H3	Fortification Sample, ME 01, Painter's Hat, 3rd High Level
AEA09-FF-01-AR-C1	Fortification Sample, ME 01, Air Sampling Tube, 1st Control
AEA09-FF-01-AR-C2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Control
AEA09-FF-01-AR-L1	Fortification Sample, ME 01, Air Sampling Tube, 1st Low Level
AEA09-FF-01-AR-L2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Low Level
AEA09-FF-01-AR-L3	Fortification Sample, ME 01, Air Sampling Tube, 3rd Low Level
AEA09-FF-01-AR-H1	Fortification Sample, ME 01, Air Sampling Tube, 1st High Level
AEA09-FF-01-AR-H2	Fortification Sample, ME 01, Air Sampling Tube, 2nd High Level
AEA09-FF-01-AR-H3	Fortification Sample, ME 01, Air Sampling Tube, 3rd High Level
AEA09-FF-01-RES-C1	Fortification Sample, ME 01, RespiCon, 1st Control
AEA09-FF-01-RES-C2	Fortification Sample, ME 01, RespiCon, 2nd Control
AEA09-FF-01-RES-L1	Fortification Sample, ME 01, RespiCon, 1st Low Level
AEA09-FF-01-RES-L2	Fortification Sample, ME 01, RespiCon, 2nd Low Level
AEA09-FF-01-RES-L3	Fortification Sample, ME 01, RespiCon, 3rd Low Level
AEA09-FF-01-RES-H1	Fortification Sample, ME 01, RespiCon, 1st High Level
AEA09-FF-01-RES-H2	Fortification Sample, ME 01, RespiCon, 2nd High Level
AEA09-FF-01-RES-H3	Fortification Sample, ME 01, RespiCon, 3rd High Level
AEA09-FF-01-HW-C1	Fortification Sample, ME 01, Hand Wash, 1st Control
AEA09-FF-01-HW-C2	Fortification Sample, ME 01, Hand Wash, 2nd Control
AEA09-FF-01-HW-L1	Fortification Sample, ME 01, Hand Wash, 1st Low Level
AEA09-FF-01-HW-L2	Fortification Sample, ME 01, Hand Wash, 2nd Low Level
AEA09-FF-01-HW-L3	Fortification Sample, ME 01, Hand Wash, 3rd Low Level
AEA09-FF-01-HW-H1	Fortification Sample, ME 01, Hand Wash, 1st High Level
AEA09-FF-01-HW-H2	Fortification Sample, ME 01, Hand Wash, 2nd High Level
AEA09-FF-01-HW-H3	Fortification Sample, ME 01, Hand Wash, 3rd High Level
AEA09-FF-01-FW-C1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Control
AEA09-FF-01-FW-C2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Control
AEA09-FF-01-FW-L1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Low Level
AEA09-FF-01-FW-L2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Low Level
AEA09-FF-01-FW-L3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd Low Level
AEA09-FF-01-FW-H1	Fortification Sample, ME 01, Face and Neck Wipe, 1st High Level
AEA09-FF-01-FW-H2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd High Level
AEA09-FF-01-FW-H3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd High Level

Sample ID Number	Description
AEA09-FF-01-ID-C1	Fortification Sample, ME 01, Inner Dosimeter, 1st Control
AEA09-FF-01-ID-C2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Control
AEA09-FF-01-ID-L1	Fortification Sample, ME 01, Inner Dosimeter, 1st Low Level
AEA09-FF-01-ID-L2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Low Level
AEA09-FF-01-ID-L3	Fortification Sample, ME 01, Inner Dosimeter, 3rd Low Level
AEA09-FF-01-ID-H1	Fortification Sample, ME 01, Inner Dosimeter, 1st High Level
AEA09-FF-01-ID-H2	Fortification Sample, ME 01, Inner Dosimeter, 2nd High Level
AEA09-FF-01-ID-H3	Fortification Sample, ME 01, Inner Dosimeter, 3rd High Level
AEA09-FF-01-OD-C1	Fortification Sample, ME 01, Outer Dosimeter, 1st Control
AEA09-FF-01-OD-C2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Control
AEA09-FF-01-OD-L1	Fortification Sample, ME 01, Outer Dosimeter, 1st Low Level
AEA09-FF-01-OD-L2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Low Level
AEA09-FF-01-OD-L3	Fortification Sample, ME 01, Outer Dosimeter, 3rd Low Level
AEA09-FF-01-OD-H1	Fortification Sample, ME 01, Outer Dosimeter, 1st High Level
AEA09-FF-01-OD-H2	Fortification Sample, ME 01, Outer Dosimeter, 2nd High Level
AEA09-FF-01-OD-H3	Fortification Sample, ME 01, Outer Dosimeter, 3rd High Level
AEA09-FF-02-PH-C1	Fortification Sample, ME 02, Painter's Hat, 1st Control
AEA09-FF-02-PH-C2	Fortification Sample, ME 02, Painter's Hat, 2nd Control
AEA09-FF-02-PH-L1	Fortification Sample, ME 02, Painter's Hat, 1st Low Level
AEA09-FF-02-PH-L2	Fortification Sample, ME 02, Painter's Hat, 2nd Low Level
AEA09-FF-02-PH-L3	Fortification Sample, ME 02, Painter's Hat, 3rd Low Level
AEA09-FF-02-PH-H1	Fortification Sample, ME 02, Painter's Hat, 1st High Level
AEA09-FF-02-PH-H2	Fortification Sample, ME 02, Painter's Hat, 2nd High Level
AEA09-FF-02-PH-H3	Fortification Sample, ME 02, Painter's Hat, 3rd High Level
AEA09-FF-02-AR-C1	Fortification Sample, ME 02, Air Sampling Tube, 1st Control
AEA09-FF-02-AR-C2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Control
AEA09-FF-02-AR-L1	Fortification Sample, ME 02, Air Sampling Tube, 1st Low Level
AEA09-FF-02-AR-L2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Low Level
AEA09-FF-02-AR-L3	Fortification Sample, ME 02, Air Sampling Tube, 3rd Low Level
AEA09-FF-02-AR-H1	Fortification Sample, ME 02, Air Sampling Tube, 1st High Level
AEA09-FF-02-AR-H2	Fortification Sample, ME 02, Air Sampling Tube, 2nd High Level
AEA09-FF-02-AR-H3	Fortification Sample, ME 02, Air Sampling Tube, 3rd High Level
AEA09-FF-02-RES-C1	Fortification Sample, ME 02, RespiCon, 1st Control
AEA09-FF-02-RES-C2	Fortification Sample, ME 02, RespiCon, 2nd Control
AEA09-FF-02-RES-L1	Fortification Sample, ME 02, RespiCon, 1st Low Level
AEA09-FF-02-RES-L2	Fortification Sample, ME 02, RespiCon, 2nd Low Level
AEA09-FF-02-RES-L3	Fortification Sample, ME 02, RespiCon, 3rd Low Level
AEA09-FF-02-RES-H1	Fortification Sample, ME 02, RespiCon, 1st High Level
AEA09-FF-02-RES-H2	Fortification Sample, ME 02, RespiCon, 2nd High Level
AEA09-FF-02-RES-H3	Fortification Sample, ME 02, RespiCon, 3rd High Level
AEA09-FF-02-HW-C1	Fortification Sample, ME 02, Hand Wash, 1st Control
AEA09-FF-02-HW-C2	Fortification Sample, ME 02, Hand Wash, 2nd Control
AEA09-FF-02-HW-L1	Fortification Sample, ME 02, Hand Wash, 1st Low Level
AEA09-FF-02-HW-L2	Fortification Sample, ME 02, Hand Wash, 2nd Low Level
AEA09-FF-02-HW-L3	Fortification Sample, ME 02, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-02-HW-H1	Fortification Sample, ME 02, Hand Wash, 1st High Level
AEA09-FF-02-HW-H2	Fortification Sample, ME 02, Hand Wash, 2nd High Level
AEA09-FF-02-HW-H3	Fortification Sample, ME 02, Hand Wash, 3rd High Level
AEA09-FF-02-FW-C1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Control
AEA09-FF-02-FW-C2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Control
AEA09-FF-02-FW-L1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Low Level
AEA09-FF-02-FW-L2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Low Level
AEA09-FF-02-FW-L3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd Low Level
AEA09-FF-02-FW-H1	Fortification Sample, ME 02, Face and Neck Wipe, 1st High Level
AEA09-FF-02-FW-H2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd High Level
AEA09-FF-02-FW-H3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd High Level
AEA09-FF-02-ID-C1	Fortification Sample, ME 02, Inner Dosimeter, 1st Control
AEA09-FF-02-ID-C2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Control
AEA09-FF-02-ID-L1	Fortification Sample, ME 02, Inner Dosimeter, 1st Low Level
AEA09-FF-02-ID-L2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Low Level
AEA09-FF-02-ID-L3	Fortification Sample, ME 02, Inner Dosimeter, 3rd Low Level
AEA09-FF-02-ID-H1	Fortification Sample, ME 02, Inner Dosimeter, 1st High Level
AEA09-FF-02-ID-H2	Fortification Sample, ME 02, Inner Dosimeter, 2nd High Level
AEA09-FF-02-ID-H3	Fortification Sample, ME 02, Inner Dosimeter, 3rd High Level
AEA09-FF-02-OD-C1	Fortification Sample, ME 02, Outer Dosimeter, 1st Control
AEA09-FF-02-OD-C2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Control
AEA09-FF-02-OD-L1	Fortification Sample, ME 02, Outer Dosimeter, 1st Low Level
AEA09-FF-02-OD-L2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Low Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-02-OD-H1	Fortification Sample, ME 02, Outer Dosimeter, 1st High Level
AEA09-FF-02-OD-H2	Fortification Sample, ME 02, Outer Dosimeter, 2nd High Level
AEA09-FF-02-OD-H3	Fortification Sample, ME 02, Outer Dosimeter, 3rd High Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-03-PH-C1	Fortification Sample, ME 03, Painter's Hat, 1st Control
AEA09-FF-03-PH-C2	Fortification Sample, ME 03, Painter's Hat, 2nd Control
AEA09-FF-03-PH-L1	Fortification Sample, ME 03, Painter's Hat, 1st Low Level
AEA09-FF-03-PH-L2	Fortification Sample, ME 03, Painter's Hat, 2nd Low Level
AEA09-FF-03-PH-L3	Fortification Sample, ME 03, Painter's Hat, 3rd Low Level
AEA09-FF-03-PH-H1	Fortification Sample, ME 03, Painter's Hat, 1st High Level
AEA09-FF-03-PH-H2	Fortification Sample, ME 03, Painter's Hat, 2nd High Level
AEA09-FF-03-PH-H3	Fortification Sample, ME 03, Painter's Hat, 3rd High Level
AEA09-FF-03-AR-C1	Fortification Sample, ME 03, Air Sampling Tube, 1st Control
AEA09-FF-03-AR-C2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Control
AEA09-FF-03-AR-L1	Fortification Sample, ME 03, Air Sampling Tube, 1st Low Level
AEA09-FF-03-AR-L2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Low Level
AEA09-FF-03-AR-L3	Fortification Sample, ME 03, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-AR-H1	Fortification Sample, ME 03, Air Sampling Tube, 1st High Level
AEA09-FF-03-AR-H2	Fortification Sample, ME 03, Air Sampling Tube, 2nd High Level
AEA09-FF-03-AR-H3	Fortification Sample, ME 03, Air Sampling Tube, 3rd High Level
AEA09-FF-03-RES-C1	Fortification Sample, ME 03, RespiCon, 1st Control
AEA09-FF-03-RES-C2	Fortification Sample, ME 03, RespiCon, 2nd Control
AEA09-FF-03-RES-L1	Fortification Sample, ME 03, RespiCon, 1st Low Level
AEA09-FF-03-RES-L2	Fortification Sample, ME 03, RespiCon, 2nd Low Level
AEA09-FF-03-RES-L3	Fortification Sample, ME 03, RespiCon, 3rd Low Level
AEA09-FF-03-RES-H1	Fortification Sample, ME 03, RespiCon, 1st High Level
AEA09-FF-03-RES-H2	Fortification Sample, ME 03, RespiCon, 2nd High Level
AEA09-FF-03-RES-H3	Fortification Sample, ME 03, RespiCon, 3rd High Level
AEA09-FF-03-HW-C1	Fortification Sample, ME 03, Hand Wash, 1st Control
AEA09-FF-03-HW-C2	Fortification Sample, ME 03, Hand Wash, 2nd Control
AEA09-FF-03-HW-L1	Fortification Sample, ME 03, Hand Wash, 1st Low Level
AEA09-FF-03-HW-L2	Fortification Sample, ME 03, Hand Wash, 2nd Low Level
AEA09-FF-03-HW-L3	Fortification Sample, ME 03, Hand Wash, 3rd Low Level
AEA09-FF-03-HW-H1	Fortification Sample, ME 03, Hand Wash, 1st High Level
AEA09-FF-03-HW-H2	Fortification Sample, ME 03, Hand Wash, 2nd High Level
AEA09-FF-03-HW-H3	Fortification Sample, ME 03, Hand Wash, 3rd High Level
AEA09-FF-03-FW-C1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Control
AEA09-FF-03-FW-C2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Control
AEA09-FF-03-FW-L1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Low Level
AEA09-FF-03-FW-L2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Low Level
AEA09-FF-03-FW-L3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd Low Level
AEA09-FF-03-FW-H1	Fortification Sample, ME 03, Face and Neck Wipe, 1st High Level
AEA09-FF-03-FW-H2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd High Level
AEA09-FF-03-FW-H3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd High Level
AEA09-FF-03-ID-C1	Fortification Sample, ME 03, Inner Dosimeter, 1st Control
AEA09-FF-03-ID-C2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Control
AEA09-FF-03-ID-L1	Fortification Sample, ME 03, Inner Dosimeter, 1st Low Level
AEA09-FF-03-ID-L2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Low Level
AEA09-FF-03-ID-L3	Fortification Sample, ME 03, Inner Dosimeter, 3rd Low Level
AEA09-FF-03-ID-H1	Fortification Sample, ME 03, Inner Dosimeter, 1st High Level
AEA09-FF-03-ID-H2	Fortification Sample, ME 03, Inner Dosimeter, 2nd High Level
AEA09-FF-03-ID-H3	Fortification Sample, ME 03, Inner Dosimeter, 3rd High Level
AEA09-FF-03-OD-C1	Fortification Sample, ME 03, Outer Dosimeter, 1st Control
AEA09-FF-03-OD-C2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Control
AEA09-FF-03-OD-L1	Fortification Sample, ME 03, Outer Dosimeter, 1st Low Level
AEA09-FF-03-OD-L2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Low Level
AEA09-FF-03-OD-L3	Fortification Sample, ME 03, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-OD-H1	Fortification Sample, ME 03, Outer Dosimeter, 1st High Level
AEA09-FF-03-OD-H2	Fortification Sample, ME 03, Outer Dosimeter, 2nd High Level
AEA09-FF-03-OD-H3	Fortification Sample, ME 03, Outer Dosimeter, 3rd High Level
AEA09-FF-04-PH-C1	Fortification Sample, ME 04, Painter's Hat, 1st Control
AEA09-FF-04-PH-C2	Fortification Sample, ME 04, Painter's Hat, 2nd Control
AEA09-FF-04-PH-L1	Fortification Sample, ME 04, Painter's Hat, 1st Low Level
AEA09-FF-04-PH-L2	Fortification Sample, ME 04, Painter's Hat, 2nd Low Level
AEA09-FF-04-PH-L3	Fortification Sample, ME 04, Painter's Hat, 3rd Low Level
AEA09-FF-04-PH-H1	Fortification Sample, ME 04, Painter's Hat, 1st High Level
AEA09-FF-04-PH-H2	Fortification Sample, ME 04, Painter's Hat, 2nd High Level
AEA09-FF-04-PH-H3	Fortification Sample, ME 04, Painter's Hat, 3rd High Level
AEA09-FF-04-AR-C1	Fortification Sample, ME 04, Air Sampling Tube, 1st Control
AEA09-FF-04-AR-C2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Control
AEA09-FF-04-AR-L1	Fortification Sample, ME 04, Air Sampling Tube, 1st Low Level
AEA09-FF-04-AR-L2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Low Level
AEA09-FF-04-AR-L3	Fortification Sample, ME 04, Air Sampling Tube, 3rd Low Level
AEA09-FF-04-AR-H1	Fortification Sample, ME 04, Air Sampling Tube, 1st High Level
AEA09-FF-04-AR-H2	Fortification Sample, ME 04, Air Sampling Tube, 2nd High Level
AEA09-FF-04-AR-H3	Fortification Sample, ME 04, Air Sampling Tube, 3rd High Level
AEA09-FF-04-RES-C1	Fortification Sample, ME 04, RespiCon, 1st Control
AEA09-FF-04-RES-C2	Fortification Sample, ME 04, RespiCon, 2nd Control
AEA09-FF-04-RES-L1	Fortification Sample, ME 04, RespiCon, 1st Low Level
AEA09-FF-04-RES-L2	Fortification Sample, ME 04, RespiCon, 2nd Low Level
AEA09-FF-04-RES-L3	Fortification Sample, ME 04, RespiCon, 3rd Low Level
AEA09-FF-04-RES-H1	Fortification Sample, ME 04, RespiCon, 1st High Level
AEA09-FF-04-RES-H2	Fortification Sample, ME 04, RespiCon, 2nd High Level
AEA09-FF-04-RES-H3	Fortification Sample, ME 04, RespiCon, 3rd High Level
AEA09-FF-04-HW-C1	Fortification Sample, ME 04, Hand Wash, 1st Control
AEA09-FF-04-HW-C2	Fortification Sample, ME 04, Hand Wash, 2nd Control
AEA09-FF-04-HW-L1	Fortification Sample, ME 04, Hand Wash, 1st Low Level
AEA09-FF-04-HW-L2	Fortification Sample, ME 04, Hand Wash, 2nd Low Level
AEA09-FF-04-HW-L3	Fortification Sample, ME 04, Hand Wash, 3rd Low Level
AEA09-FF-04-HW-H1	Fortification Sample, ME 04, Hand Wash, 1st High Level
AEA09-FF-04-HW-H2	Fortification Sample, ME 04, Hand Wash, 2nd High Level
AEA09-FF-04-HW-H3	Fortification Sample, ME 04, Hand Wash, 3rd High Level
AEA09-FF-04-FW-C1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Control
AEA09-FF-04-FW-C2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Control
AEA09-FF-04-FW-L1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Low Level
AEA09-FF-04-FW-L2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Low Level
AEA09-FF-04-FW-L3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd Low Level
AEA09-FF-04-FW-H1	Fortification Sample, ME 04, Face and Neck Wipe, 1st High Level
AEA09-FF-04-FW-H2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd High Level

Sample ID Number	Description
AEA09-FF-04-FW-H3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd High Level
AEA09-FF-04-ID-C1	Fortification Sample, ME 04, Inner Dosimeter, 1st Control
AEA09-FF-04-ID-C2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Control
AEA09-FF-04-ID-L1	Fortification Sample, ME 04, Inner Dosimeter, 1st Low Level
AEA09-FF-04-ID-L2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Low Level
AEA09-FF-04-ID-L3	Fortification Sample, ME 04, Inner Dosimeter, 3rd Low Level
AEA09-FF-04-ID-H1	Fortification Sample, ME 04, Inner Dosimeter, 1st High Level
AEA09-FF-04-ID-H2	Fortification Sample, ME 04, Inner Dosimeter, 2nd High Level
AEA09-FF-04-ID-H3	Fortification Sample, ME 04, Inner Dosimeter, 3rd High Level
AEA09-FF-04-OD-C1	Fortification Sample, ME 04, Outer Dosimeter, 1st Control
AEA09-FF-04-OD-C2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Control
AEA09-FF-04-OD-L1	Fortification Sample, ME 04, Outer Dosimeter, 1st Low Level
AEA09-FF-04-OD-L2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Low Level
AEA09-FF-04-OD-L3	Fortification Sample, ME 04, Outer Dosimeter, 3rd Low Level
AEA09-FF-04-OD-H1	Fortification Sample, ME 04, Outer Dosimeter, 1st High Level
AEA09-FF-04-OD-H2	Fortification Sample, ME 04, Outer Dosimeter, 2nd High Level
AEA09-FF-04-OD-H3	Fortification Sample, ME 04, Outer Dosimeter, 3rd High Level
AEA09-FF-05-PH-C1	Fortification Sample, ME 05, Painter's Hat, 1st Control
AEA09-FF-05-PH-C2	Fortification Sample, ME 05, Painter's Hat, 2nd Control
AEA09-FF-05-PH-L1	Fortification Sample, ME 05, Painter's Hat, 1st Low Level
AEA09-FF-05-PH-L2	Fortification Sample, ME 05, Painter's Hat, 2nd Low Level
AEA09-FF-05-PH-L3	Fortification Sample, ME 05, Painter's Hat, 3rd Low Level
AEA09-FF-05-PH-H1	Fortification Sample, ME 05, Painter's Hat, 1st High Level
AEA09-FF-05-PH-H2	Fortification Sample, ME 05, Painter's Hat, 2nd High Level
AEA09-FF-05-PH-H3	Fortification Sample, ME 05, Painter's Hat, 3rd High Level
AEA09-FF-05-AR-C1	Fortification Sample, ME 05, Air Sampling Tube, 1st Control
AEA09-FF-05-AR-C2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Control
AEA09-FF-05-AR-L1	Fortification Sample, ME 05, Air Sampling Tube, 1st Low Level
AEA09-FF-05-AR-L2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Low Level
AEA09-FF-05-AR-L3	Fortification Sample, ME 05, Air Sampling Tube, 3rd Low Level
AEA09-FF-05-AR-H1	Fortification Sample, ME 05, Air Sampling Tube, 1st High Level
AEA09-FF-05-AR-H2	Fortification Sample, ME 05, Air Sampling Tube, 2nd High Level
AEA09-FF-05-AR-H3	Fortification Sample, ME 05, Air Sampling Tube, 3rd High Level
AEA09-FF-05-RES-C1	Fortification Sample, ME 05, RespiCon, 1st Control
AEA09-FF-05-RES-C2	Fortification Sample, ME 05, RespiCon, 2nd Control
AEA09-FF-05-RES-L1	Fortification Sample, ME 05, RespiCon, 1st Low Level
AEA09-FF-05-RES-L2	Fortification Sample, ME 05, RespiCon, 2nd Low Level
AEA09-FF-05-RES-L3	Fortification Sample, ME 05, RespiCon, 3rd Low Level
AEA09-FF-05-RES-H1	Fortification Sample, ME 05, RespiCon, 1st High Level
AEA09-FF-05-RES-H2	Fortification Sample, ME 05, RespiCon, 2nd High Level
AEA09-FF-05-RES-H3	Fortification Sample, ME 05, RespiCon, 3rd High Level
AEA09-FF-05-HW-C1	Fortification Sample, ME 05, Hand Wash, 1st Control
AEA09-FF-05-HW-C2	Fortification Sample, ME 05, Hand Wash, 2nd Control
AEA09-FF-05-HW-L1	Fortification Sample, ME 05, Hand Wash, 1st Low Level
AEA09-FF-05-HW-L2	Fortification Sample, ME 05, Hand Wash, 2nd Low Level
AEA09-FF-05-HW-L3	Fortification Sample, ME 05, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-05-HW-H1	Fortification Sample, ME 05, Hand Wash, 1st High Level
AEA09-FF-05-HW-H2	Fortification Sample, ME 05, Hand Wash, 2nd High Level
AEA09-FF-05-HW-H3	Fortification Sample, ME 05, Hand Wash, 3rd High Level
AEA09-FF-05-FW-C1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Control
AEA09-FF-05-FW-C2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Control
AEA09-FF-05-FW-L1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Low Level
AEA09-FF-05-FW-L2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Low Level
AEA09-FF-05-FW-L3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd Low Level
AEA09-FF-05-FW-H1	Fortification Sample, ME 05, Face and Neck Wipe, 1st High Level
AEA09-FF-05-FW-H2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd High Level
AEA09-FF-05-FW-H3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd High Level
AEA09-FF-05-ID-C1	Fortification Sample, ME 05, Inner Dosimeter, 1st Control
AEA09-FF-05-ID-C2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Control
AEA09-FF-05-ID-L1	Fortification Sample, ME 05, Inner Dosimeter, 1st Low Level
AEA09-FF-05-ID-L2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Low Level
AEA09-FF-05-ID-L3	Fortification Sample, ME 05, Inner Dosimeter, 3rd Low Level
AEA09-FF-05-ID-H1	Fortification Sample, ME 05, Inner Dosimeter, 1st High Level
AEA09-FF-05-ID-H2	Fortification Sample, ME 05, Inner Dosimeter, 2nd High Level
AEA09-FF-05-ID-H3	Fortification Sample, ME 05, Inner Dosimeter, 3rd High Level
AEA09-FF-05-OD-C1	Fortification Sample, ME 05, Outer Dosimeter, 1st Control
AEA09-FF-05-OD-C2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Control
AEA09-FF-05-OD-L1	Fortification Sample, ME 05, Outer Dosimeter, 1st Low Level
AEA09-FF-05-OD-L2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Low Level
AEA09-FF-05-OD-L3	Fortification Sample, ME 05, Outer Dosimeter, 3rd Low Level
AEA09-FF-05-OD-H1	Fortification Sample, ME 05, Outer Dosimeter, 1st High Level
AEA09-FF-05-OD-H2	Fortification Sample, ME 05, Outer Dosimeter, 2nd High Level
AEA09-FF-05-OD-H3	Fortification Sample, ME 05, Outer Dosimeter, 3rd High Level
AEA09-FF-06-PH-C1	Fortification Sample, ME 06, Painter's Hat, 1st Control
AEA09-FF-06-PH-C2	Fortification Sample, ME 06, Painter's Hat, 2nd Control
AEA09-FF-06-PH-L1	Fortification Sample, ME 06, Painter's Hat, 1st Low Level
AEA09-FF-06-PH-L2	Fortification Sample, ME 06, Painter's Hat, 2nd Low Level
AEA09-FF-06-PH-L3	Fortification Sample, ME 06, Painter's Hat, 3rd Low Level
AEA09-FF-06-PH-H1	Fortification Sample, ME 06, Painter's Hat, 1st High Level
AEA09-FF-06-PH-H2	Fortification Sample, ME 06, Painter's Hat, 2nd High Level
AEA09-FF-06-PH-H3	Fortification Sample, ME 06, Painter's Hat, 3rd High Level
AEA09-FF-06-AR-C1	Fortification Sample, ME 06, Air Sampling Tube, 1st Control
AEA09-FF-06-AR-C2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Control
AEA09-FF-06-AR-L1	Fortification Sample, ME 06, Air Sampling Tube, 1st Low Level
AEA09-FF-06-AR-L2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Low Level
AEA09-FF-06-AR-L3	Fortification Sample, ME 06, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-AR-H1	Fortification Sample, ME 06, Air Sampling Tube, 1st High Level
AEA09-FF-06-AR-H2	Fortification Sample, ME 06, Air Sampling Tube, 2nd High Level
AEA09-FF-06-AR-H3	Fortification Sample, ME 06, Air Sampling Tube, 3rd High Level
AEA09-FF-06-RES-C1	Fortification Sample, ME 06, RespiCon, 1st Control
AEA09-FF-06-RES-C2	Fortification Sample, ME 06, RespiCon, 2nd Control
AEA09-FF-06-RES-L1	Fortification Sample, ME 06, RespiCon, 1st Low Level
AEA09-FF-06-RES-L2	Fortification Sample, ME 06, RespiCon, 2nd Low Level
AEA09-FF-06-RES-L3	Fortification Sample, ME 06, RespiCon, 3rd Low Level
AEA09-FF-06-RES-H1	Fortification Sample, ME 06, RespiCon, 1st High Level
AEA09-FF-06-RES-H2	Fortification Sample, ME 06, RespiCon, 2nd High Level
AEA09-FF-06-RES-H3	Fortification Sample, ME 06, RespiCon, 3rd High Level
AEA09-FF-06-HW-C1	Fortification Sample, ME 06, Hand Wash, 1st Control
AEA09-FF-06-HW-C2	Fortification Sample, ME 06, Hand Wash, 2nd Control
AEA09-FF-06-HW-L1	Fortification Sample, ME 06, Hand Wash, 1st Low Level
AEA09-FF-06-HW-L2	Fortification Sample, ME 06, Hand Wash, 2nd Low Level
AEA09-FF-06-HW-L3	Fortification Sample, ME 06, Hand Wash, 3rd Low Level
AEA09-FF-06-HW-H1	Fortification Sample, ME 06, Hand Wash, 1st High Level
AEA09-FF-06-HW-H2	Fortification Sample, ME 06, Hand Wash, 2nd High Level
AEA09-FF-06-HW-H3	Fortification Sample, ME 06, Hand Wash, 3rd High Level
AEA09-FF-06-FW-C1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Control
AEA09-FF-06-FW-C2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Control
AEA09-FF-06-FW-L1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Low Level
AEA09-FF-06-FW-L2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Low Level
AEA09-FF-06-FW-L3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd Low Level
AEA09-FF-06-FW-H1	Fortification Sample, ME 06, Face and Neck Wipe, 1st High Level
AEA09-FF-06-FW-H2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd High Level
AEA09-FF-06-FW-H3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd High Level
AEA09-FF-06-ID-C1	Fortification Sample, ME 06, Inner Dosimeter, 1st Control
AEA09-FF-06-ID-C2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Control
AEA09-FF-06-ID-L1	Fortification Sample, ME 06, Inner Dosimeter, 1st Low Level
AEA09-FF-06-ID-L2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Low Level
AEA09-FF-06-ID-L3	Fortification Sample, ME 06, Inner Dosimeter, 3rd Low Level
AEA09-FF-06-ID-H1	Fortification Sample, ME 06, Inner Dosimeter, 1st High Level
AEA09-FF-06-ID-H2	Fortification Sample, ME 06, Inner Dosimeter, 2nd High Level
AEA09-FF-06-ID-H3	Fortification Sample, ME 06, Inner Dosimeter, 3rd High Level
AEA09-FF-06-OD-C1	Fortification Sample, ME 06, Outer Dosimeter, 1st Control
AEA09-FF-06-OD-C2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Control
AEA09-FF-06-OD-L1	Fortification Sample, ME 06, Outer Dosimeter, 1st Low Level
AEA09-FF-06-OD-L2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Low Level
AEA09-FF-06-OD-L3	Fortification Sample, ME 06, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-OD-H1	Fortification Sample, ME 06, Outer Dosimeter, 1st High Level
AEA09-FF-06-OD-H2	Fortification Sample, ME 06, Outer Dosimeter, 2nd High Level
AEA09-FF-06-OD-H3	Fortification Sample, ME 06, Outer Dosimeter, 3rd High Level
AEA09-FF-07-PH-C1	Fortification Sample, ME 07, Painter's Hat, 1st Control
AEA09-FF-07-PH-C2	Fortification Sample, ME 07, Painter's Hat, 2nd Control
AEA09-FF-07-PH-L1	Fortification Sample, ME 07, Painter's Hat, 1st Low Level
AEA09-FF-07-PH-L2	Fortification Sample, ME 07, Painter's Hat, 2nd Low Level
AEA09-FF-07-PH-L3	Fortification Sample, ME 07, Painter's Hat, 3rd Low Level
AEA09-FF-07-PH-H1	Fortification Sample, ME 07, Painter's Hat, 1st High Level
AEA09-FF-07-PH-H2	Fortification Sample, ME 07, Painter's Hat, 2nd High Level
AEA09-FF-07-PH-H3	Fortification Sample, ME 07, Painter's Hat, 3rd High Level
AEA09-FF-07-AR-C1	Fortification Sample, ME 07, Air Sampling Tube, 1st Control
AEA09-FF-07-AR-C2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Control
AEA09-FF-07-AR-L1	Fortification Sample, ME 07, Air Sampling Tube, 1st Low Level
AEA09-FF-07-AR-L2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Low Level
AEA09-FF-07-AR-L3	Fortification Sample, ME 07, Air Sampling Tube, 3rd Low Level
AEA09-FF-07-AR-H1	Fortification Sample, ME 07, Air Sampling Tube, 1st High Level
AEA09-FF-07-AR-H2	Fortification Sample, ME 07, Air Sampling Tube, 2nd High Level
AEA09-FF-07-AR-H3	Fortification Sample, ME 07, Air Sampling Tube, 3rd High Level
AEA09-FF-07-RES-C1	Fortification Sample, ME 07, RespiCon, 1st Control
AEA09-FF-07-RES-C2	Fortification Sample, ME 07, RespiCon, 2nd Control
AEA09-FF-07-RES-L1	Fortification Sample, ME 07, RespiCon, 1st Low Level
AEA09-FF-07-RES-L2	Fortification Sample, ME 07, RespiCon, 2nd Low Level
AEA09-FF-07-RES-L3	Fortification Sample, ME 07, RespiCon, 3rd Low Level
AEA09-FF-07-RES-H1	Fortification Sample, ME 07, RespiCon, 1st High Level
AEA09-FF-07-RES-H2	Fortification Sample, ME 07, RespiCon, 2nd High Level
AEA09-FF-07-RES-H3	Fortification Sample, ME 07, RespiCon, 3rd High Level
AEA09-FF-07-HW-C1	Fortification Sample, ME 07, Hand Wash, 1st Control
AEA09-FF-07-HW-C2	Fortification Sample, ME 07, Hand Wash, 2nd Control
AEA09-FF-07-HW-L1	Fortification Sample, ME 07, Hand Wash, 1st Low Level
AEA09-FF-07-HW-L2	Fortification Sample, ME 07, Hand Wash, 2nd Low Level
AEA09-FF-07-HW-L3	Fortification Sample, ME 07, Hand Wash, 3rd Low Level
AEA09-FF-07-HW-H1	Fortification Sample, ME 07, Hand Wash, 1st High Level
AEA09-FF-07-HW-H2	Fortification Sample, ME 07, Hand Wash, 2nd High Level
AEA09-FF-07-HW-H3	Fortification Sample, ME 07, Hand Wash, 3rd High Level
AEA09-FF-07-FW-C1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Control
AEA09-FF-07-FW-C2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Control
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Low Level
AEA09-FF-07-FW-L3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd Low Level
AEA09-FF-07-FW-H1	Fortification Sample, ME 07, Face and Neck Wipe, 1st High Level

Sample ID Number	Description
AEA09-FF-07-FW-H2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd High Level
AEA09-FF-07-FW-H3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd High Level
AEA09-FF-07-ID-C1	Fortification Sample, ME 07, Inner Dosimeter, 1st Control
AEA09-FF-07-ID-C2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Control
AEA09-FF-07-ID-L1	Fortification Sample, ME 07, Inner Dosimeter, 1st Low Level
AEA09-FF-07-ID-L2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Low Level
AEA09-FF-07-ID-L3	Fortification Sample, ME 07, Inner Dosimeter, 3rd Low Level
AEA09-FF-07-ID-H1	Fortification Sample, ME 07, Inner Dosimeter, 1st High Level
AEA09-FF-07-ID-H2	Fortification Sample, ME 07, Inner Dosimeter, 2nd High Level
AEA09-FF-07-ID-H3	Fortification Sample, ME 07, Inner Dosimeter, 3rd High Level
AEA09-FF-07-OD-C1	Fortification Sample, ME 07, Outer Dosimeter, 1st Control
AEA09-FF-07-OD-C2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Control
AEA09-FF-07-OD-L1	Fortification Sample, ME 07, Outer Dosimeter, 1st Low Level
AEA09-FF-07-OD-L2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Low Level
AEA09-FF-07-OD-L3	Fortification Sample, ME 07, Outer Dosimeter, 3rd Low Level
AEA09-FF-07-OD-H1	Fortification Sample, ME 07, Outer Dosimeter, 1st High Level
AEA09-FF-07-OD-H2	Fortification Sample, ME 07, Outer Dosimeter, 2nd High Level
AEA09-FF-07-OD-H3	Fortification Sample, ME 07, Outer Dosimeter, 3rd High Level
AEA09-FF-08-PH-C1	Fortification Sample, ME 08, Painter's Hat, 1st Control
AEA09-FF-08-PH-C2	Fortification Sample, ME 08, Painter's Hat, 2nd Control
AEA09-FF-08-PH-L1	Fortification Sample, ME 08, Painter's Hat, 1st Low Level
AEA09-FF-08-PH-L2	Fortification Sample, ME 08, Painter's Hat, 2nd Low Level
AEA09-FF-08-PH-L3	Fortification Sample, ME 08, Painter's Hat, 3rd Low Level
AEA09-FF-08-PH-H1	Fortification Sample, ME 08, Painter's Hat, 1st High Level
AEA09-FF-08-PH-H2	Fortification Sample, ME 08, Painter's Hat, 2nd High Level
AEA09-FF-08-PH-H3	Fortification Sample, ME 08, Painter's Hat, 3rd High Level
AEA09-FF-08-AR-C1	Fortification Sample, ME 08, Air Sampling Tube, 1st Control
AEA09-FF-08-AR-C2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Control
AEA09-FF-08-AR-L1	Fortification Sample, ME 08, Air Sampling Tube, 1st Low Level
AEA09-FF-08-AR-L2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Low Level
AEA09-FF-08-AR-L3	Fortification Sample, ME 08, Air Sampling Tube, 3rd Low Level
AEA09-FF-08-AR-H1	Fortification Sample, ME 08, Air Sampling Tube, 1st High Level
AEA09-FF-08-AR-H2	Fortification Sample, ME 08, Air Sampling Tube, 2nd High Level
AEA09-FF-08-AR-H3	Fortification Sample, ME 08, Air Sampling Tube, 3rd High Level
AEA09-FF-08-RES-C1	Fortification Sample, ME 08, RespiCon, 1st Control
AEA09-FF-08-RES-C2	Fortification Sample, ME 08, RespiCon, 2nd Control
AEA09-FF-08-RES-L1	Fortification Sample, ME 08, RespiCon, 1st Low Level
AEA09-FF-08-RES-L2	Fortification Sample, ME 08, RespiCon, 2nd Low Level
AEA09-FF-08-RES-L3	Fortification Sample, ME 08, RespiCon, 3rd Low Level
AEA09-FF-08-RES-H1	Fortification Sample, ME 08, RespiCon, 1st High Level
AEA09-FF-08-RES-H2	Fortification Sample, ME 08, RespiCon, 2nd High Level
AEA09-FF-08-RES-H3	Fortification Sample, ME 08, RespiCon, 3rd High Level
AEA09-FF-08-HW-C1	Fortification Sample, ME 08, Hand Wash, 1st Control
AEA09-FF-08-HW-C2	Fortification Sample, ME 08, Hand Wash, 2nd Control

Sample ID Number	Description
AEA09-FF-08-HW-L1	Fortification Sample, ME 08, Hand Wash, 1st Low Level
AEA09-FF-08-HW-L2	Fortification Sample, ME 08, Hand Wash, 2nd Low Level
AEA09-FF-08-HW-L3	Fortification Sample, ME 08, Hand Wash, 3rd Low Level
AEA09-FF-08-HW-H1	Fortification Sample, ME 08, Hand Wash, 1st High Level
AEA09-FF-08-HW-H2	Fortification Sample, ME 08, Hand Wash, 2nd High Level
AEA09-FF-08-HW-H3	Fortification Sample, ME 08, Hand Wash, 3rd High Level
AEA09-FF-08-FW-C1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Control
AEA09-FF-08-FW-C2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Control
AEA09-FF-08-FW-L1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Low Level
AEA09-FF-08-FW-L2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Low Level
AEA09-FF-08-FW-L3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd Low Level
AEA09-FF-08-FW-H1	Fortification Sample, ME 08, Face and Neck Wipe, 1st High Level
AEA09-FF-08-FW-H2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd High Level
AEA09-FF-08-FW-H3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd High Level
AEA09-FF-08-ID-C1	Fortification Sample, ME 08, Inner Dosimeter, 1st Control
AEA09-FF-08-ID-C2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Control
AEA09-FF-08-ID-L1	Fortification Sample, ME 08, Inner Dosimeter, 1st Low Level
AEA09-FF-08-ID-L2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Low Level
AEA09-FF-08-ID-L3	Fortification Sample, ME 08, Inner Dosimeter, 3rd Low Level
AEA09-FF-08-ID-H1	Fortification Sample, ME 08, Inner Dosimeter, 1st High Level
AEA09-FF-08-ID-H2	Fortification Sample, ME 08, Inner Dosimeter, 2nd High Level
AEA09-FF-08-ID-H3	Fortification Sample, ME 08, Inner Dosimeter, 3rd High Level
AEA09-FF-08-OD-C1	Fortification Sample, ME 08, Outer Dosimeter, 1st Control
AEA09-FF-08-OD-C2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Control
AEA09-FF-08-OD-L1	Fortification Sample, ME 08, Outer Dosimeter, 1st Low Level
AEA09-FF-08-OD-L2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Low Level
AEA09-FF-08-OD-L3	Fortification Sample, ME 08, Outer Dosimeter, 3rd Low Level
AEA09-FF-08-OD-H1	Fortification Sample, ME 08, Outer Dosimeter, 1st High Level
AEA09-FF-08-OD-H2	Fortification Sample, ME 08, Outer Dosimeter, 2nd High Level
AEA09-FF-08-OD-H3	Fortification Sample, ME 08, Outer Dosimeter, 3rd High Level
AEA09-FF-09-PH-C1	Fortification Sample, ME 09, Painter's Hat, 1st Control
AEA09-FF-09-PH-C2	Fortification Sample, ME 09, Painter's Hat, 2nd Control
AEA09-FF-09-PH-L1	Fortification Sample, ME 09, Painter's Hat, 1st Low Level
AEA09-FF-09-PH-L2	Fortification Sample, ME 09, Painter's Hat, 2nd Low Level
AEA09-FF-09-PH-L3	Fortification Sample, ME 09, Painter's Hat, 3rd Low Level
AEA09-FF-09-PH-H1	Fortification Sample, ME 09, Painter's Hat, 1st High Level
AEA09-FF-09-PH-H2	Fortification Sample, ME 09, Painter's Hat, 2nd High Level
AEA09-FF-09-PH-H3	Fortification Sample, ME 09, Painter's Hat, 3rd High Level
AEA09-FF-09-AR-C1	Fortification Sample, ME 09, Air Sampling Tube, 1st Control
AEA09-FF-09-AR-C2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Control

Sample ID Number	Description
AEA09-FF-09-AR-L1	Fortification Sample, ME 09, Air Sampling Tube, 1st Low Level
AEA09-FF-09-AR-L2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Low Level
AEA09-FF-09-AR-L3	Fortification Sample, ME 09, Air Sampling Tube, 3rd Low Level
AEA09-FF-09-AR-H1	Fortification Sample, ME 09, Air Sampling Tube, 1st High Level
AEA09-FF-09-AR-H2	Fortification Sample, ME 09, Air Sampling Tube, 2nd High Level
AEA09-FF-09-AR-H3	Fortification Sample, ME 09, Air Sampling Tube, 3rd High Level
AEA09-FF-09-RES-C1	Fortification Sample, ME 09, RespiCon, 1st Control
AEA09-FF-09-RES-C2	Fortification Sample, ME 09, RespiCon, 2nd Control
AEA09-FF-09-RES-L1	Fortification Sample, ME 09, RespiCon, 1st Low Level
AEA09-FF-09-RES-L2	Fortification Sample, ME 09, RespiCon, 2nd Low Level
AEA09-FF-09-RES-L3	Fortification Sample, ME 09, RespiCon, 3rd Low Level
AEA09-FF-09-RES-H1	Fortification Sample, ME 09, RespiCon, 1st High Level
AEA09-FF-09-RES-H2	Fortification Sample, ME 09, RespiCon, 2nd High Level
AEA09-FF-09-RES-H3	Fortification Sample, ME 09, RespiCon, 3rd High Level
AEA09-FF-09-HW-C1	Fortification Sample, ME 09, Hand Wash, 1st Control
AEA09-FF-09-HW-C2	Fortification Sample, ME 09, Hand Wash, 2nd Control
AEA09-FF-09-HW-L1	Fortification Sample, ME 09, Hand Wash, 1st Low Level
AEA09-FF-09-HW-L2	Fortification Sample, ME 09, Hand Wash, 2nd Low Level
AEA09-FF-09-HW-L3	Fortification Sample, ME 09, Hand Wash, 3rd Low Level
AEA09-FF-09-HW-H1	Fortification Sample, ME 09, Hand Wash, 1st High Level
AEA09-FF-09-HW-H2	Fortification Sample, ME 09, Hand Wash, 2nd High Level
AEA09-FF-09-HW-H3	Fortification Sample, ME 09, Hand Wash, 3rd High Level
AEA09-FF-09-FW-C1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Control
AEA09-FF-09-FW-C2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Control
AEA09-FF-09-FW-L1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Low Level
AEA09-FF-09-FW-L2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Low Level
AEA09-FF-09-FW-L3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd Low Level
AEA09-FF-09-FW-H1	Fortification Sample, ME 09, Face and Neck Wipe, 1st High Level
AEA09-FF-09-FW-H2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd High Level
AEA09-FF-09-FW-H3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd High Level
AEA09-FF-09-ID-C1	Fortification Sample, ME 09, Inner Dosimeter, 1st Control
AEA09-FF-09-ID-C2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Control
AEA09-FF-09-ID-L1	Fortification Sample, ME 09, Inner Dosimeter, 1st Low Level
AEA09-FF-09-ID-L2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Low Level
AEA09-FF-09-ID-L3	Fortification Sample, ME 09, Inner Dosimeter, 3rd Low Level
AEA09-FF-09-ID-H1	Fortification Sample, ME 09, Inner Dosimeter, 1st High Level
AEA09-FF-09-ID-H2	Fortification Sample, ME 09, Inner Dosimeter, 2nd High Level
AEA09-FF-09-ID-H3	Fortification Sample, ME 09, Inner Dosimeter, 3rd High Level
AEA09-FF-09-OD-C1	Fortification Sample, ME 09, Outer Dosimeter, 1st Control
AEA09-FF-09-OD-C2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Control

Sample ID Number	Description
AEA09-FF-09-OD-L1	Fortification Sample, ME 09, Outer Dosimeter, 1st Low Level
AEA09-FF-09-OD-L2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Low Level
AEA09-FF-09-OD-L3	Fortification Sample, ME 09, Outer Dosimeter, 3rd Low Level
AEA09-FF-09-OD-H1	Fortification Sample, ME 09, Outer Dosimeter, 1st High Level
AEA09-FF-09-OD-H2	Fortification Sample, ME 09, Outer Dosimeter, 2nd High Level
AEA09-FF-09-OD-H3	Fortification Sample, ME 09, Outer Dosimeter, 3rd High Level
AEA09-FF-10-PH-C1	Fortification Sample, ME 10, Painter's Hat, 1st Control
AEA09-FF-10-PH-C2	Fortification Sample, ME 10, Painter's Hat, 2nd Control
AEA09-FF-10-PH-L1	Fortification Sample, ME 10, Painter's Hat, 1st Low Level
AEA09-FF-10-PH-L2	Fortification Sample, ME 10, Painter's Hat, 2nd Low Level
AEA09-FF-10-PH-L3	Fortification Sample, ME 10, Painter's Hat, 3rd Low Level
AEA09-FF-10-PH-H1	Fortification Sample, ME 10, Painter's Hat, 1st High Level
AEA09-FF-10-PH-H2	Fortification Sample, ME 10, Painter's Hat, 2nd High Level
AEA09-FF-10-PH-H3	Fortification Sample, ME 10, Painter's Hat, 3rd High Level
AEA09-FF-10-AR-C1	Fortification Sample, ME 10, Air Sampling Tube, 1st Control
AEA09-FF-10-AR-C2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Control
AEA09-FF-10-AR-L1	Fortification Sample, ME 10, Air Sampling Tube, 1st Low Level
AEA09-FF-10-AR-L2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Low Level
AEA09-FF-10-AR-L3	Fortification Sample, ME 10, Air Sampling Tube, 3rd Low Level
AEA09-FF-10-AR-H1	Fortification Sample, ME 10, Air Sampling Tube, 1st High Level
AEA09-FF-10-AR-H2	Fortification Sample, ME 10, Air Sampling Tube, 2nd High Level
AEA09-FF-10-AR-H3	Fortification Sample, ME 10, Air Sampling Tube, 3rd High Level
AEA09-FF-10-RES-C1	Fortification Sample, ME 10, RespiCon, 1st Control
AEA09-FF-10-RES-C2	Fortification Sample, ME 10, RespiCon, 2nd Control
AEA09-FF-10-RES-L1	Fortification Sample, ME 10, RespiCon, 1st Low Level
AEA09-FF-10-RES-L2	Fortification Sample, ME 10, RespiCon, 2nd Low Level
AEA09-FF-10-RES-L3	Fortification Sample, ME 10, RespiCon, 3rd Low Level
AEA09-FF-10-RES-H1	Fortification Sample, ME 10, RespiCon, 1st High Level
AEA09-FF-10-RES-H2	Fortification Sample, ME 10, RespiCon, 2nd High Level
AEA09-FF-10-RES-H3	Fortification Sample, ME 10, RespiCon, 3rd High Level
AEA09-FF-10-HW-C1	Fortification Sample, ME 10, Hand Wash, 1st Control
AEA09-FF-10-HW-C2	Fortification Sample, ME 10, Hand Wash, 2nd Control
AEA09-FF-10-HW-L1	Fortification Sample, ME 10, Hand Wash, 1st Low Level
AEA09-FF-10-HW-L2	Fortification Sample, ME 10, Hand Wash, 2nd Low Level
AEA09-FF-10-HW-L3	Fortification Sample, ME 10, Hand Wash, 3rd Low Level
AEA09-FF-10-HW-H1	Fortification Sample, ME 10, Hand Wash, 1st High Level
AEA09-FF-10-HW-H2	Fortification Sample, ME 10, Hand Wash, 2nd High Level
AEA09-FF-10-HW-H3	Fortification Sample, ME 10, Hand Wash, 3rd High Level
AEA09-FF-10-FW-C1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Control
AEA09-FF-10-FW-C2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Control
AEA09-FF-10-FW-L1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Low Level
AEA09-FF-10-FW-L2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Low Level
AEA09-FF-10-FW-L3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-10-FW-H1	Fortification Sample, ME 10, Face and Neck Wipe, 1st High Level
AEA09-FF-10-FW-H2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd High Level
AEA09-FF-10-FW-H3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd High Level
AEA09-FF-10-ID-C1	Fortification Sample, ME 10, Inner Dosimeter, 1st Control
AEA09-FF-10-ID-C2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Control
AEA09-FF-10-ID-L1	Fortification Sample, ME 10, Inner Dosimeter, 1st Low Level
AEA09-FF-10-ID-L2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Low Level
AEA09-FF-10-ID-L3	Fortification Sample, ME 10, Inner Dosimeter, 3rd Low Level
AEA09-FF-10-ID-H1	Fortification Sample, ME 10, Inner Dosimeter, 1st High Level
AEA09-FF-10-ID-H2	Fortification Sample, ME 10, Inner Dosimeter, 2nd High Level
AEA09-FF-10-ID-H3	Fortification Sample, ME 10, Inner Dosimeter, 3rd High Level
AEA09-FF-10-OD-C1	Fortification Sample, ME 10, Outer Dosimeter, 1st Control
AEA09-FF-10-OD-C2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Control
AEA09-FF-10-OD-L1	Fortification Sample, ME 10, Outer Dosimeter, 1st Low Level
AEA09-FF-10-OD-L2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Low Level
AEA09-FF-10-OD-L3	Fortification Sample, ME 10, Outer Dosimeter, 3rd Low Level
AEA09-FF-10-OD-H1	Fortification Sample, ME 10, Outer Dosimeter, 1st High Level
AEA09-FF-10-OD-H2	Fortification Sample, ME 10, Outer Dosimeter, 2nd High Level
AEA09-FF-10-OD-H3	Fortification Sample, ME 10, Outer Dosimeter, 3rd High Level
AEA09-FF-11-PH-C1	Fortification Sample, ME 11, Painter's Hat, 1st Control
AEA09-FF-11-PH-C2	Fortification Sample, ME 11, Painter's Hat, 2nd Control
AEA09-FF-11-PH-L1	Fortification Sample, ME 11, Painter's Hat, 1st Low Level
AEA09-FF-11-PH-L2	Fortification Sample, ME 11, Painter's Hat, 2nd Low Level
AEA09-FF-11-PH-L3	Fortification Sample, ME 11, Painter's Hat, 3rd Low Level
AEA09-FF-11-PH-H1	Fortification Sample, ME 11, Painter's Hat, 1st High Level
AEA09-FF-11-PH-H2	Fortification Sample, ME 11, Painter's Hat, 2nd High Level
AEA09-FF-11-PH-H3	Fortification Sample, ME 11, Painter's Hat, 3rd High Level
AEA09-FF-11-AR-C1	Fortification Sample, ME 11, Air Sampling Tube, 1st Control
AEA09-FF-11-AR-C2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Control
AEA09-FF-11-AR-L1	Fortification Sample, ME 11, Air Sampling Tube, 1st Low Level
AEA09-FF-11-AR-L2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Low Level
AEA09-FF-11-AR-L3	Fortification Sample, ME 11, Air Sampling Tube, 3rd Low Level
AEA09-FF-11-AR-H1	Fortification Sample, ME 11, Air Sampling Tube, 1st High Level
AEA09-FF-11-AR-H2	Fortification Sample, ME 11, Air Sampling Tube, 2nd High Level
AEA09-FF-11-AR-H3	Fortification Sample, ME 11, Air Sampling Tube, 3rd High Level
AEA09-FF-11-RES-C1	Fortification Sample, ME 11, RespiCon, 1st Control
AEA09-FF-11-RES-C2	Fortification Sample, ME 11, RespiCon, 2nd Control
AEA09-FF-11-RES-L1	Fortification Sample, ME 11, RespiCon, 1st Low Level
AEA09-FF-11-RES-L2	Fortification Sample, ME 11, RespiCon, 2nd Low Level
AEA09-FF-11-RES-L3	Fortification Sample, ME 11, RespiCon, 3rd Low Level
AEA09-FF-11-RES-H1	Fortification Sample, ME 11, RespiCon, 1st High Level
AEA09-FF-11-RES-H2	Fortification Sample, ME 11, RespiCon, 2nd High Level
AEA09-FF-11-RES-H3	Fortification Sample, ME 11, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-11-HW-C1	Fortification Sample, ME 11, Hand Wash, 1st Control
AEA09-FF-11-HW-C2	Fortification Sample, ME 11, Hand Wash, 2nd Control
AEA09-FF-11-HW-L1	Fortification Sample, ME 11, Hand Wash, 1st Low Level
AEA09-FF-11-HW-L2	Fortification Sample, ME 11, Hand Wash, 2nd Low Level
AEA09-FF-11-HW-L3	Fortification Sample, ME 11, Hand Wash, 3rd Low Level
AEA09-FF-11-HW-H1	Fortification Sample, ME 11, Hand Wash, 1st High Level
AEA09-FF-11-HW-H2	Fortification Sample, ME 11, Hand Wash, 2nd High Level
AEA09-FF-11-HW-H3	Fortification Sample, ME 11, Hand Wash, 3rd High Level
AEA09-FF-11-FW-C1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Control
AEA09-FF-11-FW-C2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Control
AEA09-FF-11-FW-L1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Low Level
AEA09-FF-11-FW-L2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Low Level
AEA09-FF-11-FW-L3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd Low Level
AEA09-FF-11-FW-H1	Fortification Sample, ME 11, Face and Neck Wipe, 1st High Level
AEA09-FF-11-FW-H2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd High Level
AEA09-FF-11-FW-H3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd High Level
AEA09-FF-11-ID-C1	Fortification Sample, ME 11, Inner Dosimeter, 1st Control
AEA09-FF-11-ID-C2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Control
AEA09-FF-11-ID-L1	Fortification Sample, ME 11, Inner Dosimeter, 1st Low Level
AEA09-FF-11-ID-L2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Low Level
AEA09-FF-11-ID-L3	Fortification Sample, ME 11, Inner Dosimeter, 3rd Low Level
AEA09-FF-11-ID-H1	Fortification Sample, ME 11, Inner Dosimeter, 1st High Level
AEA09-FF-11-ID-H2	Fortification Sample, ME 11, Inner Dosimeter, 2nd High Level
AEA09-FF-11-ID-H3	Fortification Sample, ME 11, Inner Dosimeter, 3rd High Level
AEA09-FF-11-OD-C1	Fortification Sample, ME 11, Outer Dosimeter, 1st Control
AEA09-FF-11-OD-C2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Control
AEA09-FF-11-OD-L1	Fortification Sample, ME 11, Outer Dosimeter, 1st Low Level
AEA09-FF-11-OD-L2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Low Level
AEA09-FF-11-OD-L3	Fortification Sample, ME 11, Outer Dosimeter, 3rd Low Level
AEA09-FF-11-OD-H1	Fortification Sample, ME 11, Outer Dosimeter, 1st High Level
AEA09-FF-11-OD-H2	Fortification Sample, ME 11, Outer Dosimeter, 2nd High Level
AEA09-FF-11-OD-H3	Fortification Sample, ME 11, Outer Dosimeter, 3rd High Level
AEA09-FF-12-PH-C1	Fortification Sample, ME 12, Painter's Hat, 1st Control
AEA09-FF-12-PH-C2	Fortification Sample, ME 12, Painter's Hat, 2nd Control
AEA09-FF-12-PH-L1	Fortification Sample, ME 12, Painter's Hat, 1st Low Level
AEA09-FF-12-PH-L2	Fortification Sample, ME 12, Painter's Hat, 2nd Low Level
AEA09-FF-12-PH-L3	Fortification Sample, ME 12, Painter's Hat, 3rd Low Level
AEA09-FF-12-PH-H1	Fortification Sample, ME 12, Painter's Hat, 1st High Level
AEA09-FF-12-PH-H2	Fortification Sample, ME 12, Painter's Hat, 2nd High Level
AEA09-FF-12-PH-H3	Fortification Sample, ME 12, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-AR-C1	Fortification Sample, ME 12, Air Sampling Tube, 1st Control
AEA09-FF-12-AR-C2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Control
AEA09-FF-12-AR-L1	Fortification Sample, ME 12, Air Sampling Tube, 1st Low Level
AEA09-FF-12-AR-L2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Low Level
AEA09-FF-12-AR-L3	Fortification Sample, ME 12, Air Sampling Tube, 3rd Low Level
AEA09-FF-12-AR-H1	Fortification Sample, ME 12, Air Sampling Tube, 1st High Level
AEA09-FF-12-AR-H2	Fortification Sample, ME 12, Air Sampling Tube, 2nd High Level
AEA09-FF-12-AR-H3	Fortification Sample, ME 12, Air Sampling Tube, 3rd High Level
AEA09-FF-12-RES-C1	Fortification Sample, ME 12, RespiCon, 1st Control
AEA09-FF-12-RES-C2	Fortification Sample, ME 12, RespiCon, 2nd Control
AEA09-FF-12-RES-L1	Fortification Sample, ME 12, RespiCon, 1st Low Level
AEA09-FF-12-RES-L2	Fortification Sample, ME 12, RespiCon, 2nd Low Level
AEA09-FF-12-RES-L3	Fortification Sample, ME 12, RespiCon, 3rd Low Level
AEA09-FF-12-RES-H1	Fortification Sample, ME 12, RespiCon, 1st High Level
AEA09-FF-12-RES-H2	Fortification Sample, ME 12, RespiCon, 2nd High Level
AEA09-FF-12-RES-H3	Fortification Sample, ME 12, RespiCon, 3rd High Level
AEA09-FF-12-HW-C1	Fortification Sample, ME 12, Hand Wash, 1st Control
AEA09-FF-12-HW-C2	Fortification Sample, ME 12, Hand Wash, 2nd Control
AEA09-FF-12-HW-L1	Fortification Sample, ME 12, Hand Wash, 1st Low Level
AEA09-FF-12-HW-L2	Fortification Sample, ME 12, Hand Wash, 2nd Low Level
AEA09-FF-12-HW-L3	Fortification Sample, ME 12, Hand Wash, 3rd Low Level
AEA09-FF-12-HW-H1	Fortification Sample, ME 12, Hand Wash, 1st High Level
AEA09-FF-12-HW-H2	Fortification Sample, ME 12, Hand Wash, 2nd High Level
AEA09-FF-12-HW-H3	Fortification Sample, ME 12, Hand Wash, 3rd High Level
AEA09-FF-12-FW-C1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Control
AEA09-FF-12-FW-C2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Control
AEA09-FF-12-FW-L1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Low Level
AEA09-FF-12-FW-L2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Low Level
AEA09-FF-12-FW-L3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd Low Level
AEA09-FF-12-FW-H1	Fortification Sample, ME 12, Face and Neck Wipe, 1st High Level
AEA09-FF-12-FW-H2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd High Level
AEA09-FF-12-FW-H3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd High Level
AEA09-FF-12-ID-C1	Fortification Sample, ME 12, Inner Dosimeter, 1st Control
AEA09-FF-12-ID-C2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Control
AEA09-FF-12-ID-L1	Fortification Sample, ME 12, Inner Dosimeter, 1st Low Level
AEA09-FF-12-ID-L2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Low Level
AEA09-FF-12-ID-L3	Fortification Sample, ME 12, Inner Dosimeter, 3rd Low Level
AEA09-FF-12-ID-H1	Fortification Sample, ME 12, Inner Dosimeter, 1st High Level
AEA09-FF-12-ID-H2	Fortification Sample, ME 12, Inner Dosimeter, 2nd High Level
AEA09-FF-12-ID-H3	Fortification Sample, ME 12, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-OD-C1	Fortification Sample, ME 12, Outer Dosimeter, 1st Control
AEA09-FF-12-OD-C2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Control
AEA09-FF-12-OD-L1	Fortification Sample, ME 12, Outer Dosimeter, 1st Low Level
AEA09-FF-12-OD-L2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Low Level
AEA09-FF-12-OD-L3	Fortification Sample, ME 12, Outer Dosimeter, 3rd Low Level
AEA09-FF-12-OD-H1	Fortification Sample, ME 12, Outer Dosimeter, 1st High Level
AEA09-FF-12-OD-H2	Fortification Sample, ME 12, Outer Dosimeter, 2nd High Level
AEA09-FF-12-OD-H3	Fortification Sample, ME 12, Outer Dosimeter, 3rd High Level
AEA09-FF-13-PH-C1	Fortification Sample, ME 13, Painter's Hat, 1st Control
AEA09-FF-13-PH-C2	Fortification Sample, ME 13, Painter's Hat, 2nd Control
AEA09-FF-13-PH-L1	Fortification Sample, ME 13, Painter's Hat, 1st Low Level
AEA09-FF-13-PH-L2	Fortification Sample, ME 13, Painter's Hat, 2nd Low Level
AEA09-FF-13-PH-L3	Fortification Sample, ME 13, Painter's Hat, 3rd Low Level
AEA09-FF-13-PH-H1	Fortification Sample, ME 13, Painter's Hat, 1st High Level
AEA09-FF-13-PH-H2	Fortification Sample, ME 13, Painter's Hat, 2nd High Level
AEA09-FF-13-PH-H3	Fortification Sample, ME 13, Painter's Hat, 3rd High Level
AEA09-FF-13-AR-C1	Fortification Sample, ME 13, Air Sampling Tube, 1st Control
AEA09-FF-13-AR-C2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Control
AEA09-FF-13-AR-L1	Fortification Sample, ME 13, Air Sampling Tube, 1st Low Level
AEA09-FF-13-AR-L2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Low Level
AEA09-FF-13-AR-L3	Fortification Sample, ME 13, Air Sampling Tube, 3rd Low Level
AEA09-FF-13-AR-H1	Fortification Sample, ME 13, Air Sampling Tube, 1st High Level
AEA09-FF-13-AR-H2	Fortification Sample, ME 13, Air Sampling Tube, 2nd High Level
AEA09-FF-13-AR-H3	Fortification Sample, ME 13, Air Sampling Tube, 3rd High Level
AEA09-FF-13-RES-C1	Fortification Sample, ME 13, RespiCon, 1st Control
AEA09-FF-13-RES-C2	Fortification Sample, ME 13, RespiCon, 2nd Control
AEA09-FF-13-RES-L1	Fortification Sample, ME 13, RespiCon, 1st Low Level
AEA09-FF-13-RES-L2	Fortification Sample, ME 13, RespiCon, 2nd Low Level
AEA09-FF-13-RES-L3	Fortification Sample, ME 13, RespiCon, 3rd Low Level
AEA09-FF-13-RES-H1	Fortification Sample, ME 13, RespiCon, 1st High Level
AEA09-FF-13-RES-H2	Fortification Sample, ME 13, RespiCon, 2nd High Level
AEA09-FF-13-RES-H3	Fortification Sample, ME 13, RespiCon, 3rd High Level
AEA09-FF-13-HW-C1	Fortification Sample, ME 13, Hand Wash, 1st Control
AEA09-FF-13-HW-C2	Fortification Sample, ME 13, Hand Wash, 2nd Control
AEA09-FF-13-HW-L1	Fortification Sample, ME 13, Hand Wash, 1st Low Level
AEA09-FF-13-HW-L2	Fortification Sample, ME 13, Hand Wash, 2nd Low Level
AEA09-FF-13-HW-L3	Fortification Sample, ME 13, Hand Wash, 3rd Low Level
AEA09-FF-13-HW-H1	Fortification Sample, ME 13, Hand Wash, 1st High Level
AEA09-FF-13-HW-H2	Fortification Sample, ME 13, Hand Wash, 2nd High Level
AEA09-FF-13-HW-H3	Fortification Sample, ME 13, Hand Wash, 3rd High Level
AEA09-FF-13-FW-C1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Control
AEA09-FF-13-FW-C2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Control
AEA09-FF-13-FW-L1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Low Level
AEA09-FF-13-FW-L2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Low Level
AEA09-FF-13-FW-L3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-13-FW-H1	Fortification Sample, ME 13, Face and Neck Wipe, 1st High Level
AEA09-FF-13-FW-H2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd High Level
AEA09-FF-13-FW-H3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd High Level
AEA09-FF-13-ID-C1	Fortification Sample, ME 13, Inner Dosimeter, 1st Control
AEA09-FF-13-ID-C2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Control
AEA09-FF-13-ID-L1	Fortification Sample, ME 13, Inner Dosimeter, 1st Low Level
AEA09-FF-13-ID-L2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Low Level
AEA09-FF-13-ID-L3	Fortification Sample, ME 13, Inner Dosimeter, 3rd Low Level
AEA09-FF-13-ID-H1	Fortification Sample, ME 13, Inner Dosimeter, 1st High Level
AEA09-FF-13-ID-H2	Fortification Sample, ME 13, Inner Dosimeter, 2nd High Level
AEA09-FF-13-ID-H3	Fortification Sample, ME 13, Inner Dosimeter, 3rd High Level
AEA09-FF-13-OD-C1	Fortification Sample, ME 13, Outer Dosimeter, 1st Control
AEA09-FF-13-OD-C2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Control
AEA09-FF-13-OD-L1	Fortification Sample, ME 13, Outer Dosimeter, 1st Low Level
AEA09-FF-13-OD-L2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Low Level
AEA09-FF-13-OD-L3	Fortification Sample, ME 13, Outer Dosimeter, 3rd Low Level
AEA09-FF-13-OD-H1	Fortification Sample, ME 13, Outer Dosimeter, 1st High Level
AEA09-FF-13-OD-H2	Fortification Sample, ME 13, Outer Dosimeter, 2nd High Level
AEA09-FF-13-OD-H3	Fortification Sample, ME 13, Outer Dosimeter, 3rd High Level
AEA09-FF-14-PH-C1	Fortification Sample, ME 14, Painter's Hat, 1st Control
AEA09-FF-14-PH-C2	Fortification Sample, ME 14, Painter's Hat, 2nd Control
AEA09-FF-14-PH-L1	Fortification Sample, ME 14, Painter's Hat, 1st Low Level
AEA09-FF-14-PH-L2	Fortification Sample, ME 14, Painter's Hat, 2nd Low Level
AEA09-FF-14-PH-L3	Fortification Sample, ME 14, Painter's Hat, 3rd Low Level
AEA09-FF-14-PH-H1	Fortification Sample, ME 14, Painter's Hat, 1st High Level
AEA09-FF-14-PH-H2	Fortification Sample, ME 14, Painter's Hat, 2nd High Level
AEA09-FF-14-PH-H3	Fortification Sample, ME 14, Painter's Hat, 3rd High Level
AEA09-FF-14-AR-C1	Fortification Sample, ME 14, Air Sampling Tube, 1st Control
AEA09-FF-14-AR-C2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Control
AEA09-FF-14-AR-L1	Fortification Sample, ME 14, Air Sampling Tube, 1st Low Level
AEA09-FF-14-AR-L2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Low Level
AEA09-FF-14-AR-L3	Fortification Sample, ME 14, Air Sampling Tube, 3rd Low Level
AEA09-FF-14-AR-H1	Fortification Sample, ME 14, Air Sampling Tube, 1st High Level
AEA09-FF-14-AR-H2	Fortification Sample, ME 14, Air Sampling Tube, 2nd High Level
AEA09-FF-14-AR-H3	Fortification Sample, ME 14, Air Sampling Tube, 3rd High Level
AEA09-FF-14-RES-C1	Fortification Sample, ME 14, RespiCon, 1st Control
AEA09-FF-14-RES-C2	Fortification Sample, ME 14, RespiCon, 2nd Control
AEA09-FF-14-RES-L1	Fortification Sample, ME 14, RespiCon, 1st Low Level
AEA09-FF-14-RES-L2	Fortification Sample, ME 14, RespiCon, 2nd Low Level
AEA09-FF-14-RES-L3	Fortification Sample, ME 14, RespiCon, 3rd Low Level
AEA09-FF-14-RES-H1	Fortification Sample, ME 14, RespiCon, 1st High Level
AEA09-FF-14-RES-H2	Fortification Sample, ME 14, RespiCon, 2nd High Level
AEA09-FF-14-RES-H3	Fortification Sample, ME 14, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-14-HW-C1	Fortification Sample, ME 14, Hand Wash, 1st Control
AEA09-FF-14-HW-C2	Fortification Sample, ME 14, Hand Wash, 2nd Control
AEA09-FF-14-HW-L1	Fortification Sample, ME 14, Hand Wash, 1st Low Level
AEA09-FF-14-HW-L2	Fortification Sample, ME 14, Hand Wash, 2nd Low Level
AEA09-FF-14-HW-L3	Fortification Sample, ME 14, Hand Wash, 3rd Low Level
AEA09-FF-14-HW-H1	Fortification Sample, ME 14, Hand Wash, 1st High Level
AEA09-FF-14-HW-H2	Fortification Sample, ME 14, Hand Wash, 2nd High Level
AEA09-FF-14-HW-H3	Fortification Sample, ME 14, Hand Wash, 3rd High Level
AEA09-FF-14-FW-C1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Control
AEA09-FF-14-FW-C2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Control
AEA09-FF-14-FW-L1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Low Level
AEA09-FF-14-FW-L2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Low Level
AEA09-FF-14-FW-L3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd Low Level
AEA09-FF-14-FW-H1	Fortification Sample, ME 14, Face and Neck Wipe, 1st High Level
AEA09-FF-14-FW-H2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd High Level
AEA09-FF-14-FW-H3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd High Level
AEA09-FF-14-ID-C1	Fortification Sample, ME 14, Inner Dosimeter, 1st Control
AEA09-FF-14-ID-C2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Control
AEA09-FF-14-ID-L1	Fortification Sample, ME 14, Inner Dosimeter, 1st Low Level
AEA09-FF-14-ID-L2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Low Level
AEA09-FF-14-ID-L3	Fortification Sample, ME 14, Inner Dosimeter, 3rd Low Level
AEA09-FF-14-ID-H1	Fortification Sample, ME 14, Inner Dosimeter, 1st High Level
AEA09-FF-14-ID-H2	Fortification Sample, ME 14, Inner Dosimeter, 2nd High Level
AEA09-FF-14-ID-H3	Fortification Sample, ME 14, Inner Dosimeter, 3rd High Level
AEA09-FF-14-OD-C1	Fortification Sample, ME 14, Outer Dosimeter, 1st Control
AEA09-FF-14-OD-C2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Control
AEA09-FF-14-OD-L1	Fortification Sample, ME 14, Outer Dosimeter, 1st Low Level
AEA09-FF-14-OD-L2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Low Level
AEA09-FF-14-OD-L3	Fortification Sample, ME 14, Outer Dosimeter, 3rd Low Level
AEA09-FF-14-OD-H1	Fortification Sample, ME 14, Outer Dosimeter, 1st High Level
AEA09-FF-14-OD-H2	Fortification Sample, ME 14, Outer Dosimeter, 2nd High Level
AEA09-FF-14-OD-H3	Fortification Sample, ME 14, Outer Dosimeter, 3rd High Level
AEA09-FF-15-PH-C1	Fortification Sample, ME 15, Painter's Hat, 1st Control
AEA09-FF-15-PH-C2	Fortification Sample, ME 15, Painter's Hat, 2nd Control
AEA09-FF-15-PH-L1	Fortification Sample, ME 15, Painter's Hat, 1st Low Level
AEA09-FF-15-PH-L2	Fortification Sample, ME 15, Painter's Hat, 2nd Low Level
AEA09-FF-15-PH-L3	Fortification Sample, ME 15, Painter's Hat, 3rd Low Level
AEA09-FF-15-PH-H1	Fortification Sample, ME 15, Painter's Hat, 1st High Level
AEA09-FF-15-PH-H2	Fortification Sample, ME 15, Painter's Hat, 2nd High Level
AEA09-FF-15-PH-H3	Fortification Sample, ME 15, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-AR-C1	Fortification Sample, ME 15, Air Sampling Tube, 1st Control
AEA09-FF-15-AR-C2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Control
AEA09-FF-15-AR-L1	Fortification Sample, ME 15, Air Sampling Tube, 1st Low Level
AEA09-FF-15-AR-L2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Low Level
AEA09-FF-15-AR-L3	Fortification Sample, ME 15, Air Sampling Tube, 3rd Low Level
AEA09-FF-15-AR-H1	Fortification Sample, ME 15, Air Sampling Tube, 1st High Level
AEA09-FF-15-AR-H2	Fortification Sample, ME 15, Air Sampling Tube, 2nd High Level
AEA09-FF-15-AR-H3	Fortification Sample, ME 15, Air Sampling Tube, 3rd High Level
AEA09-FF-15-RES-C1	Fortification Sample, ME 15, RespiCon, 1st Control
AEA09-FF-15-RES-C2	Fortification Sample, ME 15, RespiCon, 2nd Control
AEA09-FF-15-RES-L1	Fortification Sample, ME 15, RespiCon, 1st Low Level
AEA09-FF-15-RES-L2	Fortification Sample, ME 15, RespiCon, 2nd Low Level
AEA09-FF-15-RES-L3	Fortification Sample, ME 15, RespiCon, 3rd Low Level
AEA09-FF-15-RES-H1	Fortification Sample, ME 15, RespiCon, 1st High Level
AEA09-FF-15-RES-H2	Fortification Sample, ME 15, RespiCon, 2nd High Level
AEA09-FF-15-RES-H3	Fortification Sample, ME 15, RespiCon, 3rd High Level
AEA09-FF-15-HW-C1	Fortification Sample, ME 15, Hand Wash, 1st Control
AEA09-FF-15-HW-C2	Fortification Sample, ME 15, Hand Wash, 2nd Control
AEA09-FF-15-HW-L1	Fortification Sample, ME 15, Hand Wash, 1st Low Level
AEA09-FF-15-HW-L2	Fortification Sample, ME 15, Hand Wash, 2nd Low Level
AEA09-FF-15-HW-L3	Fortification Sample, ME 15, Hand Wash, 3rd Low Level
AEA09-FF-15-HW-H1	Fortification Sample, ME 15, Hand Wash, 1st High Level
AEA09-FF-15-HW-H2	Fortification Sample, ME 15, Hand Wash, 2nd High Level
AEA09-FF-15-HW-H3	Fortification Sample, ME 15, Hand Wash, 3rd High Level
AEA09-FF-15-FW-C1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Control
AEA09-FF-15-FW-C2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Control
AEA09-FF-15-FW-L1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Low Level
AEA09-FF-15-FW-L2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Low Level
AEA09-FF-15-FW-L3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd Low Level
AEA09-FF-15-FW-H1	Fortification Sample, ME 15, Face and Neck Wipe, 1st High Level
AEA09-FF-15-FW-H2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd High Level
AEA09-FF-15-FW-H3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd High Level
AEA09-FF-15-ID-C1	Fortification Sample, ME 15, Inner Dosimeter, 1st Control
AEA09-FF-15-ID-C2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Control
AEA09-FF-15-ID-L1	Fortification Sample, ME 15, Inner Dosimeter, 1st Low Level
AEA09-FF-15-ID-L2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Low Level
AEA09-FF-15-ID-L3	Fortification Sample, ME 15, Inner Dosimeter, 3rd Low Level
AEA09-FF-15-ID-H1	Fortification Sample, ME 15, Inner Dosimeter, 1st High Level
AEA09-FF-15-ID-H2	Fortification Sample, ME 15, Inner Dosimeter, 2nd High Level
AEA09-FF-15-ID-H3	Fortification Sample, ME 15, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-OD-C1	Fortification Sample, ME 15, Outer Dosimeter, 1st Control
AEA09-FF-15-OD-C2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Control
AEA09-FF-15-OD-L1	Fortification Sample, ME 15, Outer Dosimeter, 1st Low Level
AEA09-FF-15-OD-L2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Low Level
AEA09-FF-15-OD-L3	Fortification Sample, ME 15, Outer Dosimeter, 3rd Low Level
AEA09-FF-15-OD-H1	Fortification Sample, ME 15, Outer Dosimeter, 1st High Level
AEA09-FF-15-OD-H2	Fortification Sample, ME 15, Outer Dosimeter, 2nd High Level
AEA09-FF-15-OD-H3	Fortification Sample, ME 15, Outer Dosimeter, 3rd High Level
AEA09-FF-16-PH-C1	Fortification Sample, ME 16, Painter's Hat, 1st Control
AEA09-FF-16-PH-C2	Fortification Sample, ME 16, Painter's Hat, 2nd Control
AEA09-FF-16-PH-L1	Fortification Sample, ME 16, Painter's Hat, 1st Low Level
AEA09-FF-16-PH-L2	Fortification Sample, ME 16, Painter's Hat, 2nd Low Level
AEA09-FF-16-PH-L3	Fortification Sample, ME 16, Painter's Hat, 3rd Low Level
AEA09-FF-16-PH-H1	Fortification Sample, ME 16, Painter's Hat, 1st High Level
AEA09-FF-16-PH-H2	Fortification Sample, ME 16, Painter's Hat, 2nd High Level
AEA09-FF-16-PH-H3	Fortification Sample, ME 16, Painter's Hat, 3rd High Level
AEA09-FF-16-AR-C1	Fortification Sample, ME 16, Air Sampling Tube, 1st Control
AEA09-FF-16-AR-C2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Control
AEA09-FF-16-AR-L1	Fortification Sample, ME 16, Air Sampling Tube, 1st Low Level
AEA09-FF-16-AR-L2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Low Level
AEA09-FF-16-AR-L3	Fortification Sample, ME 16, Air Sampling Tube, 3rd Low Level
AEA09-FF-16-AR-H1	Fortification Sample, ME 16, Air Sampling Tube, 1st High Level
AEA09-FF-16-AR-H2	Fortification Sample, ME 16, Air Sampling Tube, 2nd High Level
AEA09-FF-16-AR-H3	Fortification Sample, ME 16, Air Sampling Tube, 3rd High Level
AEA09-FF-16-RES-C1	Fortification Sample, ME 16, RespiCon, 1st Control
AEA09-FF-16-RES-C2	Fortification Sample, ME 16, RespiCon, 2nd Control
AEA09-FF-16-RES-L1	Fortification Sample, ME 16, RespiCon, 1st Low Level
AEA09-FF-16-RES-L2	Fortification Sample, ME 16, RespiCon, 2nd Low Level
AEA09-FF-16-RES-L3	Fortification Sample, ME 16, RespiCon, 3rd Low Level
AEA09-FF-16-RES-H1	Fortification Sample, ME 16, RespiCon, 1st High Level
AEA09-FF-16-RES-H2	Fortification Sample, ME 16, RespiCon, 2nd High Level
AEA09-FF-16-RES-H3	Fortification Sample, ME 16, RespiCon, 3rd High Level
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-HW-C2	Fortification Sample, ME 16, Hand Wash, 2nd Control
AEA09-FF-16-HW-L1	Fortification Sample, ME 16, Hand Wash, 1st Low Level
AEA09-FF-16-HW-L2	Fortification Sample, ME 16, Hand Wash, 2nd Low Level
AEA09-FF-16-HW-L3	Fortification Sample, ME 16, Hand Wash, 3rd Low Level
AEA09-FF-16-HW-H1	Fortification Sample, ME 16, Hand Wash, 1st High Level
AEA09-FF-16-HW-H2	Fortification Sample, ME 16, Hand Wash, 2nd High Level
AEA09-FF-16-HW-H3	Fortification Sample, ME 16, Hand Wash, 3rd High Level
AEA09-FF-16-FW-C1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Control
AEA09-FF-16-FW-C2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Control
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-FW-L1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Low Level
AEA09-FF-16-FW-L2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Low Level

Sample ID Number	Description
AEA09-FF-16-FW-L3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd Low Level
AEA09-FF-16-FW-H1	Fortification Sample, ME 16, Face and Neck Wipe, 1st High Level
AEA09-FF-16-FW-H2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd High Level
AEA09-FF-16-FW-H3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd High Level
AEA09-FF-16-ID-C1	Fortification Sample, ME 16, Inner Dosimeter, 1st Control
AEA09-FF-16-ID-C2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Control
AEA09-FF-16-ID-L1	Fortification Sample, ME 16, Inner Dosimeter, 1st Low Level
AEA09-FF-16-ID-L2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Low Level
AEA09-FF-16-ID-L3	Fortification Sample, ME 16, Inner Dosimeter, 3rd Low Level
AEA09-FF-16-ID-H1	Fortification Sample, ME 16, Inner Dosimeter, 1st High Level
AEA09-FF-16-ID-H2	Fortification Sample, ME 16, Inner Dosimeter, 2nd High Level
AEA09-FF-16-ID-H3	Fortification Sample, ME 16, Inner Dosimeter, 3rd High Level
AEA09-FF-16-OD-C1	Fortification Sample, ME 16, Outer Dosimeter, 1st Control
AEA09-FF-16-OD-C2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Control
AEA09-FF-16-OD-L1	Fortification Sample, ME 16, Outer Dosimeter, 1st Low Level
AEA09-FF-16-OD-L2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Low Level
AEA09-FF-16-OD-L3	Fortification Sample, ME 16, Outer Dosimeter, 3rd Low Level
AEA09-FF-16-OD-H1	Fortification Sample, ME 16, Outer Dosimeter, 1st High Level
AEA09-FF-16-OD-H2	Fortification Sample, ME 16, Outer Dosimeter, 2nd High Level
AEA09-FF-16-OD-H3	Fortification Sample, ME 16, Outer Dosimeter, 3rd High Level
AEA09-FF-17-PH-C1	Fortification Sample, ME 17, Painter's Hat, 1st Control
AEA09-FF-17-PH-C2	Fortification Sample, ME 17, Painter's Hat, 2nd Control
AEA09-FF-17-PH-L1	Fortification Sample, ME 17, Painter's Hat, 1st Low Level
AEA09-FF-17-PH-L2	Fortification Sample, ME 17, Painter's Hat, 2nd Low Level
AEA09-FF-17-PH-L3	Fortification Sample, ME 17, Painter's Hat, 3rd Low Level
AEA09-FF-17-PH-H1	Fortification Sample, ME 17, Painter's Hat, 1st High Level
AEA09-FF-17-PH-H2	Fortification Sample, ME 17, Painter's Hat, 2nd High Level
AEA09-FF-17-PH-H3	Fortification Sample, ME 17, Painter's Hat, 3rd High Level
AEA09-FF-17-AR-C1	Fortification Sample, ME 17, Air Sampling Tube, 1st Control
AEA09-FF-17-AR-C2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Control
AEA09-FF-17-AR-L1	Fortification Sample, ME 17, Air Sampling Tube, 1st Low Level
AEA09-FF-17-AR-L2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Low Level
AEA09-FF-17-AR-L3	Fortification Sample, ME 17, Air Sampling Tube, 3rd Low Level
AEA09-FF-17-AR-H1	Fortification Sample, ME 17, Air Sampling Tube, 1st High Level
AEA09-FF-17-AR-H2	Fortification Sample, ME 17, Air Sampling Tube, 2nd High Level
AEA09-FF-17-AR-H3	Fortification Sample, ME 17, Air Sampling Tube, 3rd High Level
AEA09-FF-17-RES-C1	Fortification Sample, ME 17, RespiCon, 1st Control
AEA09-FF-17-RES-C2	Fortification Sample, ME 17, RespiCon, 2nd Control
AEA09-FF-17-RES-L1	Fortification Sample, ME 17, RespiCon, 1st Low Level
AEA09-FF-17-RES-L2	Fortification Sample, ME 17, RespiCon, 2nd Low Level
AEA09-FF-17-RES-L3	Fortification Sample, ME 17, RespiCon, 3rd Low Level

Sample ID Number	Description
AEA09-FF-17-RES-H1	Fortification Sample, ME 17, RespiCon, 1st High Level
AEA09-FF-17-RES-H2	Fortification Sample, ME 17, RespiCon, 2nd High Level
AEA09-FF-17-RES-H3	Fortification Sample, ME 17, RespiCon, 3rd High Level
AEA09-FF-17-HW-C1	Fortification Sample, ME 17, Hand Wash, 1st Control
AEA09-FF-17-HW-C2	Fortification Sample, ME 17, Hand Wash, 2nd Control
AEA09-FF-17-HW-L1	Fortification Sample, ME 17, Hand Wash, 1st Low Level
AEA09-FF-17-HW-L2	Fortification Sample, ME 17, Hand Wash, 2nd Low Level
AEA09-FF-17-HW-L3	Fortification Sample, ME 17, Hand Wash, 3rd Low Level
AEA09-FF-17-HW-H1	Fortification Sample, ME 17, Hand Wash, 1st High Level
AEA09-FF-17-HW-H2	Fortification Sample, ME 17, Hand Wash, 2nd High Level
AEA09-FF-17-HW-H3	Fortification Sample, ME 17, Hand Wash, 3rd High Level
AEA09-FF-17-FW-C1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Control
AEA09-FF-17-FW-C2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Control
AEA09-FF-17-FW-L1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Low Level
AEA09-FF-17-FW-L2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Low Level
AEA09-FF-17-FW-L3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd Low Level
AEA09-FF-17-FW-H1	Fortification Sample, ME 17, Face and Neck Wipe, 1st High Level
AEA09-FF-17-FW-H2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd High Level
AEA09-FF-17-FW-H3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd High Level
AEA09-FF-17-ID-C1	Fortification Sample, ME 17, Inner Dosimeter, 1st Control
AEA09-FF-17-ID-C2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Control
AEA09-FF-17-ID-L1	Fortification Sample, ME 17, Inner Dosimeter, 1st Low Level
AEA09-FF-17-ID-L2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Low Level
AEA09-FF-17-ID-L3	Fortification Sample, ME 17, Inner Dosimeter, 3rd Low Level
AEA09-FF-17-ID-H1	Fortification Sample, ME 17, Inner Dosimeter, 1st High Level
AEA09-FF-17-ID-H2	Fortification Sample, ME 17, Inner Dosimeter, 2nd High Level
AEA09-FF-17-ID-H3	Fortification Sample, ME 17, Inner Dosimeter, 3rd High Level
AEA09-FF-17-OD-C1	Fortification Sample, ME 17, Outer Dosimeter, 1st Control
AEA09-FF-17-OD-C2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Control
AEA09-FF-17-OD-L1	Fortification Sample, ME 17, Outer Dosimeter, 1st Low Level
AEA09-FF-17-OD-L2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Low Level
AEA09-FF-17-OD-L3	Fortification Sample, ME 17, Outer Dosimeter, 3rd Low Level
AEA09-FF-17-OD-H1	Fortification Sample, ME 17, Outer Dosimeter, 1st High Level
AEA09-FF-17-OD-H2	Fortification Sample, ME 17, Outer Dosimeter, 2nd High Level
AEA09-FF-17-OD-H3	Fortification Sample, ME 17, Outer Dosimeter, 3rd High Level
AEA09-FF-18-PH-C1	Fortification Sample, ME 18, Painter's Hat, 1st Control
AEA09-FF-18-PH-C2	Fortification Sample, ME 18, Painter's Hat, 2nd Control
AEA09-FF-18-PH-L1	Fortification Sample, ME 18, Painter's Hat, 1st Low Level
AEA09-FF-18-PH-L2	Fortification Sample, ME 18, Painter's Hat, 2nd Low Level
AEA09-FF-18-PH-L3	Fortification Sample, ME 18, Painter's Hat, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-PH-H1	Fortification Sample, ME 18, Painter's Hat, 1st High Level
AEA09-FF-18-PH-H2	Fortification Sample, ME 18, Painter's Hat, 2nd High Level
AEA09-FF-18-PH-H3	Fortification Sample, ME 18, Painter's Hat, 3rd High Level
AEA09-FF-18-AR-C1	Fortification Sample, ME 18, Air Sampling Tube, 1st Control
AEA09-FF-18-AR-C2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Control
AEA09-FF-18-AR-L1	Fortification Sample, ME 18, Air Sampling Tube, 1st Low Level
AEA09-FF-18-AR-L2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Low Level
AEA09-FF-18-AR-L3	Fortification Sample, ME 18, Air Sampling Tube, 3rd Low Level
AEA09-FF-18-AR-H1	Fortification Sample, ME 18, Air Sampling Tube, 1st High Level
AEA09-FF-18-AR-H2	Fortification Sample, ME 18, Air Sampling Tube, 2nd High Level
AEA09-FF-18-AR-H3	Fortification Sample, ME 18, Air Sampling Tube, 3rd High Level
AEA09-FF-18-RES-C1	Fortification Sample, ME 18, RespiCon, 1st Control
AEA09-FF-18-RES-C2	Fortification Sample, ME 18, RespiCon, 2nd Control
AEA09-FF-18-RES-L1	Fortification Sample, ME 18, RespiCon, 1st Low Level
AEA09-FF-18-RES-L2	Fortification Sample, ME 18, RespiCon, 2nd Low Level
AEA09-FF-18-RES-L3	Fortification Sample, ME 18, RespiCon, 3rd Low Level
AEA09-FF-18-RES-H1	Fortification Sample, ME 18, RespiCon, 1st High Level
AEA09-FF-18-RES-H2	Fortification Sample, ME 18, RespiCon, 2nd High Level
AEA09-FF-18-RES-H3	Fortification Sample, ME 18, RespiCon, 3rd High Level
AEA09-FF-18-HW-C1	Fortification Sample, ME 18, Hand Wash, 1st Control
AEA09-FF-18-HW-C2	Fortification Sample, ME 18, Hand Wash, 2nd Control
AEA09-FF-18-HW-L1	Fortification Sample, ME 18, Hand Wash, 1st Low Level
AEA09-FF-18-HW-L2	Fortification Sample, ME 18, Hand Wash, 2nd Low Level
AEA09-FF-18-HW-L3	Fortification Sample, ME 18, Hand Wash, 3rd Low Level
AEA09-FF-18-HW-H1	Fortification Sample, ME 18, Hand Wash, 1st High Level
AEA09-FF-18-HW-H2	Fortification Sample, ME 18, Hand Wash, 2nd High Level
AEA09-FF-18-HW-H3	Fortification Sample, ME 18, Hand Wash, 3rd High Level
AEA09-FF-18-FW-C1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Control
AEA09-FF-18-FW-C2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Control
AEA09-FF-18-FW-L1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Low Level
AEA09-FF-18-FW-L2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Low Level
AEA09-FF-18-FW-L3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd Low Level
AEA09-FF-18-FW-H1	Fortification Sample, ME 18, Face and Neck Wipe, 1st High Level
AEA09-FF-18-FW-H2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd High Level
AEA09-FF-18-FW-H3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd High Level
AEA09-FF-18-ID-C1	Fortification Sample, ME 18, Inner Dosimeter, 1st Control
AEA09-FF-18-ID-C2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Control
AEA09-FF-18-ID-L1	Fortification Sample, ME 18, Inner Dosimeter, 1st Low Level
AEA09-FF-18-ID-L2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Low Level
AEA09-FF-18-ID-L3	Fortification Sample, ME 18, Inner Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-ID-H1	Fortification Sample, ME 18, Inner Dosimeter, 1st High Level
AEA09-FF-18-ID-H2	Fortification Sample, ME 18, Inner Dosimeter, 2nd High Level
AEA09-FF-18-ID-H3	Fortification Sample, ME 18, Inner Dosimeter, 3rd High Level
AEA09-FF-18-OD-C1	Fortification Sample, ME 18, Outer Dosimeter, 1st Control
AEA09-FF-18-OD-C2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Control
AEA09-FF-18-OD-L1	Fortification Sample, ME 18, Outer Dosimeter, 1st Low Level
AEA09-FF-18-OD-L2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Low Level
AEA09-FF-18-OD-L3	Fortification Sample, ME 18, Outer Dosimeter, 3rd Low Level
AEA09-FF-18-OD-H1	Fortification Sample, ME 18, Outer Dosimeter, 1st High Level
AEA09-FF-18-OD-H2	Fortification Sample, ME 18, Outer Dosimeter, 2nd High Level
AEA09-FF-18-OD-H3	Fortification Sample, ME 18, Outer Dosimeter, 3rd High Level

Antimicrobial Exposure Assessment Task Force II (AEATF II)

INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN

October 25, 2013

Revision Date: 10/25/2013

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INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN

1. Introduction

This document summarizes the rationale for critical elements of the design of the AEATF II interior latex paint application with brush and roller monitoring study. Brush and roller application of interior latex paint represents an exposure scenario being addressed as part of the overall AEATF II monitoring program. Airless sprayer application of interior latex paint represents another exposure scenario which will be addressed by AEATF II in a separate study as part of the overall AEATF II monitoring program. AEATF II in consultation with EPA made the decision to separate the brush and roller, and airless sprayer, interior latex paint application studies after a careful evaluation was made of the appropriate study designs. AEATF II proposes to conduct the brush and roller study using consumer applicators (without experience as professional painters), as use by typical consumer painters is likely to result in higher exposure than would be seen using professional painters as applicators. In contrast, AEATF II proposes to conduct a separate airless sprayer study using applicators with recent experience as professional painters using airless spray equipment. AEATF II anticipates that the level of training and experience necessary to safely operate commercial airless spraying equipment necessitates the use of experienced professional painters. Since the pool of potential subjects is separate for these two painting scenarios, AEATF II intends to perform each scenario as a separate study.

2. Scenario definition

A scenario is defined as a set of related tasks, pesticide formulations, equipment, engineering controls, and worker and/or consumer practices. For the purposes of the AEATF II Monitoring Program, the **interior latex paint application with brush and roller scenario** is defined as the hand-held application using a paint brush and/or paint roller of a formulated interior latex paint containing an antimicrobial chemical. This includes the task of actual painting for purposes of protection and beautification of architectural and other surfaces. The application of paint with a brush and roller represents a common application method by consumers, and is also used by commercial painters, as an alternative to a paint spray system. The interior latex paint application with brush and roller scenario is being used to address potential exposures to paint products in general, including latex paints, acrylic paints, epoxy paints, stains, sealants, etc. The interior latex paint was selected to represent this group of paint products because it is a commonly used product type, the application process (brush and roller) is similar across all paint product types, and all paint categories are considered similar for exposure purposes (*Standard Operating Procedures (SOPs) for Residential Exposure Assessment,* US Environmental Protection Agency, 2012).

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In practice, paint application may or may not involve follow-on tasks, such as cleaning of the painting equipment, removing protective barriers from non-target surfaces, etc. Only the actual paint application is covered by this scenario. Applicator exposure associated with cleaning painting equipment is likely to result in a decrease in residues on the applicator's hands as washing equipment with water will also wash the applicator's hands. Cleaning of equipment may result in increased residues on the applicator's clothing due to splashing, however this may be less than any reduction in hand residues. In addition, applicators may not clean their equipment after each days use. As a result, AEATF II feels the more conservative approach is to monitor only the actual painting.

The AEATF II study restricts the paint application with brush and roller scenario to consumer applicators only. This focus on consumer applicators is considered the more conservative approach, given that consumer painters are expected to be less skilled than professional painters. A less skilled painter is more likely to expose themselves to drips and paint spills. It is expected that consumer painter exposure will be above the limits of quantification/detection of the analytical method. The amount of product handled per task, and per day can be used to extrapolate potential exposure to professional painters.

Thus, the AEATF II exposure data for brush and roller paint application of antimicrobial pesticides would be 'conservative' (i.e., would over-predict) if used to describe professional application exposure. However, it would be reasonable for regulatory agencies using the data to assume that exposure levels for professional applicators, when normalized for the amount of active ingredient handled, are not greater than those for consumer applicators.

3. Existing paint application with brush and roller exposure data

3.1. PHED studies

Since 1992 the EPA has conducted professional and consumer mixer/loader and applicator exposure and risk assessments relying primarily on the exposure data in PHED. PHED version 1.01 was initially released in February 1992, followed by PHED version 1.1 in February 1995. PHED version 1.1 was described by the Agency as an incremental improvement over the 1.01 version (Pesticide Handlers Exposure Database, User's Guide Version 1.1, Health Canada, U.S. Environmental Protection Agency, American Crop Protection Association, February 1995). PHED does include one study conducted using paintbrush application methods, but the data does not include paint roller application. Relevant characteristics of this study are summarized in Table 1.

Table 1: Summary of Paintbrush Application Studies in PHED

Study Design	Study 467
Active Ingredient:	Surrogate
Type of Use:	Paintbrush application
Monitoring Events (ME):	15
Product Applied:	~0.05 lb a.i.
Location:	MD
Analytical Grade(s)	AB (hands), C (dermal, inhalation)

Unfortunately, this study has limitations that reduce its value for an antimicrobial-oriented generic database. This study monitors paintbrush application only, but is being used to extrapolate to application with brush and roller combined. It appears that every ME within the study applied an identical amount of product. Thus, there is no variation in amount of a.i. handled within the study. In addition, both the dermal and inhalation exposure data from study 467 have only an analytical quality grade of C. To support the registration of a pesticide, the data should have an analytical grade of A or B. As a result, study 467 has limitations for use in regulatory exposure assessments.

3.2. Gijsbers study

In addition to PHED, a review of published literature was made to look for studies evaluating exposure to non-volatile paint components. Although numerous studies were available evaluating exposure to paint solvents, only one suitable study was located which studied a non-volatile chemical (Gijsbers et. al., 2004).

This study was a comprehensive investigation including dermal exposure from painting with a brush/roller conducted in The Netherlands to provide data to the European risk assessment database (RISKODERM). The study evaluated subject exposure to DEGBE (2-(2-Butoxyethoxy)ethanol) which was a component of the latex paint used at concentrations ranging from 0.4-3.2%. Subjects painted surfaces at construction sites primarily with a brush and sometimes a roller. Dermal and hand exposure were evaluated. However, this study was found to be lacking in several key areas.

1) No mention was made of good laboratory practices, quality assurance reviews, or other regulatory standards being followed.

2) No evaluation was made of potential inhalation exposure to DEGBE.

3) Non-hand dermal samples were only collected from 12 monitoring events.

4) Field recoveries were unacceptable due to background contamination at multiple sites, reducing the number of data points available.

5) The same subject was used for up to four monitoring events with most subjects monitored twice resulting in less than 12 valid and unique monitoring events for hand residues.

3.3. Removal efficiency studies

A review of published literature was made to look for studies evaluating removal efficiency of the proposed active ingredient, benzisothiazoline-3-one (BIT), from human skin. No studies were found which addressed this issue. A pilot experiment conducted at Golden Pacific Laboratories using mannequin hands as a surrogate recovered 88% of BIT applied in latex paint. AEATF II proposes conducting a separate study for the purpose of determining removal efficiency from human skin of BIT at two application levels in latex paint and solvent (n=10 hands per group). These subjects would have a small volume of latex paint containing BIT, or BIT in isopropyl alcohol, applied to the palmar surfaces of each hand and allowed to dry. Following 30 minutes drying time the paint would be removed using the technique developed with mannequin hands: scrubbing the hand with dressing sponges wetted with isopropyl alcohol/water (1/1) followed by rinsing with the same solvent. Each hand would be evaluated separately to increase sample size while minimizing the number of subjects.

4. Goal of the AEATF II paint application with brush and roller monitoring study

The AEATF II program, as described in the Governing Document (2008), intends to develop a database of exposure monitoring data that can be used to support practical regulatory decisions about future exposures for different (including currently nonexistent) active ingredients and their associated products. The database needs to address a variety of exposure scenarios for which no or limited data currently exist. The paint application with brush and roller scenario is an important component of the AEATF II program and the focus of this protocol. As noted in the previous section, existing monitoring data for this scenario are considered inadequate.

The primary purpose of the paint application with brush and roller monitoring study is to develop more accurate information on potential consumer and worker exposures to antimicrobials. These data will consist of dermal and inhalation exposure estimates derived from monitoring subjects under conditions constructed to broadly represent those expected for the future application of arbitrary antimicrobial pesticides. AEATF II

anticipates the resulting database will contain sufficient data to support exposure assessments for paint application with brush and roller.

For the paint application with brush and roller scenario (as is true for all AEATF II scenarios) only a small number of expensive experimentally-obtained monitoring events (MEs) are possible. Each ME represents the exposure possible for a single future handler-day. Although it is only a single task, paint application with a brush and roller still encompasses more handling conditions than any small number of MEs can practically include in a single study. For example, there are many possible active ingredients (ai), different application equipment used, multiple concentrations of active ingredient used, different volumes of product used, different workers and their associated behaviors, and multiple environmental and other handling conditions. All of these are expected to affect exposure to varying degrees.

In view of this limitation, a practical goal for this study is that the small sample of paint application with brush and roller MEs be biased towards increased diversity of handling conditions. As a result, the diverse sample of MEs is expected to at least cover the middle portion of the future exposure distribution, cover the upper portion of the future exposure distribution, and capture the range of exposure variation that is expected to exist. It is important to recognize that some degree of overestimation bias is inherent in any study if the exposures measured on the inner dosimeters from MEs are less than limit of quantitation (LOQ). This is more likely to occur in the lower exposure groups, although AEATF II is making every effort to obtain measurable exposures at all intervals. Another potential source of inherent overestimation bias in the study design described in this document and the associated protocol is reusing the same rooms for multiple painters. The residue remaining from prior uses represents a source of potential contamination for subsequent users, and will require adequate drying time and background monitoring to mitigate. A final source of overestimation bias in the study design is the use of an indoor site. AEATF II feels that an indoor painting environment is likely to increase dermal exposure over an outdoor painting environment due to the painting of ceiling surfaces which represent a significant source for drips and splatter. The AEATF II also feels that an indoor painting environment has a higher potential for inhalation exposure due to the limited air exchanges compared to an outdoor painting environment. The AEATF II does not foresee significant sources of underestimation bias for exposure estimates derived from data resulting from the proposed study.

The successful use of a small sample of MEs to represent the diversity in the target population of future 'painting-days' is aided by the following:

1. Dermal and inhalation exposure to the chemicals are considered generic (i.e., independent of the particular active ingredient used). This *generic principle* permits use of a small set of surrogate active ingredients to predict exposure for other active ingredients;
2. The *principle of proportionality* of exposure to the true amount of active ingredient contact. If a diverse amount of active ingredient handled (AaiH) is used across MEs, then exposures measured for one level of AaiH can be used to predict different levels of AaiH; and

3. *Expert knowledge* of possible handler conditions expected throughout the scenario permits re-construction (and/or selection) of synthetic MEs that represent a diverse set of future paint application with brush and roller conditions.

5. Diversity selection of monitoring events

A diversity selection approach is being used by the AEATF II to implement the paint application with brush and roller study. In the AEATF II approach, instances of possible handler-day conditions under the scenario are synthetically constructed and handler-day exposures measured using surrogate painters. These conditions (including painters) are either purposively or randomly chosen in such a manner that the synthetic handler-days (i.e., monitoring events, or "MEs") span the diversity of conditions in the scenario. The ME construction approach used by the AEATF II achieves diversity by:

1. Using multiple application dates within purpose built painting rooms in the study area (Fresno Co., CA);
2. Varying the levels of potential AI contact; and
3. Using different workers for each ME rather than repeated use of the same worker.

Diversifying these three 'meta-characteristics' indirectly varies many known and unknown handling-conditions. Purposively varying other minor handling-conditions, such as the sequence of surfaces painted, can further reduce homogeneity of MEs within the single site.

The AEATF II has determined, in consultation with the U.S. EPA, Health Canada, and California EPA, that a purposive diversity selection (PDS) approach is appropriate considering the regulatory purpose of the data and feasibility. A PDS approach is one that is primarily purposive but can be coupled with random choice elements when feasible to reduce intentional selection bias. The AEATF II Governing Document (2008) describes diversity and purposive diversity selection more generally in the context of the AEATF II Monitoring Program.

5.1. Painting rooms and equipment

The paint application with brush and roller monitoring study will be conducted in purpose built monitoring rooms inside a vacant building in Fresno County, CA. This particular geographic area was selected given its proximity to the analytical laboratory. Fresno County also contains a moderately large metropolitan area and offers a population of over 1,000,000 persons. Consequently, there is a substantial pool of possible subjects and a large number of vacant commercial buildings that are potentially acceptable for monitoring activities.

The use of a single geographic area and site is based on the premise that indoor paint application with brush and roller tasks being performed at a site in one geographical

area will not differ substantially from a similar array of tasks being performed at sites in another geographical area. That is, the variation in exposure associated with paint application with brush and roller inside of a building in Fresno County, CA would not be expected to differ substantially if another building in Fresno County, or in another metropolitan area were used or multiple cities over the country were spanned. This premise is supported by the Popendorf et al. (1992) antimicrobial exposure monitoring study which concluded that variability in dermal and inhalation exposures across workers was primarily influenced by the application method and by implication, each individual worker's implementation of that application method (i.e., their work practices and behavior), rather than the location or setting in which the application method is performed. This implies that monitoring multiple subjects and capturing diversity in indoor paint application with brush and roller conditions that might influence behavior is more important than geographic or site diversity.

Geographic differences in exposure that have been observed in some agricultural cohorts are not expected for paint application with brush and rollers. For example, in harvesters, climatic conditions that influence the degree of dustiness, the rate of dissipation of foliar pesticide residues, or the amount of perspiration may influence exposure. Those differences cannot really be considered regional, but rather environmental. In the case of painting services conducted indoors, the environmental conditions are constrained by heating, ventilating and air conditioning systems that control dustiness, temperature, humidity and airflow. Therefore, these conditions are expected to be similar throughout the country. Further the majority of exposure from painting is expected to be dermal due to drips and spills. This type of exposure is expected to be most associated with equipment and application technique.

Limited standardization of painting practices is another factor that is expected to lessen the importance of geographic area. Consumer painters may receive informal training in brush and roller application techniques from multiple sources. Some of these sources include: instruction from staff at paint sales outlets, instruction from other consumers with painting experience, and watching of home improvement television shows. This helps to insure that painting tasks are conducted somewhat uniformly across the country.

Lastly, there is increased efficiency, convenience, and cost savings associated with the use of a single site location near the analytical laboratory. The use of buildings located over multiple geographical locations would be especially costly. The cost of selecting both buildings and subjects would increase at least in proportion to the number of geographic locations due to construction, field team logistics and resources required. For the reasons outlined above, there would appear to be little benefit from such an increase in cost.

Monitoring will always be conducted inside purpose built rooms within a vacant commercial building or vacant areas and rooms within this building. The purpose built rooms will include walls, ceiling, door with frame, window frame, and baseboards. These rooms will be built to represent a "typical" residential room and provide a

combination of trim surfaces to be painted with a brush plus flat surfaces to be painted with a roller. The purpose in conducting these studies in a vacant building/area is to be free from personal interferences with non-subjects and the potential contamination from other sources of a commonly-used active ingredient (i.e., BIT). It also makes it easier to design monitoring events that focus on paint application with brush and roller only as opposed to the broad range of painting activities a subject might engage in that could also involve the active ingredient. Using vacant buildings also offers greater control of the scheduling of monitoring events. This combination of facility (building or building complex) and monitoring period (i.e. dates) is termed a 'site'. Only a single site will be used for this study.

Monitoring events will use a single type of application equipment (brush and roller). Generically speaking the type of equipment used will represent the most commonly used consumer equipment. The "most commonly used" designation was determined by AEATF II from available "top seller" lists on websites of national home improvement stores, and from conversations with paint store personnel. The equipment is defined by materials and techniques used in the construction of the roller and brush. The equipment used will be recommended by the manufacturer for use with indoor latex paint. For example the following set of painting equipment would be considered appropriate:

Table 2: Example brush and roller selection

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

Common materials used in constructing paint rollers including medium density polyester, high density polyester, microfiber, lambswool, and others including combinations. The roller nap generally ranges from 1/4" to 3/4", but can also be smooth foam. The construction material and nap length determine how much paint the roller holds, how well it spreads, the ability to penetrate rough surfaces, and the smoothness of the applied paint. The 3/8" nap high density polyester is the most commonly used roller cover and is considered appropriate for semi-rough to smooth surfaces such as interior walls. A longer nap would be appropriate for rough surfaces such as exterior stucco. Paintbrushes for home painting are typically 1 to 5" in width and either straight or angled. The most common sizes are 2 to 3" and both straight and angled brushes are commonly sold. Paintbrush materials include various synthetic and natural fibers, with synthetic fibers generally being more common and less expensive. AEATF II has selected a 3" straight polyester brush as a common design which is a Home Depot best seller. AEATF II is not aware of any studies relating roller or paintbrush construction with painter exposure.

As part of the painting task, painters will be allowed the use of dry "painter's rags." These rags will be used by surrogate painters to wipe excessive liquid paint drips and spills. AEATF II believes that the use of painter's rags represents standard practice for both consumer and professional painters, and is a practical necessity to deal with spills and large drips while painting.

5.2. Varying concentration of product applied

The second key diversity meta-parameter controlled by diversity selection for the paint application with brush and roller study is the amount of active ingredient handled (AaiH) per workday. All MEs in the study will use the same active ingredient, benzisothiazoline-3-one (BIT), at one of three concentrations using pre-formulated latex paint. The target concentrations of BIT in the paint will be 120 ppm (mg/Kg), 400 ppm and 600 ppm. The selected target concentrations are the expected native level of BIT in the manufactured paint, a concentration 5X the lowest concentration, and an intermediate level. The paint concentrations are expected to be sufficient to allow good method sensitivity, but include a safety margin to ensure BIT does not exceed safe levels. AEATF II feels that use of three concentrations of BIT is appropriate since the primary exposure medium is paint. Consequently, AaiH will be directly proportional to the concentration times the total amount of paint applied over the entire workday. To determine the amount of paint applied, some reasonable value for the expected range of this meta-parameter among painters is needed.

Table 3 summarizes information on the frequency and amount of paint applied by consumers annually. These data were obtained from the Exposure Factors Handbook (EPA 2011).

Table 3: The amount of latex paint applied for consumer painters.

Applicator Type	Mean number of painting events per year	Mean Annual Latex Paint Use	90th Percentile Annual Latex Paint Use
Consumer	4	371 oz	857 oz

A household survey of interior painters (Westat, 1987) reported a mean of 4 painting events per year with latex paint, and a mean of 4 gallons of paint used. It was unclear from the Westat question if respondents were indicating gallons per year or per event.

Using Table 3 the amount of paint applied by consumers per painting event has a mean of 0.7 gallons and a 90th percentile value of 1.7 gallons. The actual amount will vary from room to room, from day to day, and from person to person. However, this amount

is not expected to vary independently. There will certainly be some degree of correlation for all rooms painted by the same individual. There is likely to be correlation between different painters as well, since the goal of all painters is to cover the painted surface completely but avoid drips. In order to accomplish this goal the paint needs to be applied to a similar coating thickness by all painters.

For the AEATF II paint application with brush and roller study, the analytical method LOQ sets a practical lower limit on the amount of paint that should be used for an ME. Obviously it is desirable to obtain actual measurements, rather than non-detects, beneath normal work clothing. For this scenario, it is felt that an application of approximately 2 gallons (target range 1.75 to 2.25 gallons) per ME will achieve detectable levels of active ingredients on dosimetry matrices.

The time spent applying paint with a brush and roller will also limit the number of gallons applied. The Exposure Factors Handbook lists the mean time painting for consumer painters as 3 hours correlated with a mean volume of paint applied of 0.7 gallons. Although there are no preparation and cleanup tasks required for painters in the paint application with brush and roller study, it is expected that the application of approximately 2 gallons of paint will take multiple hours. The time spent painting will be recorded and reported for each ME, but no specific time will be required as volume of paint applied will be the primary parameter.

Thus, these results suggest that reasonable diversity in AaiH among MEs could be obtained by varying the concentration of paint applied with a fixed volume of approximately 2 gallons. Each ME will be randomly assigned to one of the three concentration strata.

5.3. Varying surrogate painters

The final meta-characteristic that is formally varied is the surrogate painter. These are consumers without professional painting experience, who are available and consent to perform these tasks at/in appropriate facilities on the specified dates. These are referred to as surrogate painters because they are not viewed as any sample from an existing population of painters. Rather they are viewed simply as another component of the synthetic ME that is being constructed to predict a single instance of a future day's exposure to an arbitrary antimicrobial pesticide. Each surrogate painter provides his/her unique set of behaviors to the painting task. Use of the same painter for all monitoring events would over-represent a single type of behavior. As a result, diversification of painter behavior among MEs is accomplished by simply requiring that each ME be based on a different surrogate painter.

Surrogate painters will all be consumers with at least one residential painting experience in the past 5 years, but no professional painting experience, who reside in the Fresno CA metropolitan area. AEATF II intends to require painting experience as an inclusion criterion since a completely inexperienced painter will require instruction.

Subjects with prior painting experience may have obtained instruction from a variety of sources including friends, paint supply stores, how-to articles, etc. AEATF II feels it important to maintain diversity by requiring subjects have this prior experience, rather than receiving instruction from study personnel. Advertisements soliciting subjects will be posted in the major local newspaper, the Fresno Bee, as well as newspapers circulating in the Spanish speaking community and the African-American community. Individuals who express a desire to participate in the study within a fixed period of time will be contacted and screened in random order. Individuals who meet the study requirements will be recruited until the required number of surrogate painters is obtained. Surrogate painters are randomly assigned to MEs. As a precaution, more participants are recruited than are expected to be needed.

This process results in a simple random sample of qualifying subjects from the volunteer pool. Note, however, that is not the same as a random sample from the existing population of non-professional consumer painters. By definition, volunteers are self-selected and could have different characteristics than non-volunteers. Such distinctions have no relevance in this case, however. There is no particular need to obtain a random sample from the Fresno consumer painter population. This existing population is not the target population for the study. The MEs are synthetic constructs that attempt to predict aspects of a future handler-day population. It is purposive by definition. Thus, a random sample of just one ME component (e.g. subject) from a subpopulation (e.g. Fresno County) provides no statistical advantage. In fact, a random sample of subjects from the volunteer pool is not the only possibility. For example, a more diverse sample of surrogate painters from this pool could also be acceptable if a clear diversifying characteristic were available for all painters. Lacking this, the paint application with brush and roller study uses the reasonable default option of a random sample from the volunteer pool.

6. Sample size determination

The sample size of this study will be 18 MEs, with 6 MEs randomly assigned to each AI concentration strata. The number of MEs was determined by EPA in discussion with AEATF II to be appropriate to achieve the benchmark objective in studies of this general design type. For the paint application with brush and roller study, the benchmark objective is that sample estimates of the arithmetic mean and 95th percentile of normalized exposure are accurate to within 3-fold 95% of the time. The EPA, in discussion with AEATF II, determined that this benchmark is sufficient for regulatory purposes. If the benchmark objective is not achieved after completion of the 18 MEs AEATF II will consult with EPA to determine if additional MEs are required.

7. References

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. American Chemistry Council, Arlington, VA.

AHETF (Agricultural Handlers Exposure Task Force). 2007. Governing Document Document for A Multi-Year Pesticide Handler Worker Exposure Monitoring Program. 2007. Draft Report. Agricultural Handlers Exposure Task Force. Johnson Management & Consulting, LLC, Macon, MO.

Aklam and Associates Inc. and the National Food Laboratory. 2006. AEJV "Amount Used" Study. Prepared for the Antimicrobial Exposure Joint Venture, Chemical Specialty Products Association, Washington, DC.

EPA (U.S. Environmental Protection Agency). 1998. PHED Surrogate Exposure Guide, Estimates of Worker Exposure from the Pesticide Handler Exposure Database, Version 1.1, August (1988).

EPA (U.S. Environmental Protection Agency). 2007. SAP Minutes No. 2007-03. A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Review of Worker Exposure Assessment Methods. January 9 – 12, 2007. FIFRA Scientific Advisory Panel Meeting. U.S. EPA, Arlington, VA.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol.* Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Jacobs, L. and L. Juster. (2006). ANTIMICROBIAL EXPOSURE JOINT VENTURE NATIONAL ANTIMICROBIAL USE SURVEY: DIARY STUDY (PHASE II). Prepared for the Antimicrobial Exposure Joint Venture, Chemical Specialty Products Association, Washington, DC. Prepared by TNO NFO, Chicago, IL.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa.

Westat Inc., 1987. *National Household Survey of Interior Painters*. Final Report.

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the

American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or paint products; if you have psoriasis, eczema, sores or open cuts on your skin; if you have severe diabetes; if you have a suppressed immune system such as with an organ transplant or active chemotherapy; or if you have heart or breathing problems.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, or the laboratory General Manager, Thomas Moate, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your safety glasses. We will give you a closed

paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The research will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an

allergic reaction to the paint. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates Independent Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of each informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Schulman Associates Independent Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.

Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation

CERTIFICATE OF COMPLETION

This certificate is herby granted to:

ROBERT TESTMAN

to certify that he/she has completed

Collaborative Institutional Training Initiative (CITI Training)
Investigator Biomedical Basic Modules

Granted: April 15, 2011

Anita McSharry, IO — Date: 5/2/11

Megan Boatwright

From: Robert Testman
Sent: Friday, November 08, 2013 10:46 AM
To: Megan Boatwright
Subject: FW: eSubmission System - Document Submission Confirmation
Attachments: CV PI AND SUBI.pdf; EPA INSPECTION.pdf

From: Robert Testman
Sent: Friday, November 8, 2013 8:54 AM
To: 'Jeffrey Atlas'
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Jeff,

Remaining docs attached. We have not received an official close out letter for the 2012 EPA inspection so I included the inspectors handwritten findings sheet. His only finding relates to the sponsor of a study we did the analytical on, not to our facility.

Let me know if there is anything missing, etc.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, November 8, 2013 8:43 AM
To: Robert Testman
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Robert,

No problem. Feel free to send them as an attachment in your response to this email. I will be sure they get included with the entire study submission.

Thanks.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
tlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, November 08, 2013 11:42 AM
To: Jeffrey Atlas
Subject: FW: eSubmission System - Document Submission Confirmation
Importance: High

Hi Jeff,

I had a problem submitting a new study. I attached the site submission document but did not get the other documents attached. Not sure how I was supposed to go back and get more documents. Hitting Browse Files then submitted the study. How do I submit the remaining documents?

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Friday, November 8, 2013 8:39 AM
To: Robert Testman
Subject: eSubmission System - Document Submission Confirmation
Importance: High

Robert,

The following documents have been successfully submitted via Schulman IRB **eSubmission** system:

Submission Type:	Initial Submission - New Study (Single-Site)
Document Types Checked:	Site Submission Form CVs (PI/QI and Sub-Investigators) Protocol Informed Consent (Unlocked Word Version) Additional documents
Additional Document Types Listed:	Study Design Rationale
Additional Instructions:	For the Florida review board

List of Uploaded Files
(1) submission form.docx (101.8 KB)

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone	559-275-9091

Email: rtestman@gplabs.com

CHULMAN Associates IRB, Inc.
www.sairb.com

CURRICULUM VITAE

NAME AND TITLE:

Robert J. Testman, President

EDUCATION:

University of Southern California – Masters of Business Administration, 2001
University of California, Berkeley, B.A., Molecular Biology/Biophysics, 1991

PROFESSIONAL EXPERIENCE:

Date: March 2010 to Present
Title: President, Golden Pacific Laboratories, Fresno, CA.

Responsible for setting up, developing, and managing an analytical laboratory which conducts residue analysis in soils, water, raw agricultural commodities, processed commodities, worker exposure and re-entry media. All studies are conducted in compliance with FDA GLP standards, FIFRA GLP Standards and various EPA Pesticide Assessment Guidelines as appropriate. Worker exposure studies are conducted in compliance with IRB, HSRB, CDPR, and other applicable guidelines. Laboratory setup included ordering instrumentation, glassware, chemicals, solvents, along with equipment/instrument installation. Setup also included developing procedures, data forms, SOPs, and all other items necessary to be in compliance with GLPs. Responsible for developing cost quotations, study-specific protocols, and interacting with personnel from major agriculture chemical companies, along with interviewing, hiring, training, directing, and supervising senior chemists, chemists, and laboratory technicians. Directly supervises worker exposure studies assuring proper training of staff participating in human subject research as well as ethical treatment of subjects, IRB review of protocols, etc. Directly involved with the conduct of analytical sample analysis, methods development, and the training and supervision of chemists and laboratory technicians. Act as study director or assign study director for ongoing studies.

Date: February 16, 2004 to March 2010
Title: Vice President, Services Development, Golden Pacific Laboratories, LLC (GPL), Fresno, CA

Responsible for operational support and business development for analytical chemistry lab including:

- Strategic planning for new business areas
- Prepare marketing strategy and materials
- Prepare laboratory procedures
- Identify needed equipment / supplies
- Identify and negotiate with laboratory partners
- Train lab personnel in execution of procedures
- Prepare template protocols and reports
- Prepare customer proposals and contracts
- Supervise and troubleshoot projects as needed
- Serve as Study Director as needed
- Serve as Study Director's Management when President of company is functioning as Study Director (e.g. worker exposure studies).
- Serve as Laboratory Management to oversee studies as needed
- Ensure compliance with GLP regulations
- Follow-up with customers to ensure satisfaction

Date: October 2001 to February 2004
Title: West Coast Business Development Manager, Charles River Laboratories, Wilmington, MA

- Responsible for forecasting and achieving revenue targets from West Coast clients.
- Responsible for management of client relationships in Western U.S. including:
  - Development of opportunities for Charles River to work with new clients throughout the Western U.S.
  - Maintenance of existing client relationships
- Problem solving resource for clients
- Negotiated new service agreements and fee schedules
- Presented capabilities and data to numerous sponsors
- Attend scientific conferences and meetings to understand and report on market trends, competitor strengths / weaknesses, etc.

Date: September 1997 to October 2001
Title: Manager, Pharmacokinetics and Drug Metabolism, B/Braun Medical, Irvine, CA

- Served as Study Director on numerous GLP and non-GLP studies, responsible for planning, execution, review, report preparation and presentation of results.
- Responsible for successful completion of numerous studies, including:
  - ADME, blood kinetics, ocular distribution, toxicokinetics, etc.
  - Development and validation of new analytical methods.
  - Optimization of formulation for oral absorption.
- Participated in phase 1/2 clinical trial planning and observed conduct of trials.
- Developed relationships with numerous study sponsors including: initial discussions, customer audits, study design and planning, presentations, preparing price quotations, follow-up contacts, etc.
- Supervised and managed all work of in-house staff of 11 Technicians and 2 Scientists as well as numerous programs at outside contract labs.
- Responsible for interaction with FDA and EPA during GLP audits with no 483 items in last three biannual FDA inspections.

Date: September 1995 to September 1997
Title: Group Leader, Pharmacokinetics and Drug Metabolism, B/Braun Medical, Irvine, CA

- Responsible for all aspects of Preclinical Development for former parent corporation (IVAX Inc.) including evaluation of efficacy and safety for new drug candidates in conjunction with company Toxicologist.
- Corporate Radiation Safety Officer.

Date: January 1992 to September 1994
Title: Senior/Associate Chemist, Pharmacokinetics and Drug Metabolism, B/Braun Medical, Irvine, CA

- Supervised and assisted technical staff in performance of PK studies.
- Wrote Study Protocols and Reports for PK studies.
- Developed and validated analytical methods.
- Collaborated with outside mass spectroscopy facilities for bioanalytical and metabolite identification projects.

Date: September 1990 to January 1992
Title: Associate Research Scientist, Process Development, Bayer Pharmaceuticals, Berkeley, CA

- Responsible for evening and weekend supervision of MAB research facility.
- Developed new equipment and techniques.
- Performed analysis and testing including: sterility, viability and ELISA testing.

PROFESSIONAL AND TECHNICAL TRAINING:

Collaborative Institutional Training Initiative (CITI Training) Investigator Biomedical Basic Modules, Independent Investigational Review Board, Inc (IIRB), April 15, 2011
GLP Training, The International Center for Health and Environmental Education, January 14, 1993
GLP Training, GLPS E-Learning Course 2012

PROFESSIONAL MEMBERSHIPS:

American Chemical Society
American Association of Pharmaceutical Scientists
International Society for the Study of Xenobiotics

STATEMENT:

For purposes of GLP compliance, I acknowledge this to be a true and correct curriculum vitae.

Robert Testman, President — Date: 06/25/13

CURRICULUM VITAE

NAME AND TITLE:

Megan T. Boatwright, Laboratory Manager, Archivist

EDUCATION:

College of Notre Dame, Belmont, California, B.S. Biochemistry, May 2000
Madera High School, Madera, California, High School Diploma, June 1996

PROFESSIONAL EXPERIENCE:

Date: October 4, 2006 to Present
Title: Laboratory Manager/Archivist, Golden Pacific Laboratories, LLC (GPL), Fresno, CA
Date: October 1, 2001 to October 4, 2006
Title: Chemist, Golden Pacific Laboratories, LLC (GPL), Fresno, CA (formally CCRL Changed March 2004)

Responsible for managing an analytical laboratory which conducts residues analysis in soils, water, raw agricultural commodities, processed commodities, consumer products, worker exposure and re-entry media. Analyses are conducted in compliance with FIFRA GLP Standards and various EPA Pesticide Assessment Guidelines or Food and Drug Administration (FDA) guidelines. Responsible for developing cost quotations, study-specific protocols, and interacting with personnel from major agricultural chemical companies. Directly involved with conduct of analytical sample analysis and method development, along with training, directing and supervising chemists, laboratory technicians and laboratory assistants. Ensures all safety requirements are met, including conducting safety training of laboratory personnel and enforcing safety policies. Directly train and supervise data coordinator in assigned tasks. Responsible as Quality Control (QC) to conduct daily review of data sets being generated by analyst.

Functions as a Principal Analytical Investigator and/or Study Director for GLP studies. Responsible for the conduct of methods development, method validation, and sample analysis from start to completion of studies. Conducts exposure studies in environmental exposure room and analysis of samples generated from Magnitude of the Residue, Turf Transferable, Worker Exposure and other assigned studies. Compiles and tabulates data for analytical reports for submission to sponsor or study director. Interacts with and addresses Quality Assurance Unit report and in-life audit comments and ensures GLP compliance on assigned projects. Interacts and communicates with sponsors on project status and technical aspects of projects on a regular basis.

Accurately measure weights and volumes. Handles solvents, acids, bases and hazardous chemicals. Documents in logbooks and other raw data forms, in accordance with SOPs and the Good Laboratory Practice (GLP) Standards, applicable Environmental Protection Agency (EPA) or Food and Drug Administration (FDA) requirements. Designs or modifies data forms to accommodate simple or routine procedures. Follows laboratory procedures and written procedures. Performs extractions and prepares final extracts for analysis. Operates laboratory equipment such as GC's. HPLC's, LC/MS/MS, centrifuges, rotary evaporators, pH meters, ovens, balances, etc. Calibrates applicable equipment. Responsible for routine maintenance of equipment and basic troubleshooting. Performs and understands basic mathematical calculations (e.g., addition, subtraction, multiplication, division, simple proportions, standard curve calculations, unit conversions, etc.). Enters data into computer programs. Performs other duties as instructed by laboratory management.

Archivist responsibilities include archiving and tracking of reports and raw data in accordance with the GLP standards. Also responsible for updating and maintaining the archive systems.

Date: May 2000 to September 2001
Title: APS Analytical Standards – Chemist; Advances Polymer System, Redwood City, CA

Responsible for formulation of all product lines; developed new product lines; maintained maintenance and calibration of all instruments; worked in high stress atmosphere; trouble shot product related questions, communication with end user via telephone and website forum.

Date: June 1997 to September 1999
Title: Surgical Services; University Medical Center, Fresno, CA

Delivers specimens, blood, and other needed products between the laboratory and the operating room; transported patients to and from the operating room; kept inventory of supply room and stocked supplies as needed.

Date: August 1997 to May 2000
Title: Office Assistant/Coordinator – Student Activities, College of Notre Dame, Belmont, CA

Assisted Student Director in daily tasks; informed staff and students of upcoming events; worked independently on projects pertaining to student activities.

PROFESSIONAL AND TECHNICAL TRAINING:

Protecting Human Research Participants, National Institute of Health (NIH) Online Course, May 25, 2011
Business Writing and Grammar Skills Made Easy and Fun!, SkillPath Seminars, March 8-9, 2011
Human Participant Protection Education for Research Teams, National Institute of Health (NIH) Online Course, May 7, 2007
Excelling as a First-Time Manager or Supervisor, SkillPath Seminars, March 14, 2007
4000/3200 Q Trap Small Molecule Basic Training, Applied Biosystems, January 9-12, 2007
Analyst Software Training, Applied Biosystems, August 2006
HPLC/MS/MS Seminar, Applied Biosystems, April 2006
Bioanalytical Chemistry Training using LC/MS/MS, Bioanalytical Chemistry Training and Consulting, April 2004
GLP Training, CCRL, November 2001

PROFESSIONAL MEMBERSHIPS:

The National Alliance of Independent Crop Consultants (NAICC), January 2012

STATEMENT:

For purposes of GLP compliance, I acknowledge this to be a true and correct curriculum vitae.

Megan T. Boatwright
Megan T. Boatwright, Laboratory Manger, Archivist

June 26, 2013
Date

06/26/13

CURRICULUM VITAE

NAME AND TITLE:

Natan R. Chavez , Laboratory Technician

EDUCATION:

Fresno City College, A.S Liberal studies 2002-2008
High School Graduate - 2002

PROFESSIONAL AND TECHNICIAL EXPERIENCE:

Date: October 2009 to Present
Title: Laboratory Technician, Golden Pacific Laboratories, LLC(GPL), Fresno, CA (Changed January 2010)
Laboratory Assistant, Golden Pacific Laboratories, LLC (GPL), Fresno, CA

Responsible for processing, handling and storing samples. Maintains proper storage and cleaning of glassware, equipment and work areas in the laboratory. Performs basic laboratory duties such as washing glassware, cleaning pipets and syringes. Assists with administrative duties such as pagination copying of raw data, preparation of raw data package indexes and title pages. Accurately measure weights and volumes. Handles solvents, acids, bases and hazardous chemicals. Documents in log books and other raw data forms, in accordance with SOP's and the Good Laboratory Practice (GLP) Standards, applicable Environmental Protection Agency (EPA) or Food and Drug Administration (FDA) requirements. Designs or modifies data forms to accommodate simple or routine procedures. Follows Laboratory procedures and written procedures. Performs extractions and prepares final extracts for analysis. Operates general laboratory equipment such as centrifuges, rotary evaporators, pH meters, ovens, balances, etc. Calibrates applicable equipment. Conducts exposure studies in environmental exposure room. Responsible for routine maintenance of equipment and basic trouble shooting. Performs and understands basic mathematical calculations(e.g., addition, subtraction, multiplication, division, simple proportions, standard curve calculations, unit conversions, etc.). Enters data into computer programs. Addresses QA recommendations/ findings with guidance from senior staff. Performs other duties as instructed and supervised by laboratory management.

Date: May 2008 to September 2008
Title: Bergelectric- Apprentice, Rancho Cordova, CA

Duties included installing electrical systems in all phases of construction.

Date: October 2006 to January 2008
Title: BSK Labs- Lab Technician, Fresno, CA

Duties included, performing analysis such as BOD, COD, and BTU's as per standard methods.

PROFESSIONAL AND TECHNICAL TRAINING:

GLP Training, GPL, November 2008
NIH Web-based training course "Protecting Human Research Participants", GPL, July 2009
Dionex Corporation "ASE Operators Training Couse on ASE 200", Dionex, December 2009

Bi-Lingual, English-Spanish fluent

STATEMENT:
For purposes of GLP compliance, I acknowledge this to be a true and correct Curriculum Vitae.

8/2/2012
Natan R. Chavez, Laboratory Technician — Date

FM 08/02/12
FM 06/26/13

CURRICULUM VITAE

NAME AND TITLE:

Thomas F. Moate, General Manager

EDUCATION:

Oregon State University, 1996, M.S. Toxicology, Minor – Agricultural Chemistry
University of Idaho, 1991, B.S. Chemistry Education

PROFESSIONAL AND TECHNICIAL EXPERIENCE:

Date: August 2009 to Present
Title: General Manager, Golden Pacific Laboratories, LLC (GPL), Fresno, CA

Responsible for managing an analytical laboratory which conducts residues analysis in soils, water, raw agricultural commodities, processed commodities, consumer products, worker exposure and re-entry media and bioanalytical studies supporting the pharmaceutical industry. Residue analyses are conducted in compliance with FIFRA GLP Standards and various EPA Pesticide Assessment Guidelines or Food and Drug Administration (FDA) guidelines. Responsible for developing cost quotations, study-specific protocols, and interacting with personnel from major agricultural chemical and pharmaceutical companies. Direct laboratory staff and provide a supportive environment for research and occupational development. Manage operations of facility including procurement of instrumentation and acquisition of resources to meet business objectives. Review and approve analytical phase Sponsor reports for submission to the Environmental Protection Agency (EPA). Experience in marketing an analytical laboratory to prospective clients.

Function as a Principal Analytical Investigator and/or Study Director for GLP and non-GLP studies. Responsible for the conduct of method development, method validation, and sample analysis from start to completion of studies. Interacts with and addresses Quality Assurance Unit report and in-life audit comments and ensures GLP compliance on assigned projects. Interacts and communicates with sponsors on project status and technical aspects of projects on a regular basis. Perform other duties as instructed by GPL President.

Date: May 2006 to July 2009
Title: Study Director, MDS Pharma Services, Bothell, WA

Study Director for discovery pharmacokinetic (PK) research projects. Responsible for study conduct, client communication and reporting. Assemble and lead project teams of up to five scientists and technicians. Design and write study protocols and reports to meet internal and client specifications. Compile, calculate and analyze bioanalytical and PK data. Assist business development group in pricing and contracting new projects for first time clients. First point of contact for new studies with repeat clients.

Lead scientist for bioanalytical method development and qualification of LC/MS/MS assays. Train and assist junior staff in LC/MS/MS instrument operation and bioanalytical procedures. Research, test and implement methods of analysis for challenging compounds. Source and procure laboratory equipment and services for instrumentation including negotiating service contracts.

Date: June 2001 to April 2006
Title: Supervisor, Analytical Chemistry, SNBL USA, Everett, WA

Managed Analytical Chemistry Laboratory in the Department of Formulations and Analytical Services. Supervised three full-time and several part-time chemists and research associates, including staff with advanced degrees. Assigned staff and instrumentation resources for up to thirty concurrent projects and scheduled regular, intermediate goals on tight time schedules. Created, developed, and reviewed project protocols, procedures and reports. Set and reviewed performance criteria for analytical and bioanalytical method validations. Facilitated regular communication for the completion of interdepartmental goals and business functions with cooperative stakeholders, i.e., Clients, Study Monitors, Quality Assurance, Toxicology, Business Development & Contracts, Information Technology, and Health & Safety. Responsible for analytical laboratory equipment including HPLC, HPLC-MS, and LC/MS/MS instruments.

Ensured regulatory compliance with FDA Good Laboratory Practices (GLPs) in support of preclinical studies. Responded to regulatory audits for laboratory and project compliance to GLPs from clients, internal QAU personnel and the FDA (three successful inspections). Coordinated and implemented equipment qualifications including computerized systems for FDA 21 CFR Part 11 regulatory compliance.

Date: April 1997 to June 2001
Title: Research Scientist, University of Washington School of Public Health and Community Medicine, Seattle, WA

Lead scientist for the analytical chemistry in support of a research initiative to determine the potential exposure of children to environmental sources of pesticides. Developed, transferred and validated analytical methods for the quantitative determination of pesticide residues and metabolites. Wrote, reviewed and approved technical analytical reports to describe study conditions, experiments, results and conclusions. Prepared cost estimates for analytical services to internal, cost center clients. Wrote, revised and reviewed SOPs in support of laboratory and facility functions compliant with national American Industrial Hygiene Association laboratory accreditation standards. Supervised two part-time technicians. Participated on graduate student committees.

Date: September 1992 to April 1997
Title: Faculty Research Assistant, Oregon State University Department of Agricultural Chemistry, Corvallis, OR

Developed a pesticide exposure assessment model for agricultural workers. Conducted research on agricultural worker pesticide exposure with a focus on biomonitoring, field sampling, and development of trace analytical residue methods for HPLC, GC and GC-MS analyses. Practiced modern human health risk assessment methodology for inhalation and dermal exposures. Performed statistical analyses and presented research results graphically and orally at scientific conferences. Supervised laboratory activities for graduate students and technicians. Directed undergraduate student research.

PROFESSIONAL AND TECHNICAL TRAINING:

SELECTED SPECIALIZED TRAINING:

National Institute of Health	Online	Human Participant Protection Education For Research Teams	2009
University of Arizona	Tucson, AZ	Principles of Pharmacokinetics and Toxicokinetics	2007
Applied Biosystems	Foster City, CA	API4000 QTrap Advanced Operator	2006
The Leadership Edge	Everett, WA	Laboratory to Leadership	2006
Applied Biosystems	Foster City, CA	API 4000 Operator LC/MS/MS System	2004
SNBL USA, Ltd.	Everett, WA	Techniques of Effective Management	2004
Meta Technologies Inc.	Everett, WA	21 CFR Part 11 Compliance	2002
West Coast Quality Training	Everett, WA	GLP's for Scientists and Study Directors	2002

FIRST AUTHOR PUBLICATIONS:

T.F. Moate, M. Furia, C. Curl, J.F. Muniz, J. Yu, and R.A. Fenske, *Size Exclusion Chromatographic Cleanup for GC/MS Determination of Organophosphorus Pesticide Residues in Household and Vehicle Dust.* J. AOAC International **85** 2002 Number 1, p. 36.

T.F. Moate, C. Lu, R.A. Fenske, R.M.A. Hahne, D.A. Kalman, *Improved Cleanup and Determination of Dialkyl Phosphates in the Urine of Children Exposed to Organophosphorus Insecticides.* J. of Analytical Toxicology, **23** 1999 Number 4, p. 230.

T.F. Moate, J.J. Jenkins, *Gas Chromatographic Determination of Airborne Residues of Azinphosmethyl and Azinphosmethyl-oxon With Cool On-Column Injection.* Journal of Chromatography, **1997.**

OTHER PROFESSIONAL ACTIVITIES:

- Officer, Pacific Northwest Mass Spectrometry Group. Treasurer 2006 to 2009.
- Instructor, Short Course: Organophosphate Residues & Their Metabolites; Field Sampling & Analysis for Human Health Research. Center for Advanced Studies of Environmental Toxicology, Mexico City, 1999.

PROFESSIONAL SOCIETIES:

American Chemical Society, 1992 - present
Pacific Northwest Mass Spectrometry Group, 2002 - present

STATEMENT:

For purposes of GLP compliance, I acknowledge this to be a true and correct Curriculum Vitae.

Thomas F. Moate, General Manager — Date 08/01/12

RJT 8/1/12

reviewed TM 06/26/13

RJT 06/26/13

EPA

INSPECTION OBSERVATIONS

ADDRESS (EPA OFFICE)
1200 Pennsylvania Ave, NW
Washington, D.C. 20460

DATE
Sept 18, 2012

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Robert J. Testman

TITLE
President

FIRM NAME AND ADDRESS:
Golden Pacific Laboratories

FACILITY INSPECTED ADDRESS:
4720 West Jennifer Ave
Suite 105
FRESNO, CA 93722

DURING AN INSPECTION/AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Study [redacted] the study director did not include the Laboratory's exclusion noted in their final Report GLP Compliance state into the Overall GLP Compliance State. The Study director did not include the QA inspections from the Laboratory (Analytical) into the Final Report of the sponsor. The above finding pertains to the sponsor of the final report.

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT

THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE	TITLE
Robert J. Testman	President
PREPARED BY: Elmer Griffin	TITLE Compliance Officer

EPA 3540-38 (12-95)

U.S. ENVIRONMENTAL PROTECTION AGENCY

RECEIPT FOR SAMPLES

ADDRESS (EPA Regional Office)
1200 Pennsylvania Ave, NW
Washington. D.C 20460

DATE
Sept 18, 2012

NAME OF INDIVIDUAL
Mr. Robert J. Testman

TITLE
President

FIRM NAME
Golden Pacific Laboratories

ADDRESS (Street, City, State and Zip Code)
4720 West Jennifer Ave
Suite 105
FRESNO, CA 93722

SAMPLE NUMBERS

SAMPLES COLLECTED (Describe fully. List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.)

The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged persuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form.

(1) Organization Chart
(2) Floor Plan

ACKNOWLEDGMENT OF PRODUCER/REGISTRANT

The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.

SIGNATURE (Owner, Operator, or Agent)
Robert J. Testman

TITLE (Owner, Operator or Agent)
President

☐ DUPLICATE SAMPLES REQUESTED AND PROVIDED ☐ DUPLICATE SAMPLES NOT REQUESTED

SAMPLES WERE ☐ PURCHASED ☐ BORROWED

AMOUNT PAID FOR SAMPLES
$

☐ CASH ☐ VOUCHER ☐ TO BE BILLED

NAME OF COLLECTOR (Print or type)	TITLE OF COLLECTOR	SIGNATURE OF COLLECTOR
Elmer Griffin	Compliance Officer	Elmer Griffin

EPA Form 3540-3 (Rev. 8-75) PREVIOUS EDITION TO BE USED UNTIL SUPPLY IS EXHAUSTED.

ESTABLISHMENT COPY

U.S. ENVIRONMENTAL PROTECTION AGENCY

GOOD LABORATORY PRACTICE
NOTICE OF INSPECTION

ADDRESS (EPA Office) 1200 Pennsylvania Ave, NW Washington, D.C. 20460

DATE 18 Sept 2012

HOUR 9 45 AM PM

FIRM NAME: Golden Pacific Laboratories	FIRM ADDRESS (NUMBER, STREET, CITY, STATE AND ZIP CODE): 4720 West Jennifer Ave Suite 105 Fresno, CA 93722
NAME OF OWNER OR AGENT IN CHARGE: Thomas Moate	
SIGNATURE OF OWNER OR AGENT IN CHARGE (*SIGNATURE GRANTS CONSENT TO INSPECTION*): Thomas F. Moate	SIGNATURE OF EPA EMPLOYEE: Elmer Griffin
TITLE: General Manager	TITLE: Compliance Officer

REASON FOR INSPECTION:

☒ FOR THE PURPOSE OF PERFORMING AN INSPECTION PURSUANT TO THE GOOD LABORATORY PRACTICE STANDARDS SPECIFIED IN SECTION 40 CFR PART 160

☒ FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, SECTIONS 8 and 12(a)(2)(B), AND IN SECTION 40 CFR PART 169.

☐

☐

VIOLATION SUSPECTED: None

EPA Form 3540-40 (1-94)
★U.S. GPO: 1994-300-835/00253

2 - ESTABLISHMENT COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 2 3 2011

Ms. Anantdeep K. Kang
Golden Pacific Laboratories
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722-6420

Re: December 7 - 8, 2010 Good Laboratory Practice Standards inspection and data quality audit under 40 CFR Parts 160 and 169 of the Federal Insecticide, Fungicide and Rodenticide Act.

Dear Ms. Kang:

I am pleased to inform you that based upon a review of the information gathered at the above referenced inspection and data audit, we are closing the file regarding this inspection. As the enclosed inspection report indicates, the inspector did not identify any potential compliance problems.

Please remember that our determination is not an endorsement of your laboratory, and this letter is not an approval of your facility; accordingly it may not be used in any marketing or marketing activities.

Thank you for your cooperation during the inspection. If you have questions, please contact me at (202) 564-2365.

Sincerely,

Francisca Liem, Director
Good Laboratory Practice (GLP) Program
Office of Compliance

Enclosure

Internet Address (URL) • http://www.epa.gov
Recycled/Recyclable • Printed with Vegetable Oil Based Inks on Recycled Paper (Minimum 25% Postconsumer)

Megan Boatwright

From: Robert Testman
Sent: Friday, November 08, 2013 10:41 AM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Jeff,

I checked on the prior study I referenced. I believe IIRB used the study number 070270b since revisions were made following HSRB review, although we used 070270 as our study number. That's where I was hoping to avoid confusion this time. I am fine with getting a conditional approval or whatever you want to call it and submitting a final protocol after any HSRB comments are incorporated.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, November 8, 2013 8:43 AM
To: Robert Testman
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Robert,

No problem. Feel free to send them as an attachment in your response to this email. I will be sure they get included with the entire study submission.

Thanks.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, November 08, 2013 11:42 AM

To: Jeffrey Atlas
Subject: FW: eSubmission System - Document Submission Confirmation
Importance: High

Hi Jeff,

I had a problem submitting a new study. I attached the site submission document but did not get the other documents attached. Not sure how I was supposed to go back and get more documents. Hitting Browse Files then submitted the study. How do I submit the remaining documents?

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Friday, November 8, 2013 8:39 AM
To: Robert Testman
Subject: eSubmission System - Document Submission Confirmation
Importance: High

Robert,

The following documents have been successfully submitted via Schulman IRB **eSubmission** system:

Submission Type:	Initial Submission - New Study (Single-Site)
Document Types Checked:	Site Submission Form CVs (PI/QI and Sub-Investigators) Protocol Informed Consent (Unlocked Word Version) Additional documents
Additional Document Types Listed:	Study Design Rationale
Additional Instructions:	For the Florida review board

List of Uploaded Files
(1) submission form.docx (101.8 KB)

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone	559-275-9091
Email:	rtestman@gplabs.com

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Friday, November 08, 2013 10:45 AM
To: Robert Testman
Cc: Megan Boatwright
Subject: RE: eSubmission System - Document Submission Confirmation

Hi Rob,

Thanks! That did the trick! I appreciate it.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
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Sent: Friday, November 08, 2013 1:41 PM
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Hi Jeff,

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rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

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No problem. Feel free to send them as an attachment in your response to this email. I will be sure they get included with the entire study submission.

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Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

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Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

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Sent: Friday, November 8, 2013 8:39 AM
To: Robert Testman
Subject: eSubmission System - Document Submission Confirmation
Importance: High

Robert,

The following documents have been successfully submitted via Schulman IRB **eSubmission** system:

Submission Type: Initial Submission - New Study (Single-Site)

Document Types Checked:	Site Submission Form CVs (PI/QI and Sub-Investigators) Protocol Informed Consent (Unlocked Word Version) Additional documents
Additional Document Types Listed:	Study Design Rationale
Additional Instructions:	For the Florida review board

List of Uploaded Files
(1) submission form.docx (101.8 KB)

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone	559-275-9091
Email:	rtestman@gplabs.com

SCHULMAN Associates IRB, Inc.
www.sairb.com

Megan Boatwright

From: Robert Testman
Sent: Wednesday, November 13, 2013 7:38 AM
To: Megan Boatwright
Subject: FW: Protocol 120463, for Board review on 11/14/2013

From: Robert Testman
Sent: Wednesday, November 13, 2013 7:38 AM
To: 'Denisse Guzman'
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Denisse,

In response to your questions:

1. The protocol will be reviewed by HSRB after incorporating your comments. It will then be revised to respond to any HSRB comments and submitted to you again for final approval of any changes. I would prefer to submit this as a draft and then submit a final version (including a redlined copy) if HSRB has changes, rather than issuing amendments to a protocol before it is signed.
2. The on-site health professional will be a RNs that we contract to provide study support. We have worked with two different RNs in the past and plan to work with one of those two again here since they have prior experience on these studies and have taken the appropriate course. But they are not our employees and are subject to availability (which is why we have worked with two in the past). I did not think they should be included in the sub-investigator category, but can add them if you prefer.

Feel free to give me a call to discuss either of these items.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Tuesday, November 12, 2013 11:19 AM
To: Robert Testman
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin
Subject: Protocol 120463, for Board review on 11/14/2013

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Please return your response to my attention at dguzman@sairb.com.

Should you have any questions, please do not hesitate to contact me.

Thank you for your prompt attention to this matter.

Denisse Guzman, CIM | Board Liaison
Shulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6774
dguzman@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

Megan Boatwright

From: Robert Testman
Sent: Wednesday, November 13, 2013 11:50 AM
To: Denisse Guzman
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin; Megan Boatwright
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Attachments: Willa H.pdf

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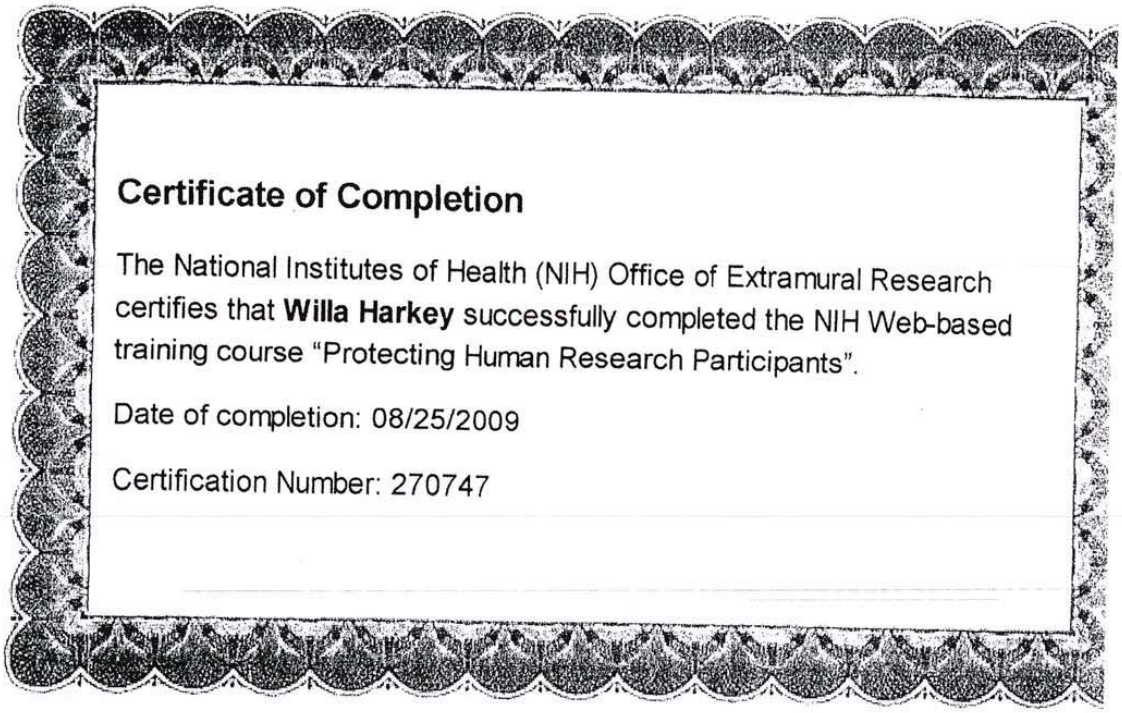
http://php.nihtraining.com/users/cert.php?c=20974



Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Willa Harkey** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 08/25/2009

Certification Number: 270747

000321

CALIFORNIA
BOARD OF REGISTERED NURSING

Registered Nurse
License: 320486

WILLA MAE HARKEY

Expiration: 01/31/2012
Status: ACTIVE

SIGNATURE

LICENSEE: The law requires that you notify the Board of name or address changes within 30 days.

EMPLOYERS: Always verify current license status by using the online verification at www.rn.ca.gov

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Registered Nursing
1625 N. Market Blvd., Suite N-217
Sacramento, CA 95834-1924
(916) 322-3350

000322

Megan Boatwright

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To: Robert Testman
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Subject: RE: Protocol 120463, for Board review on 11/14/2013

Thanks Robert. No need to send the updated copy but we will need her CV.

If you can provide us with that as soon as possible that would be great.

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Megan Boatwright

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To: Robert Testman
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013
Attachments: 120463 SSN - Conditionally Approved.pdf

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Study Status Notification

DATE: 11/14/2013

TO: Robert J. Testman, M.B.A.

FROM: **Jeff Atlas**, Operation Specialist
Schulman Associates IRB, Inc.

RE: **Protocol#:** 120463
Sponsor: Antimicrobial Exposure Assessment Task Force II
IRB#: 201307317
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board reviewed the above-referenced protocol (11/4/2013) and informed consent(s) at the 11/14/2013 meeting and identified issues to be addressed by the Sponsor/Investigator. The study status is ***Conditionally Approved*** pending response to the following ***condition of approval:***

1. The Board reviewed the site's response regarding submission of a draft protocol. The Board requested submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

2. The Board noted that female subjects will be tested for pregnancy and that the protocol states that results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. The Board requested review of the sponsor's rationale for not recording the results of the pregnancy tests as the protocol indicates that pregnancy is an exclusion.

The Board requests your written response to this Study Status Notification. Your response will be reviewed by a Board member to determine whether the condition of approval is met. You will be contacted if further information is necessary.

You may submit your response to Denisse Guzman, Board Liaison via:

- FAX: 866-258-6774
- E-mail: **dguzman**@sairb.com

Board comments regarding the informed consent(s) are currently being processed. Upon request, you can receive an informed consent(s) released for informational purposes only. Upon receipt of supporting documentation addressing these conditions, the IC can be finalized and released.

Thank you for your assistance with the above-referenced study. You may contact me at 954-327-0778 if you have concerns or questions.

Please note: This is not an approval letter. The Schulman Associates IRB approval letter will be sent under separate cover. **Please note, no research activities, including advertising and screening, are permitted until the conditions for approval are satisfied and full approval is received.**

Megan Boatwright

From: Robert Testman
Sent: Wednesday, November 20, 2013 12:48 PM
To: Jeffrey Atlas
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Jeff,

Thanks for your prompt review and notification for this study. I would like to address the board's pregnancy test question now before submitting the document for HSRB review, in case modifications are needed.

We took two issues into account when making the decision not to make a record of the subject's pregnancy test result. First, we did not see any study-related reason requiring us to maintain a record of pregnancy test results. If a female subject is allowed to participate in the study then she must have had a negative test result, but if a subject withdraws or is disallowed we can record the general category (e.g. voluntary withdrawal or medical exclusion). Second, we would prefer to maximize subject privacy and minimize subject health records maintained. Under the current procedure we record a note only that a test was administered. We are not a medical facility and have no wish to keep any private medical information unless absolutely necessary.

For the above reasons we would prefer to maintain the handling of pregnancy tests as written. This is the same procedure used in our prior SAIRB approved studies, and the staff has not had any concerns from subjects or regulators. Please feel free to contact me to discuss further.

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Sent: Wednesday, November 20, 2013 1:50 PM
To: Robert Testman
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Robert,

Your response is being reviewed internally and I will get back to you as soon as I obtain a response. I appreciate your patience during this process.

Thank you.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

Our Holiday Season Submission Deadlines and Board Meeting Schedule is now available on our website here:

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Sent: Wednesday, November 20, 2013 3:48 PM
To: Jeffrey Atlas
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013

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For the above reasons we would prefer to maintain the handling of pregnancy tests as written. This is the same procedure used in our prior SAIRB approved studies, and the staff has not had any concerns from subjects or regulators. Please feel free to contact me to discuss further.

Thanks,
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Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Thursday, November 14, 2013 12:54 PM
To: Robert Testman
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013

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For any questions or assistance regarding this submission, please feel free to contact myself or Denisse Guzman (**dguzman@sairb.com)**.

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Sent: Wednesday, November 13, 2013 8:13 AM
To: Robert Testman
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin
Subject: RE: Protocol 120463, for Board review on 11/14/2013

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Also, please provide the RN's CV for the Board and license if available.

I will address your responses to the Board tomorrow.

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To: Denisse Guzman
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Denisse,

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(949)939-3585 (cell)

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Sent: Tuesday, November 12, 2013 11:19 AM
To: Robert Testman
Cc: Nina Chinery-Hesse; Jeffrey Atlas; Sabrina Martin
Subject: Protocol 120463, for Board review on 11/14/2013

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Any changes made to the protocol will require authenticated documentation to support the change either by a Protocol Amendment or a signed Administrative Letter. Some clarifications may be provided by Sponsor or Site email.

Please return your response to my attention at dguzman@sairb.com.

Should you have any questions, please do not hesitate to contact me.

Thank you for your prompt attention to this matter.

Denisse Guzman, CIM | Board Liaison
Shulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6774
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Wednesday, December 04, 2013 9:03 AM
To: Robert Testman
Cc: Nina Chinery-Hesse; Sabrina Martin; Megan Boatwright; Denisse Guzman
Subject: RE: Protocol 120463, for Board review on 11/14/2013
Attachments: 120463 SSN II.pdf

Hi Robert,

Please see the SSN II regarding one of the conditions of approval being met.

Thank you.

Regards,

Jeff Atlas

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Please return your response to my attention at dguzman@sairb.com.

Should you have any questions, please do not hesitate to contact me.

Thank you for your prompt attention to this matter.

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Shulman Associates IRB
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Office: 954-327-0778 | FAX: 866-258-6774
dguzman@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

Study Status Notification II

DATE: 12/4/2013

TO: Robert J. Testman, M.B.A.

FROM: **Jeff Atlas**, Operation Specialist
Schulman Associates IRB, Inc.

RE: **Protocol#:** 120463
IRB#: 201307317
Sponsor: Abbott Diabetes Care
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The above-referenced item was *Conditionally Approved* at the 11/14/2013 Board meeting. On 12/2/2013, the Board reviewed in an expedited manner, the correspondence submitted in response to the Study Status Notification dated 11/14/2013.

The purpose of this memo is to inform you that the response satisfies one of the conditions of approval.

Note: The Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval as previously indicated in the Study Status Notification dated 11/14/2013.

Upon receipt of supporting documentation addressing the remaining condition, the IC can be finalized and released.

Thank you for your assistance with the above-referenced study. You may contact me at 954-327-0778 if you have concerns or questions.

Please note: This is not an approval letter. The Schulman approval letter will be sent under separate cover.

Megan Boatwright

From: Robert Testman
Sent: Wednesday, December 04, 2013 9:53 AM
To: Megan Boatwright
Subject: FW: Protocol 120463, for Board review on 11/14/2013
Attachments: 120463 SSN II.pdf

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Wednesday, December 4, 2013 9:50 AM
To: Robert Testman
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Robert,

My apologies that was overlooked. Please see the corrected new SSN.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Wednesday, December 04, 2013 12:31 PM
To: Jeffrey Atlas
Subject: RE: Protocol 120463, for Board review on 11/14/2013

Hi Jeff,

The sponsor name is incorrect on the SSN II attachment. Could you update and resend?

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
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Study Status Notification II

DATE: 12/4/2013

TO: Robert J. Testman, M.B.A.

FROM: **Jeff Atlas**, Operation Specialist
Schulman Associates IRB, Inc.

RE: **Protocol#:** 120463
IRB#: 201307317
Sponsor: Antimicrobial Exposure Assessment Task Force II
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

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Megan Boatwright

From: Megan Boatwright
Sent: Monday, January 20, 2014 4:12 PM
To: Jeffrey Atlas (JAtlas@sairb.com)
Cc: Rob Testman (rtestman@gplabs.com)
Subject: 120463 Minutes and Roster

Dear Jeff,

Can you please provide me with the minutes and member roster for the meeting or meetings in which our study protocol for 120463 was discussed for us to include in our submission package to the EPA for HSRB review.

If you have any questions please feel free to contact me.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Wednesday, January 22, 2014 5:35 AM
To: Megan Boatwright
Cc: Robert Testman
Subject: RE: 120463 Minutes and Roster
Attachments: 120463 minutes.pdf

Hi Megan,

Please see the attached minutes. Our Board membership roster is available on our website and/or via the portal when you login.

If you need anything else, please let me know.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, January 20, 2014 7:12 PM
To: Jeffrey Atlas
Cc: Robert Testman
Subject: 120463 Minutes and Roster

Dear Jeff,

Can you please provide me with the minutes and member roster for the meeting or meetings in which our study protocol for 120463 was discussed for us to include in our submission package to the EPA for HSRB review.

If you have any questions please feel free to contact me.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105

Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

3. Review of New Studies: Protocols and Consent Documents (Status: Approved (A), Hold (H), Conditional approval (CA), Withdrawn (W), Disapproved (D)); Description & Discussion

3. a) Full Board

	IRB #	Protocol #	Study Products	PI/QI	City	St/ Pr	Country	Sponsor	Vote; Status
1.	201307317	120463		*Protocol*			US	American Chemistry Council	Status: Conditionally Approved For: 5 Against: 0 Unanimous: Abstain: 0

DESCRIPTION: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

DISCUSSION: Protocol DRAFT dated 04 November 2013

This study seeks to determine the potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide. The Board noted that this study plans to enroll 24 male and female subjects, aged 18 and older. The Board noted that women of childbearing potential are allowed to participate, though pregnancy is an exclusion criterion and urine pregnancy testing will be conducted. The Board noted that the protocol states that the results of the pregnancy test will be kept in confidence, will not be recorded, and will only be discussed with the subject who provided the urine sample. The Board noted, however, that no rationale was provided for not recording the results of the pregnancy tests as pregnancy is an exclusion criterion. The Board noted that this study is under the jurisdiction of the Environmental Protection Agency (EPA) and requires review by the Human Studies Review Board (HSRB). The Board noted that the study follows EPA Subparts B, K & L [40 CFR 26.202(a)] regarding the enrollment of pregnant or nursing women. The Board noted that the study is conducted in California, but an assurance that the California Department of Pesticide Regulation (CDPR) completed a review was not provided. The Board also noted that the protocol submitted was in DRAFT form. The Board noted that appropriate safety information is provided in the protocol to conduct a safety analysis, in the absence of an Investigator's Brochure.

The Board noted that Spanish-speaking subjects will be enrolled and that appropriate safety measures (translated study materials, appropriate personnel) are in place to minimize risks to subjects. The Board noted that there is no genetic testing, and compensation is prorated and does not appear to unduly influence subjects. The Board noted that privacy and confidentiality provisions are appropriate, and data and safety oversight is sufficient. The Board noted that this study poses greater than minimal risk, but risks are minimized by the study design. The Board noted that there is scientific merit for the conduct of the study and the study design is appropriate to support study objectives. The Board noted that there is no direct benefit to subjects; however there is potential benefit to society in understanding dermal and inhalation exposures.

The Board noted that the informed consent document does not require subjects to waive their rights or release the sponsor, investigator or institution from responsibility. The Board required changes throughout the ICD for subject clarity and consistency with the protocol.

The Board determined that the criteria for approval are satisfied. Based on this assessment, conditional approval was granted for a 12-month period pending responses to the following:

(1) Provide the sponsor's rationale for not recording the results of the pregnancy tests.

(2) Submit the final version of the protocol as well as accompanying documentation from the CDRP and HSRB indicating review and approval.

The ICD can be finalized and released when the issues related to the conditions for approval are satisfied.

7. Review of Additional Sites/Investigators During Pre-Review

7. a) Requiring Full Board Review

	IRB #	Protocol #	PI/QI	Study Products	City	St/ Pr	Country	Sponsor	Original	Vote; Status
1.	201307318	120463 [Pesticide;]	Testman, Robert J.		Fresno	CA	US	American Chemistry Council	201307317	Status: Approved For: 5 Against: 0 Unanimous: Abstain: 0
Description: Single site study listed in Section 3 of the agenda;										
Discussion: The Board determined that the site and PI are appropriately qualified to conduct the study and approved the site for a 12-month period.										

SCHULMAN ASSOCIATES IRB

30 YEARS OF EXCELLENCE

Request Submitted Successfully

Reason For Contact: Board Membership List
Role: Sponsor
Name: Megan Boatwright
Title: Laboratory Manager
Company: Golden Pacific laboratories, LLC
Address: Fresno, CA 93722
Phone: 5592759091
E-Mail: mboatwright@gplabs.com
Protocol / IRB #: 120463/ 201307317 and 130503/ 201307365
Review Board: Unknown
Comments: I am looking for the roster of members for two protocols, both listed above, that attended the meeting that the protocols were reviewed at. Thank you.

You will also receive confirmation via e-mail. Please print this page for your records.

Print | Make Another Request

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Megan Boatwright

From: alertreply@sairb.com
Sent: Wednesday, January 22, 2014 12:22 PM
To: Megan Boatwright
Subject: Contact from mboatwright@gplabs.com regarding Board Membership List.

Reason For Contact: Board Membership List
Role: Sponsor
Name: Megan Boatwright
Title: Laboratory Manager
Company: Golden Pacific laboratories, LLC
Address: Fresno, CA 93722
Phone: 5592759091
E-Mail: mboatwright@gplabs.com
Protocol / IRB #: 120463/ 201307317 and 130503/ 201307365
Review Board: Unknown
Comments: I am looking for the roster of members for two protocols, both listed above, that attended the meeting that the protocols were reviewed at. Thank you.

Megan Boatwright

From: Bette Bayne <BBayne@sairb.com>
Sent: Wednesday, January 22, 2014 12:40 PM
To: Megan Boatwright
Cc: Sabrina Martin
Subject: RE: Contact from mboatwright@gplabs.com regarding Board Membership List.
Attachments: 10-01-13 TABLE FL.PDF

Dear Megan,

Hi! Please find the attached Board Membership list for your two trials. Please let me know if you need anything else.

Best regards,
Bette

Bette Bayne | Director, Institutional and Phase I Services
Schulman Associates IRB
Office: 513-794-5777 | **Mobile:** 512-431-9630 | bbayne@sairb.com
Celebrating 30 Years of Excellence

SCOPE Summit for Clinical Ops Executives **Miami, FL – Feb 4-6, 2014**
Schulman is attending.

From: mboatwright@gplabs.com [mailto:mboatwright@gplabs.com]
Sent: Wednesday, January 22, 2014 2:22 PM
To: RequestBoardRosterSponsor
Subject: Contact from mboatwright@gplabs.com regarding Board Membership List.

Reason For Contact: Board Membership List
Role: Sponsor
Name: Megan Boatwright
Title: Laboratory Manager
Company: Golden Pacific laboratories, LLC
Address: Fresno, CA 93722
Phone: 5592759091
E-Mail: mboatwright@gplabs.com
Protocol / IRB #: 120463/ 201307317 and 130503/ 201307365
Review Board: Unknown
Comments: I am looking for the roster of members for two protocols, both listed above, that attended the meeting that the protocols were reviewed at. Thank you.

AEATF II Project ID: AEA09
GPL Study No.: 120463
Page 787 of 1773

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC.
IRB ROSTER

IRB #3 REGISTRATION NUMBER: 00003563

REVISED: OCTOBER 01, 2013

NAME	MEMBERSHIP STATUS	APPLICABLE DEGREE(S)	SCIENTIFIC OR NON-SCIENTIFIC CAPACITY	PRIMARY SPECIALTY	FIRST YEAR OF MEMBERSHIP	AFFILIATED
*SUZANNE BALANDIS	MEMBER	PharmD.	SCIENTIFIC	Pharmacology	2011	YES
** KIM LOONEY	MEMBER	J.D., R.N.	NON-SCIENTIFIC	Legal	2012	NO
FARZANNA S. HAFFIZULLA	MEMBER	M.D.	SCIENTIFIC	Internal Medicine	2011	NO
KATHLEEN KYSELA	MEMBER	R.H.I.T., A.A.A.S., CIM, CIP	NON-SCIENTIFIC	Regulatory	2011	YES
AKIVA D. MANN	MEMBER	M.A.	NON-SCIENTIFIC	Ministry	1997	NO
SHARI L. SOMERSTEIN	MEMBER	R.Ph	SCIENTIFIC	Pharmacology	1999	NO
MARIJKE H. ADAMS	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	PharmD., Ph.D.	SCIENTIFIC	Pharmacology	2009	NO
PATRICIA A. ALESSI	ALTERNATE FOR: A. Mann, K. Looney	Ordained Minister	NON-SCIENTIFIC	Ministry	2010	YES
JULES COHEN	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	D.O.	SCIENTIFIC	Family Medicine	2011	NO
THERESA CUMMINGS	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	R.N., M.S.	SCIENTIFIC	Public Health	2013	YES
CHERYL DUBENEZIC	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	R.N.	SCIENTIFIC	Public Health	2012	NO
YURY R. GONZALES	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.D., F.A.C.P.	SCIENTIFIC	Internal Medicine	2013	NO
BERNARD L. HERTZMAN	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.D., C.P.I.	SCIENTIFIC	Urology	2013	NO
KARIN HSIAO	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	B.S, M.S, M.B.A.	SCIENTIFIC	Devices	2013	NO

SCHULMAN ASSOCIATES INSTITUTIONAL REVIEW BOARD, INC.
IRB #3 ROSTER

REVISED: OCTOBER 01, 2013

NAME	MEMBERSHIP STATUS	APPLICABLE DEGREE(S)	SCIENTIFIC OR NON-SCIENTIFIC CAPACITY	PRIMARY SPECIALTY	FIRST YEAR OF MEMBERSHIP	AFFILIATED
TOPAZ J. KIRLEW	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.B.A.	SCIENTIFIC	Devices	2013	NO
ROBERT D. LETTMAN	ALTERNATE FOR: A. Mann, K. Kysela, K. Looney	Esq., P.A.	NON-SCIENTIFIC	Legal	2004	NO
DANIELLE K. MACARIO	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	Ph.D.	SCIENTIFIC	Device	2013	NO
JANE MANYO-MAHONEY	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.S.N., R.N.	SCIENTIFIC	Public Health	2012	NO
HAEJUNG MARR	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.D., C.P.I.	SCIENTIFIC	Family Medicine	2013	NO
ELAINE PATERSON	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	Ph.D.	SCIENTIFIC	Physiology Nutrition	2012	YES
ARNALDO R. QUINONES	ALTERNATE FOR: S. Balandis, F. Haffizulla, S. Somerstein	M.D.	SCIENTIFIC	Internal Medicine	2013	NO
KURT F. STONE	ALTERNATE FOR: A. Mann, K, Kysela, K. Looney	D.D.	NON-SCIENTIFIC	Ministry	2013	NO

NOTES: * Denotes Chair ** Denotes Vice-Chair

ROSTER UPDATES

Name	Effective Date	Membership Change
Frederick Hamilton	6/28/2013	Removed
Kathleen Kysela	6/28/2013	Status Changed to Full
Theresa Cummings	8/12/2013	Affiliated

Megan Boatwright

From: Megan Boatwright
Sent: Monday, January 27, 2014 3:03 PM
To: Jeffrey Atlas (JAtlas@sairb.com)
Subject: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist
Attachments: 40 CFR 26 1125 Checklist -070270b.doc

Dear Jeff,

I am working on submitting two of my protocols to EPA for HSRB review and have a checklist (attached) of documents I need to submit along with the protocol(s). Line item 6 is "written procedures for the IRB…". In the past we have written that this was submitted separately to EPA under confidentiality claim. Can you verify that EPA already has this, submit this to the EPA so they have it, or supply it to me so I can submit it with my packet?

Thank you and if you have any question please don't hesitate to contact me. I will be traveling the rest of this week and will have access to my e-mail however if you need to call, please call me at (559) 917-1736.

Sincerely,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

40 CFR 26.1125 Prior submission of proposed human research for EPA review

Any person or institution who intends to conduct or sponsor human research covered by §26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by §26.1115(a), and the following additional information, to the extent not already included:

	Requirement	Y/N	Comments/Page Refs
All information relevant to the proposed research specified by § 26.1115(a)	(1) Copies of • all research proposals reviewed by the IRB, • scientific evaluations, if any, that accompanied the proposals reviewed by the IRB, • approved sample consent documents, • progress reports submitted by investigators, and reports of injuries to subjects.	Y Y Y n/a	V3: 6-223 V3: 22-219, 241-437, 461-658, 680-877 V3: 937-958
	(2) Minutes of IRB meetings . . . in sufficient detail to show • attendance at the meetings; • actions taken by the IRB; • the vote on these actions including the number of members voting for, against, and abstaining; • the basis for requiring changes in or disapproving research; • a written summary of the discussion of controverted issues and their resolution.	N Y Y n/a n/a	Letter of Approval V3:912-914 Unanimous V3: 913
	(3) Records of continuing review activities.	n/a	
	(4) Copies of all correspondence between the IRB and the investigators.	Y	V3: 6-958
	(5) • A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; • any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.	N N	
	(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).	Y	Seperately submitted to EPA under confidentiality claim
	(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).	NA	
The following Information, to the extent not already included:	§1125(a) a discussion of: (1) The potential risks to human subjects		
	§1125(a) a discussion of: (2) The measures proposed to minimize risks to the human subjects;		
	§1125(a) a discussion of: (3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue		
	§1125(a) a discussion of: (4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and		
	§1125(a) a discussion of: (5) The balance of risks and benefits of the proposed research.		
	§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.	Y	Original: V3: 82-102, 301-321, 521-541, 740-760 Approved V3: 937-957
	§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.	Y	V3: 112-113, 220, 330-331, 438, 551-550, 659, 770-771, 878, 918-922
	§1125(d): A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.		
	§1125(e): All correspondence between the IRB and the investigators or sponsors.	Y	V3: 6-958
	§1125(f): Official notification to the sponsor or investigator…that research involving human subjects has been reviewed and approved by an IRB.		

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Monday, February 03, 2014 11:41 AM
To: Megan Boatwright
Subject: RE: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist

Hi Megan,

I received your voicemail and I am still working on receiving a response. We have our QA department looking into this and I have been following up, unfortunately, I have not received a response yet. I will request an answer again today in hopes to provide you a sufficient response.

Thank you for your patience.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
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From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, January 27, 2014 6:03 PM
To: Jeffrey Atlas
Subject: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist

Dear Jeff,

I am working on submitting two of my protocols to EPA for HSRB review and have a checklist (attached) of documents I need to submit along with the protocol(s). Line item 6 is "written procedures for the IRB…". In the past we have written that this was submitted separately to EPA under confidentiality claim. Can you verify that EPA already has this, submit this to the EPA so they have it, or supply it to me so I can submit it with my packet?

Thank you and if you have any question please don't hesitate to contact me. I will be traveling the rest of this week and will have access to my e-mail however if you need to call, please call me at (559) 917-1736.

Sincerely,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC

4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Tuesday, February 04, 2014 6:16 AM
To: Megan Boatwright
Subject: RE: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist
Attachments: DOC.PDF

Hi Megan,

Please see the attached document confirmation the EPA has received our SOPs.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
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From: Jeffrey Atlas
Sent: Monday, February 03, 2014 2:41 PM
To: 'Megan Boatwright'
Subject: RE: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist

Hi Megan,

I received your voicemail and I am still working on receiving a response. We have our QA department looking into this and I have been following up, unfortunately, I have not received a response yet. I will request an answer again today in hopes to provide you a sufficient response.

Thank you for your patience.

Regards,

Jeff Atlas

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Schulman Associates IRB
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From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, January 27, 2014 6:03 PM
To: Jeffrey Atlas
Subject: Written Procedures for IRB - EPA 40 CFR 26.1125 Checklist

Dear Jeff,

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Sincerely,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

SCHULMAN ASSOCIATES IRB

Offices: Cincinnati, Ohio | Ft. Lauderdale, Florida
www.sairb.com

February 3, 2014

To whom it may concern,

Schulman Associates IRB Inc. last provided a copy of our Board Standard Operating Procedures (SOPs) to the Environmental Protection Agency (EPA) on September 12, 2013.

Please feel free to contact Heather Fitzgerald at hfitzgerald@sairb.com or a member of the Quality Assurance (QA) Team at QualityAssurance@sairb.com for additional information.

Respectfully,

Heather Fitzgerald

Heather Fitzgerald, CIP | Operations Manager
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
hfitzgerald@sairb.com |Visit us at http://www.sairb.com

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Tuesday, March 11, 2014 11:43 AM
To: Megan Boatwright; Robert Testman
Subject: Studies on Conditional Approval

Good afternoon to you both,

I just wanted to touch base today to confirm things are still going as planned with the two studies (130503 & 120463) that the IRB has recently reviewed. If a timeframe is known regarding submission to have the conditions of approval met, please let me know. If either of you need anything additional that I can assist with, please let me know.

Thank you and have a great afternoon!

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
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Megan Boatwright

From: Robert Testman
Sent: Tuesday, March 11, 2014 11:46 AM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

These studies are scheduled for review by EPA/HSRB on April 8. I would expect a delay of about 4 weeks after that date until the final written HSRB documents are released. At that point we should be able to make final changes and submit for approval.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
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Jeff Atlas

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Please consider the environment before printing this e-mail.

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Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Tuesday, June 17, 2014 10:37 AM
To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Robert,

I wanted to follow up to this email to determine if the EPA/HSRB have reviewed and provided final written documentation surrounding these studies. Please let us know a proposed date of submission so we can ensure we have this reviewed at the time of submission.

Thank you.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
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Jeff Atlas

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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Megan Boatwright

From: Robert Testman
Sent: Tuesday, June 17, 2014 10:41 AM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

HSRB met on these in April. We saw a draft HSRB report 2 weeks ago, but are still waiting for them to publish the final report/findings. Hopefully that will happen soon and then we will submit the revised protocols. I will let you know when the final HSRB report is available.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Tuesday, June 17, 2014 10:37 AM
To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Robert,

I wanted to follow up to this email to determine if the EPA/HSRB have reviewed and provided final written documentation surrounding these studies. Please let us know a proposed date of submission so we can ensure we have this reviewed at the time of submission.

Thank you.

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 11, 2014 2:46 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

These studies are scheduled for review by EPA/HSRB on April 8. I would expect a delay of about 4 weeks after that date until the final written HSRB documents are released. At that point we should be able to make final changes and submit for approval.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Tuesday, March 11, 2014 11:43 AM
To: Megan Boatwright; Robert Testman
Subject: Studies on Conditional Approval

Good afternoon to you both,

I just wanted to touch base today to confirm things are still going as planned with the two studies (130503 & 120463) that the IRB has recently reviewed. If a timeframe is known regarding submission to have the conditions of approval met, please let me know. If either of you need anything additional that I can assist with, please let me know.

Thank you and have a great afternoon!

Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Specialist II
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
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Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Thursday, September 04, 2014 12:06 PM
To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval - 120463 & 130503
Attachments: Single_Site_Study_Periodic_and_Continuing_Review_Report_Form.docx

Good afternoon,

I know during our last email, you mentioned the HSRB draft was available, however the final findings had yet to be released. I wanted to inform you that in the event the final findings are not released in time for us to review either study and provide them full approval prior to 11/13/14, we do have an option to provide a continuing review to grant an additional 6 months of conditional approval. These 6 months should allow sufficient time to have the required documentation of the HSRB and CDPR in order for the IRB to satisfy all conditions.

Please let me know if I can be of any assistance. We would request the continuing review form (attached) be submitted for each study prior to November 1.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, June 17, 2014 1:41 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

HSRB met on these in April. We saw a draft HSRB report 2 weeks ago, but are still waiting for them to publish the final report/findings. Hopefully that will happen soon and then we will submit the revised protocols. I will let you know when the final HSRB report is available.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Tuesday, June 17, 2014 10:37 AM

To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Robert,

I wanted to follow up to this email to determine if the EPA/HSRB have reviewed and provided final written documentation surrounding these studies. Please let us know a proposed date of submission so we can ensure we have this reviewed at the time of submission.

Thank you.

Regards,

Jeff Atlas

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Subject: Studies on Conditional Approval

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Regards,

Jeff Atlas

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SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

SECTION 1.0: Submission Instructions

1. Submission instructions: Submit via Secure eSubmission, email to OngoingReview@sairb.com or fax to (866) 657-7917.

SECTION 2.0: Study & Contact Information

1. PI/QI Name: _____

2. Sponsor: _____ **3. Protocol Number:** _____

4. Contact information for this Study Status Report:

Name: _____ Email: _____

Phone: _____ Fax: _____

SECTION 3.0: Report Designation

1. Submit this form to apply for re-approval of ongoing single site studies.

2. If required, for Interim reporting please submit the *Study Status Report Form*.

3. For Finals (Closure) of single site studies, please submit the *Final Study Status Report.*

SECTION 4.0: Study Status Information

1. A copy of the most recent version of the informed consent(s) (IC) signed and dated by the most recently consented subject must be submitted. Please specify one of the following:

☐ I have included the most recently approved version (subject signed and dated) of all approved IC(s) including any addendum IC, sub-study IC, CA Experimental Subjects Bill of Rights, or HIPAA Privacy Authorization and translated versions for each language.

☐ Signed IC(s) are not being submitted at this time. **>>>** Please explain: _____

2. What is the current study status?

☐ Enrollment is open at this site ☐ This site is not yet initiated to conduct this study

☐ Enrollment is closed at this site ☐ Study is on hold or terminated by the sponsor/CRO **>>>** Please submit documentation.

3. Please complete the following table for all subjects consented for this study at your site:

Subjects	Initial Study	Study Extension 1 IRB#:	Study Extension 2 IRB#:
a. # Consented			
b. # Screen Failures			
c. # Withdrawals			
d. # Completed Study			
e. # Still Active in Study			

NOTE: a. = b. + c. + d. + e.

4. Please list the specific reason for each withdrawn subject since your last submitted report (do not include reasons for screen failed subjects): _____

5. What was the date the first subject was consented at your site? _____

6. Please indicate whether any of the following have occurred at your site since your last report.

a. Protocol Amendments: ☐ No ☐ Yes

b. Change of Site Location: ☐ No ☐ Yes

c. Change of PI/QI: ☐ No ☐ Yes

d. Addition of Sub-Investigator(s): ☐ No ☐ Yes

e. Change in Compensation: ☐ No ☐ Yes

7. Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?

☐ No

☐ Yes **>>>** Please complete the *NonCompliance Report Form* if not previously reported.

8. Since your last report, have there been any unanticipated adverse device effects (UADEs)?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

☐ No

☐ Yes **>>>** Please complete the *UADE Report Form* if not previously reported.

9. Since your last report, have there been any unanticipated problems involving risk to human subjects or others?

☐ No

☐ Yes **>>>** Please complete the *Unanticipated Problem Report Form* if not previously reported.

10. Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

11. Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

12. Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk to subjects)?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

13. Since your last report, have you consented subjects from any of the following groups?

☐ No

☐ Yes **>>>** Please check all applicable groups below and attach a subject signed and dated copy of the IC (and child's assent, if applicable) for the most recently consented subject from each group checked.

- ☐ Anyone who cannot read (blind or illiterate)
- ☐ Non-English speaking persons
- ☐ Employees/immediate family members of employees
- ☐ Consented via legally authorized representative (LAR)
- ☐ Children (anyone under the age of majority in your state/province)

SECTION 5.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Environmental Protection Agency (EPA) or Health Products and Food Branch Inspectorate (HPFB) during this study?

☐ No

☐ Yes **>>>** Please complete **a.** through **c.**:

a. Please provide the name of the agency (FDA, OHRP, EPA, HPFB), name of the physician/investigator who was audited, and the date(s) of the audit(s):

Agency: _____ Physician/Investigator: _____ Date: _____

b. Was a Form FDA 483 or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?

☐ No

☐ Yes

c. Please attach all audit-related correspondence, unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

. Since your last report, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, EPA (US sites) or HPFB (Canadian sites) terminate a study?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g. suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

SECTION 6.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research****.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. Since your last report, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of **$5,000** when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?;
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the investigator that have a monetary value of more than **$5,000** exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☐ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

2. Canadian sites only: Since your last report, have there been any changes to the clinical trial budget?

☐ No

☐ Yes **>>>** Please attach a copy of the updated clinical trial budget.

SECTION 7.0: Protocol Status Information

1. When do you estimate enrollment to be closed for this study? _____

2. When do you estimate that all subjects will have completed active study participation? _____

3. When do you estimate that the study will be closed with Schulman? _____

4. Please list the approximate number of enrolled subjects in each category below (a. through c.):

a. Gender: _____ # of Males _____ # of Females

b. Ethnicity: _____ # of Hispanics _____ # of Non-Hispanics

c. Race: _____ Caucasian _____ Native American/Aboriginal _____ African _____ Asian _____ Other

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

5. Is there a safety monitoring committee (i.e. DSMB or DSMC) for this study?

☐ No

☐ Yes **>>>** Please complete the *Product Safety Submission Form* and provide copies of any summary reports that have not been previously submitted or send correspondence detailing the date of the next meeting and the anticipated date of release of that meeting's summary report.

6. Have there been any interim findings, published findings and/or multicenter trial reports pertinent to the conduct of this study since the Board's initial review or last continuing review of the protocol?

☐ No

☐ Yes **>>>** Please submit with this report unless previously submitted.

SECTION 8.0: Investigator Certification & Signature

I certify that I have reviewed all responses provided in this *Single Site Study Periodic and Continuing Review Report Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the form and agrees this information is true and accurate.

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature

Signature Date (mm/dd/yyyy)

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

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Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Monday, October 13, 2014 10:34 AM
To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Rob and Megan,

As you both are probably aware, your two studies are coming up for reapproval as the expiration is 11/13/14. Please provide us a status update regarding the HSRB meeting as well as a timeframe you may have a final protocol to submit for IRB review so we can lift the conditions and provide full approval to both studies.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, June 17, 2014 1:41 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

HSRB met on these in April. We saw a draft HSRB report 2 weeks ago, but are still waiting for them to publish the final report/findings. Hopefully that will happen soon and then we will submit the revised protocols. I will let you know when the final HSRB report is available.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Tuesday, June 17, 2014 10:37 AM
To: Robert Testman; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Robert,

I wanted to follow up to this email to determine if the EPA/HSRB have reviewed and provided final written documentation surrounding these studies. Please let us know a proposed date of submission so we can ensure we have this reviewed at the time of submission.

Thank you.

Regards,

Jeff Atlas

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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 11, 2014 2:46 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: Studies on Conditional Approval

Hi Jeff,

These studies are scheduled for review by EPA/HSRB on April 8. I would expect a delay of about 4 weeks after that date until the final written HSRB documents are released. At that point we should be able to make final changes and submit for approval.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Tuesday, March 11, 2014 11:43 AM
To: Megan Boatwright; Robert Testman
Subject: Studies on Conditional Approval

Good afternoon to you both,

I just wanted to touch base today to confirm things are still going as planned with the two studies (130503 & 120463) that the IRB has recently reviewed. If a timeframe is known regarding submission to have the conditions of approval met, please let me know. If either of you need anything additional that I can assist with, please let me know.

Thank you and have a great afternoon!

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Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Monday, November 03, 2014 8:45 AM
To: Robert Testman
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies
Attachments: Single_Site_Study_Periodic_and_Continuing_Review_Report_Form.docx

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study (you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

Please advise the approximate submission date as these have to be scheduled for FB review no later than Thursday next week, which means we need submission no later than Thursday this week.

Thank you again!

Best Regards,

Jeff Atlas

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SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

SECTION 1.0: Submission Instructions

1. Submission instructions: Submit via Secure eSubmission, email to OngoingReview@sairb.com or fax to (866) 657-7917.

SECTION 2.0: Study & Contact Information

1. PI/QI Name: _____

2. Sponsor: _____ **3. Protocol Number:** _____

4. Contact information for this Study Status Report:

Name: _____ Email: _____

Phone: _____ Fax: _____

SECTION 3.0: Report Designation

1. Submit this form to apply for re-approval of ongoing single site studies.

2. If required, for Interim reporting please submit the *Study Status Report Form*.

3. For Finals (Closure) of single site studies, please submit the *Final Study Status Report.*

SECTION 4.0: Study Status Information

1. A copy of the most recent version of the informed consent(s) (IC) signed and dated by the most recently consented subject must be submitted. Please specify one of the following:

☐ I have included the most recently approved version (subject signed and dated) of all approved IC(s) including any addendum IC, sub-study IC, CA Experimental Subjects Bill of Rights, or HIPAA Privacy Authorization and translated versions for each language.

☐ Signed IC(s) are not being submitted at this time. **>>>** Please explain: _____

2. What is the current study status?

☐ Enrollment is open at this site ☐ This site is not yet initiated to conduct this study

☐ Enrollment is closed at this site ☐ Study is on hold or terminated by the sponsor/CRO **>>>** Please submit documentation.

3. Please complete the following table for all subjects consented for this study at your site:

Subjects	Initial Study	Study Extension 1 IRB#:	Study Extension 2 IRB#:
a. # Consented			
b. # Screen Failures			
c. # Withdrawals			
d. # Completed Study			
e. # Still Active in Study			

NOTE: a. = b. + c. + d. + e.

4. Please list the specific reason for each withdrawn subject since your last submitted report (do not include reasons for screen failed subjects): _____

5. What was the date the first subject was consented at your site? _____

6. Please indicate whether any of the following have occurred at your site since your last report.

a. Protocol Amendments: ☐ No ☐ Yes

b. Change of Site Location: ☐ No ☐ Yes

c. Change of PI/QI: ☐ No ☐ Yes

d. Addition of Sub-Investigator(s): ☐ No ☐ Yes

e. Change in Compensation: ☐ No ☐ Yes

7. Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?

☐ No

☐ Yes **>>>** Please complete the *NonCompliance Report Form* if not previously reported.

8. Since your last report, have there been any unanticipated adverse device effects (UADEs)?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

☐ No

☐ Yes >>> Please complete the *UADE Report Form* if not previously reported.

9. Since your last report, have there been any unanticipated problems involving risk to human subjects or others?

☐ No

☐ Yes >>> Please complete the *Unanticipated Problem Report Form* if not previously reported.

10. Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?

☐ No

☐ Yes >>> Please attach a written explanation and copies of all relevant documents unless previously submitted.

11. Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?

☐ No

☐ Yes >>> Please attach a written explanation and copies of all relevant documents unless previously submitted.

12. Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk to subjects)?

☐ No

☐ Yes >>> Please attach a written explanation and copies of all relevant documents unless previously submitted.

13. Since your last report, have you consented subjects from any of the following groups?

☐ No

☐ Yes >>> Please check all applicable groups below and attach a subject signed and dated copy of the IC (and child's assent, if applicable) for the most recently consented subject from each group checked.

- ☐ Anyone who cannot read (blind or illiterate)
- ☐ Employees/immediate family members of employees
- ☐ Children (anyone under the age of majority in your state/province)
- ☐ Non-English speaking persons
- ☐ Consented via legally authorized representative (LAR)

SECTION 5.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Environmental Protection Agency (EPA) or Health Products and Food Branch Inspectorate (HPFB) during this study?

☐ No

☐ Yes >>> Please complete **a.** through **c.**:

a. Please provide the name of the agency (FDA, OHRP, EPA, HPFB), name of the physician/investigator who was audited, and the date(s) of the audit(s):

Agency: _____ Physician/Investigator: _____ Date: _____

b. Was a Form FDA 483 or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?

☐ No

☐ Yes

c. Please attach all audit-related correspondence, unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☐ No

☐ Yes >>> Please attach a written explanation and copies of all relevant documents unless previously submitted.

3. Since your last report, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, EPA (US sites) or HPFB (Canadian sites) terminate a study?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g. suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

SECTION 6.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research****.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. Since your last report, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of **$5,000** when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?;
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the investigator that have a monetary value of more than **$5,000** exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☐ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

2. Canadian sites only: Since your last report, have there been any changes to the clinical trial budget?

☐ No

☐ Yes **>>>** Please attach a copy of the updated clinical trial budget.

SECTION 7.0: Protocol Status Information

1. When do you estimate enrollment to be closed for this study? _____

2. When do you estimate that all subjects will have completed active study participation? _____

3. When do you estimate that the study will be closed with Schulman? _____

4. Please list the approximate number of enrolled subjects in each category below (a. through c.):

a. Gender: _____ # of Males _____ # of Females

b. Ethnicity: _____ # of Hispanics _____ # of Non-Hispanics

c. Race: _____ Caucasian _____ Native American/Aboriginal _____ African _____ Asian _____ Other

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

5. Is there a safety monitoring committee (i.e. DSMB or DSMC) for this study?

☐ No

☐ Yes **>>>** Please complete the *Product Safety Submission Form* and provide copies of any summary reports that have not been previously submitted or send correspondence detailing the date of the next meeting and the anticipated date of release of that meeting's summary report.

6. Have there been any interim findings, published findings and/or multicenter trial reports pertinent to the conduct of this study since the Board's initial review or last continuing review of the protocol?

☐ No

☐ Yes **>>>** Please submit with this report unless previously submitted.

SECTION 8.0: Investigator Certification & Signature

I certify that I have reviewed all responses provided in this *Single Site Study Periodic and Continuing Review Report Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the form and agrees this information is true and accurate.

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature	Signature Date (mm/dd/yyyy)
Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title	

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Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Thursday, November 06, 2014 6:26 AM
To: Robert Testman; Megan Boatwright
Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Attachments: Single_Site_Study_Periodic_and_Continuing_Review_Report_Form.docx

Importance: High

Hi Rob and Megan,

We are approaching the deadline for receipt of the attached form. If not received by noon tomorrow, we are forced to charge a RUSH fee for processing the item. Please try and submit this form as soon as possible today for both studies soon to expire. With that in mind, please also submit either a letter with rationale as to why the conditions cannot be met yet or a revised protocol in final format to lift the conditions. It is imperative that both the conditional approval and annual review of the study are addressed with immediate attention.

If you feel that this cannot occur in the timeframe needed, please let us know so we can prepare for allowing expiration of the two studies and provide you instruction on how to proceed after expiration occurs. If we do not receive a response by 3pm EST today, I'll give you a follow up call to ensure the email was received.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study

(you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

Please advise the approximate submission date as these have to be scheduled for FB review no later than Thursday next week, which means we need submission no later than Thursday this week.

Thank you again!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

SECTION 1.0: Submission Instructions

1. Submission instructions: Submit via Secure eSubmission, email to OngoingReview@sairb.com or fax to (866) 657-7917.

SECTION 2.0: Study & Contact Information

1. PI/QI Name: _____

2. Sponsor: _____ **3. Protocol Number:** _____

4. Contact information for this Study Status Report:

Name: _____ Email: _____

Phone: _____ Fax: _____

SECTION 3.0: Report Designation

1. Submit this form to apply for re-approval of ongoing single site studies.

2. If required, for Interim reporting please submit the *Study Status Report Form*.

3. For Finals (Closure) of single site studies, please submit the *Final Study Status Report.*

SECTION 4.0: Study Status Information

1. A copy of the most recent version of the informed consent(s) (IC) signed and dated by the most recently consented subject must be submitted. Please specify one of the following:

☐ I have included the most recently approved version (subject signed and dated) of all approved IC(s) including any addendum IC, sub-study IC, CA Experimental Subjects Bill of Rights, or HIPAA Privacy Authorization and translated versions for each language.

☐ Signed IC(s) are not being submitted at this time. **>>>** Please explain: _____

2. What is the current study status?

☐ Enrollment is open at this site ☐ This site is not yet initiated to conduct this study

☐ Enrollment is closed at this site ☐ Study is on hold or terminated by the sponsor/CRO **>>>** Please submit documentation.

3. Please complete the following table for all subjects consented for this study at your site:

Subjects	Initial Study	Study Extension 1 IRB#:	Study Extension 2 IRB#:
a. # Consented			
b. # Screen Failures			
c. # Withdrawals			
d. # Completed Study			
e. # Still Active in Study			

NOTE: a. = b. + c. + d. + e.

4. Please list the specific reason for each withdrawn subject since your last submitted report (do not include reasons for screen failed subjects): _____

5. What was the date the first subject was consented at your site? _____

6. Please indicate whether any of the following have occurred at your site since your last report.

a. Protocol Amendments: ☐ No ☐ Yes

b. Change of Site Location: ☐ No ☐ Yes

c. Change of PI/QI: ☐ No ☐ Yes

d. Addition of Sub-Investigator(s): ☐ No ☐ Yes

e. Change in Compensation: ☐ No ☐ Yes

7. Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?

☐ No

☐ Yes **>>>** Please complete the *NonCompliance Report Form* if not previously reported.

8. Since your last report, have there been any unanticipated adverse device effects (UADEs)?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

☐ No

☐ Yes **>>>** Please complete the *UADE Report Form* if not previously reported.

9. Since your last report, have there been any unanticipated problems involving risk to human subjects or others?

☐ No

☐ Yes **>>>** Please complete the *Unanticipated Problem Report Form* if not previously reported.

10. Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

11. Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

12. Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk to subjects)?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

13. Since your last report, have you consented subjects from any of the following groups?

☐ No

☐ Yes **>>>** Please check all applicable groups below and attach a subject signed and dated copy of the IC (and child's assent, if applicable) for the most recently consented subject from each group checked.

- ☐ Anyone who cannot read (blind or illiterate)
- ☐ Non-English speaking persons
- ☐ Employees/immediate family members of employees
- ☐ Consented via legally authorized representative (LAR)
- ☐ Children (anyone under the age of majority in your state/province)

SECTION 5.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Environmental Protection Agency (EPA) or Health Products and Food Branch Inspectorate (HPFB) during this study?

☐ No

☐ Yes **>>>** Please complete **a.** through **c.**:

a. Please provide the name of the agency (FDA, OHRP, EPA, HPFB), name of the physician/investigator who was audited, and the date(s) of the audit(s):

Agency: _____ Physician/Investigator: _____ Date: _____

b. Was a Form FDA 483 or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?

☐ No

☐ Yes

c. Please attach all audit-related correspondence, unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

. Since your last report, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, EPA (US sites) or HPFB (Canadian sites) terminate a study?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g. suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☐ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

SECTION 6.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research****.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. Since your last report, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of **$5,000** when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?;
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the investigator that have a monetary value of more than **$5,000** exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☐ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

2. Canadian sites only: Since your last report, have there been any changes to the clinical trial budget?

☐ No

☐ Yes **>>>** Please attach a copy of the updated clinical trial budget.

SECTION 7.0: Protocol Status Information

1. When do you estimate enrollment to be closed for this study? _____

2. When do you estimate that all subjects will have completed active study participation? _____

3. When do you estimate that the study will be closed with Schulman? _____

4. Please list the approximate number of enrolled subjects in each category below (a. through c.):

a. Gender: _____ # of Males _____ # of Females

b. Ethnicity: _____ # of Hispanics _____ # of Non-Hispanics

c. Race: _____ Caucasian _____ Native American/Aboriginal _____ African _____ Asian _____ Other

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: _____

5. Is there a safety monitoring committee (i.e. DSMB or DSMC) for this study?

☐ No

☐ Yes **>>>** Please complete the *Product Safety Submission Form* and provide copies of any summary reports that have not been previously submitted or send correspondence detailing the date of the next meeting and the anticipated date of release of that meeting's summary report.

6. Have there been any interim findings, published findings and/or multicenter trial reports pertinent to the conduct of this study since the Board's initial review or last continuing review of the protocol?

☐ No

☐ Yes **>>>** Please submit with this report unless previously submitted.

SECTION 8.0: Investigator Certification & Signature

I certify that I have reviewed all responses provided in this *Single Site Study Periodic and Continuing Review Report Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the form and agrees this information is true and accurate.

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature

Signature Date (mm/dd/yyyy)

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

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Megan Boatwright

From: Robert Testman
Sent: Thursday, November 06, 2014 11:51 AM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: Continuing approval for study 120463
Attachments: DOC110614-001.pdf

Hi Jeff,

Please see attached the continuing approval form and letter for this study as we discussed.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Thursday, November 6, 2014 6:26 AM
To: Robert Testman; Megan Boatwright
Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Importance: High

Hi Rob and Megan,

We are approaching the deadline for receipt of the attached form. If not received by noon tomorrow, we are forced to charge a RUSH fee for processing the item. Please try and submit this form as soon as possible today for both studies soon to expire. With that in mind, please also submit either a letter with rationale as to why the conditions cannot be met yet or a revised protocol in final format to lift the conditions. It is imperative that both the conditional approval and annual review of the study are addressed with immediate attention.

If you feel that this cannot occur in the timeframe needed, please let us know so we can prepare for allowing expiration of the two studies and provide you instruction on how to proceed after expiration occurs. If we do not receive a response by 3pm EST today, I'll give you a follow up call to ensure the email was received.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com | Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study (you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

Please advise the approximate submission date as these have to be scheduled for FB review no later than Thursday next week, which means we need submission no later than Thursday this week.

Thank you again!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Golden Pacific
LABORATORIES

November 6, 2014

Jeffrey Atlas, BS-HSA
Schulman Associates IRB
Sawgrass Plaza Suite 120
1550 Sawgrass Corporate Parkway
Sunrise, FL 33323

Dear Jeff,

Please find attached the single site periodic and continuing review form for GPL study 120463, Schulman IRB number 201307317. As discussed this study has been reviewed and approved by the EPA/HSRB with conditions including obtaining full approval from Schulman IRB. Due to ongoing sponsor review and internal priorities the revised protocol to gain full approval is not ready for submission today. We anticipate submitting the revised protocol within the next 30 days. Please feel free to contact me with any questions.

Sincerely,

Robert Testman
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307317

SECTION 1.0: Submission Instructions

1. Submission instructions: Submit via Secure eSubmission, email to OngoingReview@sairb.com or fax to (866) 657-7917.

SECTION 2.0: Study & Contact Information

1. PI/QI Name: Robert Testman

2. Sponsor: AEATF II **3. Protocol Number:** 120463

4. Contact information for this Study Status Report:

Name: Robert Testman Email: rtestman@gplabs.com

Phone: 949-939-3585 Fax: 559-275-9091

SECTION 3.0: Report Designation

1. Submit this form to apply for re-approval of ongoing single site studies.

2. If required, for Interim reporting please submit the *Study Status Report Form*.

3. For Finals (Closure) of single site studies, please submit the *Final Study Status Report.*

SECTION 4.0: Study Status Information

1. A copy of the most recent version of the informed consent(s) (IC) signed and dated by the most recently consented subject must be submitted. Please specify one of the following:

☐ I have included the most recently approved version (subject signed and dated) of all approved IC(s) including any addendum IC, sub-study IC, CA Experimental Subjects Bill of Rights, or HIPAA Privacy Authorization and translated versions for each language.

☒ Signed IC(s) are not being submitted at this time. **>>>** Please explain: The study has not been approved for enrollment.

2. What is the current study status?

☐ Enrollment is open at this site ☒ This site is not yet initiated to conduct this study

☐ Enrollment is closed at this site ☐ Study is on hold or terminated by the sponsor/CRO **>>>** Please submit documentation.

3. Please complete the following table for all subjects consented for this study at your site:

Subjects	Initial Study	Study Extension 1 IRB#:	Study Extension 2 IRB#:
a. # Consented			
b. # Screen Failures			
c. # Withdrawals			
d. # Completed Study			
e. # Still Active in Study			

NOTE: a. = b. + c. + d. + e.

4. Please list the specific reason for each withdrawn subject since your last submitted report (do not include reasons for screen failed subjects): n/a

5. What was the date the first subject was consented at your site? n/a

6. Please indicate whether any of the following have occurred at your site since your last report.

a. Protocol Amendments: ☒ No ☐ Yes

b. Change of Site Location: ☒ No ☐ Yes

c. Change of PI/QI: ☒ No ☐ Yes

d. Addition of Sub-Investigator(s): ☒ No ☐ Yes

e. Change in Compensation: ☒ No ☐ Yes

7. Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?

☒ No

☐ Yes **>>>** Please complete the *NonCompliance Report Form* if not previously reported.

8. Since your last report, have there been any unanticipated adverse device effects (UADEs)?

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SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307317

☒ No

☐ Yes **>>>** Please complete the *UADE Report Form* if not previously reported.

9. Since your last report, have there been any unanticipated problems involving risk to human subjects or others?

☒ No

☐ Yes **>>>** Please complete the *Unanticipated Problem Report Form* if not previously reported.

10. Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

11. Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

12. Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk to subjects)?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

13. Since your last report, have you consented subjects from any of the following groups?

☒ No

☐ Yes **>>>** Please check all applicable groups below and attach a subject signed and dated copy of the IC (and child's assent, if applicable) for the most recently consented subject from each group checked.

- ☐ Anyone who cannot read (blind or illiterate)
- ☐ Non-English speaking persons
- ☐ Employees/immediate family members of employees
- ☐ Consented via legally authorized representative (LAR)
- ☐ Children (anyone under the age of majority in your state/province)

SECTION 5.0: Regulatory History

1. Has this site and/or any investigator associated with this study been audited by the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Environmental Protection Agency (EPA) or Health Products and Food Branch Inspectorate (HPFB) during this study?

☒ No

☐ Yes **>>>** Please complete **a.** through **c.**:

a. Please provide the name of the agency (FDA, OHRP, EPA, HPFB), name of the physician/investigator who was audited, and the date(s) of the audit(s):

Agency: _____ Physician/Investigator: _____ Date: _____

b. Was a Form FDA 483 or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?

☐ No

☐ Yes

c. Please attach all audit-related correspondence, unless previously submitted.

☐ Attached ☐ Previously submitted ☐ Will submit when available

2. Are there state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

Since your last report, has any investigator involved with this study:

- Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?
- Had the FDA, OHRP, EPA (US sites) or HPFB (Canadian sites) terminate a study?

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Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307317

- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g. suspension, revocation, or restriction?
- Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?
- Been convicted or charged with a crime (misdemeanor or felony)?
- Had a state/provincial medical board taken a disciplinary action against his/her license, or is currently under investigation?

☒ No

☐ Yes **>>>** Please attach a written explanation and copies of all relevant documents unless previously submitted.

SECTION 6.0: Financial Interest

It is the policy of Schulman to require each **investigator*** who submits research studies for review and oversight to disclose any of the following **financial interests** when those financial interests are **related to the research**.**.

***Investigator:** As used in this policy, this includes the PI/QI, all Sub-Is and research staff involved in this research study, as well as spouses and dependent children of the PI/QI, Sub-Is and research staff.

****Related to the Research:** A financial interest is related to the research when financial interest is in the sponsor, product or service being tested, or competitor of the sponsor, product or service being tested.

1. Since your last report, has any investigator involved in this study:

- Been an officer, director or employee of the sponsor of this research study?;
- Held ownership interest (equity or stock options) related to the research in excess of **$5,000** when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?;
- Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity?;
- Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?;
- Had any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.);
- Received, or made any arrangement to receive, any significant payments of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the investigator that have a monetary value of more than **$5,000** exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.);
- Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?; OR
- Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.)

☒ No

☐ Yes **>>>** Please complete and attach the *Investigator Conflict of Interest Form*.

2. Canadian sites only: Since your last report, have there been any changes to the clinical trial budget?

☐ No

☐ Yes **>>>** Please attach a copy of the updated clinical trial budget.

SECTION 7.0: Protocol Status Information

1. When do you estimate enrollment to be closed for this study? 10/15/2015

2. When do you estimate that all subjects will have completed active study participation? 10/15/2015

3. When do you estimate that the study will be closed with Schulman? 12/31/2015

4. Please list the approximate number of enrolled subjects in each category below (a. through c.):

a. Gender: _____ # of Males _____ # of Females

b. Ethnicity: _____ # of Hispanics _____ # of Non-Hispanics

c. Race: _____ Caucasian _____ Native American/Aboriginal _____ African _____ Asian _____ Other

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SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307317

5. Is there a safety monitoring committee (i.e. DSMB or DSMC) for this study?

☒ No

☐ Yes **>>>** Please complete the *Product Safety Submission Form* and provide copies of any summary reports that have not been previously submitted or send correspondence detailing the date of the next meeting and the anticipated date of release of that meeting's summary report.

6. Have there been any interim findings, published findings and/or multicenter trial reports pertinent to the conduct of this study since the Board's initial review or last continuing review of the protocol?

☒ No

☐ Yes **>>>** Please submit with this report unless previously submitted.

SECTION 8.0: Investigator Certification & Signature

I certify that I have reviewed all responses provided in this *Single Site Study Periodic and Continuing Review Report Form* and that all responses are true and accurate. By submitting this form, I am confirming that I am the Principal Investigator (PI) or Qualified Investigator (QI) or the PI/QI's designee authorized to submit on behalf of the PI/QI and the PI/QI has reviewed the form and agrees this information is true and accurate.

Rob Test — 11/06/2014

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature — Signature Date (mm/dd/yyyy)

Robert Testman, MBA / Principal Investigator

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

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Megan Boatwright

From: Danielle Martz <DMartz@sairb.com>
Sent: Tuesday, November 11, 2014 10:46 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas
Subject: RE: Continuing approval for study 120463

Hi Robert,

Can you please provide a CV for Willa Harkey, RN.

Thank You,
Danielle

Danielle R. Martz, B.S. | Operations Coordinator I
Schulman Associates IRB
Sawgrass Plaza, Suite 120
1550 Sawgrass Corporate Parkway |Sunrise, Florida 33323
Office: 954-327-0778 | FAX: 866-258-6674
DMartz@sairb.com | Visit us at www.sairb.com

* Please note – our Word based Study Status Report forms will retire December 1, 2014. Please use this link to access our new SmartForm, http://www.sairb.com/Forms/Pages/ongoingreview.aspx

---

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, November 06, 2014 2:51 PM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: Continuing approval for study 120463

Hi Jeff,

Please see attached the continuing approval form and letter for this study as we discussed.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Thursday, November 6, 2014 6:26 AM
To: Robert Testman; Megan Boatwright
Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Importance: High

Hi Rob and Megan,

We are approaching the deadline for receipt of the attached form. If not received by noon tomorrow, we are forced to charge a RUSH fee for processing the item. Please try and submit this form as soon as possible today for both studies

soon to expire. With that in mind, please also submit either a letter with rationale as to why the conditions cannot be met yet or a revised protocol in final format to lift the conditions. It is imperative that both the conditional approval and annual review of the study are addressed with immediate attention.

If you feel that this cannot occur in the timeframe needed, please let us know so we can prepare for allowing expiration of the two studies and provide you instruction on how to proceed after expiration occurs. If we do not receive a response by 3pm EST today, I'll give you a follow up call to ensure the email was received.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study (you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

Please advise the approximate submission date as these have to be scheduled for FB review no later than Thursday next week, which means we need submission no later than Thursday this week.

Thank you again!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
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Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Megan Boatwright

From: Megan Boatwright
Sent: Tuesday, November 11, 2014 10:53 AM
To: 'Danielle Martz'; Robert Testman
Cc: Jeffrey Atlas
Subject: RE: Continuing approval for study 120463
Attachments: Willa CV & NURSES LICENSE.pdf

Hi Danielle,

Attached please find attached Willa's CV and current nurse's license per your request.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

From: Danielle Martz [mailto:DMartz@sairb.com]
Sent: Tuesday, November 11, 2014 10:46 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas
Subject: RE: Continuing approval for study 120463

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Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Importance: High

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Thank you.

Best Regards,

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Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study (you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

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Best Regards,

Jeff Atlas

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CURRICULUM VITAE

NAME AND TITLE:
Willa Harkey-Berglund RN

EDUCATION:
Fresno City College, AA Degree
Orosi High School , High School Diploma

PROFESSIONAL EXPERIENCE:

Date: 1980 - 1985
Title: RN

(Description) Fresno Community Hospital
Intermediate Care Nursery

Date: 1985 - 2005
Title: RN

(Description) San Bernardino County Hospital
1996 changed to ARMC (Arrowhead Regional Medical Center)
NICU (Neonatal Intensive Care)
Charge Nurse

Date: 2009 - 2013
Title: RN

(Description) Field Nurse
Golden Pacific Laboratories

PROFESSIONAL AND TECHNICAL TRAINING:
On going CEU's to maintain RN License
Current CPR Card

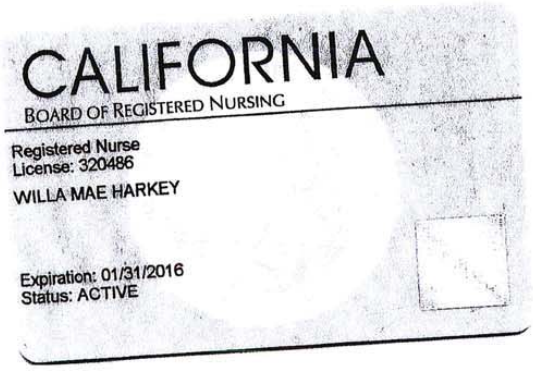
PROFESSIONAL MEMBERSHIPS:
Member, National Nurses Assn.
Member, Neonatal Nursing Assn.

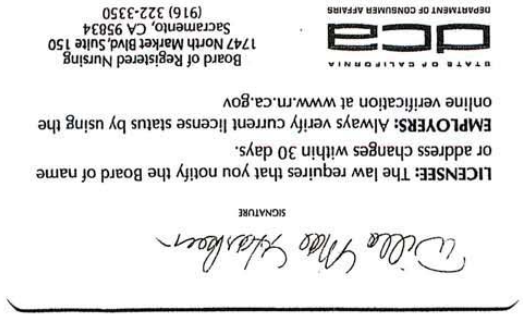
STATEMENT:

For purposes of GLP compliance, I acknowledge this to be a true and correct curriculum vitae.

W H Berglund RN 11-25-13

Willa Harkey-Berglund, RN Date


CALIFORNIA
BOARD OF REGISTERED NURSING
Registered Nurse
License: 320486
WILLA MAE HARKEY
Expiration: 01/31/2016
Status: ACTIVE


SIGNATURE
LICENSEE: The law requires that you notify the Board of name or address changes within 30 days.
EMPLOYERS: Always verify current license status by using the online verification at www.rn.ca.gov
STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
Board of Registered Nursing
1747 North Market Blvd, Suite 150
Sacramento, CA 95834
(916) 322-3350

Megan Boatwright

From: Danielle Martz <DMartz@sairb.com>
Sent: Tuesday, November 11, 2014 10:54 AM
To: Megan Boatwright
Subject: RE: Continuing approval for study 120463

Thanks so much!

Thank You,
Danielle

Danielle R. Martz, B.S. | Operations Coordinator I
Schulman Associates IRB
Sawgrass Plaza, Suite 120
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* Please note – our Word based Study Status Report forms will retire December 1, 2014. Please use this link to access our new SmartForm, http://www.sairb.com/Forms/Pages/ongoingreview.aspx

---

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Tuesday, November 11, 2014 1:54 PM
To: Danielle Martz; Robert Testman
Cc: Jeffrey Atlas
Subject: RE: Continuing approval for study 120463

Hi Danielle,

Attached please find attached Willa's CV and current nurse's license per your request.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
Fresno, CA 93722
Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

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Sent: Tuesday, November 11, 2014 10:46 AM
To: Robert Testman

Cc: Megan Boatwright; Jeffrey Atlas
Subject: RE: Continuing approval for study 120463

Hi Robert,

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Danielle

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---

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, November 06, 2014 2:51 PM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: Continuing approval for study 120463

Hi Jeff,

Please see attached the continuing approval form and letter for this study as we discussed.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Thursday, November 6, 2014 6:26 AM
To: Robert Testman; Megan Boatwright
Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Importance: High

Hi Rob and Megan,

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Thank you.

Best Regards,

Jeff Atlas

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From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
Subject: Conditionally Approved Studies

Hi Rob,

Thanks for taking the time last week to discuss these two studies. Currently, the expiration is within 2 weeks regardless of the conditions of approval being met. At this time, we are only requesting the submission of the attached form for each study. As previously mentioned, we are able to provide additional months to allow for you to provide the documentation necessary to obtain full approval, however we will require either a signed letter by the PI of each study (you and Megan) or a protocol in FINAL format for each study, as the only condition remaining is that of a FINAL formatted protocol.

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Jeff Atlas

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Please consider the environment before printing this e-mail.

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, November 17, 2014 1:58 PM
To: Robert Testman
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol 120463 [Country:US]

Importance: High

Robert,

IRB documents have been posted and are available via Schulman Associates IRB **SiteAccess**.

Document Category:	**CONTINUING/PERIODIC REVIEW**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**120463 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Re-Approval Letter	Nov 17, 2014

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN Associates IRB
www.sairb.com

REAPPROVED: 11/13/14
EXPIRATION DATE: 11/12/15

November 13, 2014

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") — Board #3
TO:	Robert J. Testman
SUBJECT:	Reapproval
SPONSOR:	American Chemistry Council
PROTOCOL NO:	120463
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board received your study status report form on the referenced protocol.

Please note that the study remains on Conditional Approval. The Board is pending receipt of a final version of the protocol to satisfy the condition of approval.

This letter is to inform you that the Board approved your site(s) to conduct this study for another twelve (12) months. Please continue to use the latest Schulman approved informed consent(s). If the study is expected to last beyond the approval period, you must request reapproval at least eight (8) weeks prior to the expiration date noted above. Your next report to the Board on the status of this study is due twelve (12) months from the approval date or at the time the study closes, whichever is earlier. You can find the Schulman Study Status Report Form at www.sairb.com.

The Board requires you to notify Schulman of the following reportable events, including, but not limited to: any new advertisements or recruitment material ("study-related materials"); change of investigator or site; unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; amendments or changes in the protocol; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study, and await a response from the Board, prior to implementing the amendments, study-related materials, and/or advertisements. Please refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on SiteAccess at www.sairb.com.

Schulman Associates IRB, Inc. is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

ja

PLEASE REFERENCE IRB #201307318 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yy format.

SCHULMAN ASSOCIATES IRB

Offices: Cincinnati, Ohio | Ft. Lauderdale, Florida
www.sairb.com

Memorandum

December 09, 2014

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Robert J. Testman
SUBJECT:	Corrected Reapproval Letter
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	120463
IRB NO:	201307318

It has been identified through internal quality control that the Reapproval Letter dated 11/13/14 referenced an approved IRB Informed Consent. Additionally, the approval box was not reflecting the current study status.

We have corrected the approval box and language within the letter.

Please file this Memo and corrected Reapproval Letter in your regulatory binder.

ja

PLEASE REFERENCE IRB #201307318 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

Corrected Letter dated 12/09/14

CONDITIONAL REAPPROVAL~~ED~~: 11/13/14
EXPIRATION DATE: 11/12/15

November 13, 2014

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") — Board #3
TO:	Robert J. Testman
SUBJECT:	Reapproval
SPONSOR:	American Chemistry Council
PROTOCOL NO:	120463
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

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Schulman Associates IRB, Inc. is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

ja

PLEASE REFERENCE IRB #201307318 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yy format.

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Monday, March 09, 2015 11:42 AM
To: Robert Testman; Megan Boatwright
Subject: AEA09 Conditional Approval

Hi Rob & Megan,

I know you've been quite busy with getting AEA08 started with the recent full approval granted. I wanted to check in regarding AEA09 and check to see if there is a proposed timeframe of submission of a final amendment for review. Please let me know at your earliest convenience.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Friday, March 27, 2015 12:54 PM
To: Megan Boatwright
Cc: Robert Testman
Subject: AEA09 (120463)

Hi Megan,

I just wanted to touch base regarding the conditional approval still remaining on this study. If you have an anticipated timeframe of submission, please let me know.

Thank you!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
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Megan Boatwright

From: Robert Testman
Sent: Friday, March 27, 2015 1:01 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: AEA09 (120463)

Hi Jeff,

This is next in line for us to work on. Megan is sending you an amendment for the removal efficiency study today. I think it will be a few weeks still before we get AEA09 submitted.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, March 27, 2015 12:54 PM
To: Megan Boatwright
Cc: Robert Testman
Subject: AEA09 (120463)

Hi Megan,

I just wanted to touch base regarding the conditional approval still remaining on this study. If you have an anticipated timeframe of submission, please let me know.

Thank you!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Friday, March 27, 2015 1:01 PM
To: Robert Testman; Megan Boatwright
Subject: RE: AEA09 (120463)

Sounds good Rob, thanks! I am in receipt of the amendment 1 for AEA08.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, March 27, 2015 4:01 PM
To: Jeffrey Atlas; Megan Boatwright
Subject: RE: AEA09 (120463)

Hi Jeff,

This is next in line for us to work on. Megan is sending you an amendment for the removal efficiency study today. I think it will be a few weeks still before we get AEA09 submitted.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Friday, March 27, 2015 12:54 PM
To: Megan Boatwright
Cc: Robert Testman
Subject: AEA09 (120463)

Hi Megan,

I just wanted to touch base regarding the conditional approval still remaining on this study. If you have an anticipated timeframe of submission, please let me know.

Thank you!

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | Operations Coordinator 1
Schulman Associates IRB
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Use our SmartForms to **save time and **minimize errors**—Log into eSubmission 2.0 to submit your new site or study**

Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Thursday, October 15, 2015 10:23 AM
To: Robert Testman
Subject: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

Megan

The following documents have been successfully submitted via Schulman Associates IRB **eSubmission™ 2.0** system:

Submission Type:	Single Site Study Periodic and Continuing Review Report
Submission Form:	Single Site Study Periodic and Continuing Review Report Form.pdf (Schulman Submission Format)
Submission Comments:	

List of Uploaded Files:

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Acknowledgement #:	201307317_10152015132252
Form ID:	OR1504566
IRB Number:	201307317
Investigator:	Robert Testman
Sponsor:	AEATF II
Protocol Number:	AEA09
Submitted Date/Time:	Oct 15 2015 1:22PM

SCHULMAN Associates IRB, Inc.
www.sairb.com

[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From: Danielle Correa <DCorrea@sairb.com>
Sent: Wednesday, October 21, 2015 9:58 AM
To: Robert Testman
Cc: Megan Boatwright
Subject: Protocol AEA09 Continuing Review Follow Up
Attachments: 01. Site Ltr.pdf

Hi Robert,

I hope this email finds you well. We have received the Continuing Review Report for AEA09. In November 2014 you provided the attached letter detailing why the remaining condition of approval had not yet been met. It is my understanding that this rationale is no longer accurate. I spoke with Jeff Atlas, he explained that the current issue is that the EPA wanted to see the results from AEA08 before allowing AEA09. Now that AEA08 is mostly complete, you intend to submit a final Protocol for AEA09 to the EPA and then to Schulman for full approval. Is this accurate?

If you could please provide us with a letter, much like the one attached, detailing the current reasoning why the remaining condition of approval is unmet. If you have any questions please feel free to reach out and contact me.

Thank You,
Danielle

Danielle (Martz) Correa, B.S. | Ongoing Review Coordinator
Schulman IRB |4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100 | FAX: 866-657-7917
DCorrea@sairb.com | Visit us at www.sairb.com

Golden Pacific
LABORATORIES

November 6, 2014

Jeffrey Atlas, BS-HSA
Schulman Associates IRB
Sawgrass Plaza Suite 120
1550 Sawgrass Corporate Parkway
Sunrise, FL 33323

Dear Jeff,

Please find attached the single site periodic and continuing review form for GPL study 120463, Schulman IRB number 201307317. As discussed this study has been reviewed and approved by the EPA/HSRB with conditions including obtaining full approval from Schulman IRB. Due to ongoing sponsor review and internal priorities the revised protocol to gain full approval is not ready for submission today. We anticipate submitting the revised protocol within the next 30 days. Please feel free to contact me with any questions.

Sincerely,

Robert Testman
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

Megan Boatwright

From: Danielle Correa <DCorrea@sairb.com>
Sent: Friday, October 23, 2015 5:46 AM
To: Robert Testman
Cc: Megan Boatwright
Subject: RE: Protocol AEA09 Continuing Review Follow Up

Hi Robert,

Do you anticipate being able to submit the below requested rationale letter today?

Thank You,
Danielle

Danielle (Martz) Correa, B.S. | Ongoing Review Coordinator
Schulman IRB |4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100 | FAX: 866-657-7917
DCorrea@sairb.com | Visit us at www.sairb.com

From: Danielle Correa
Sent: Wednesday, October 21, 2015 12:58 PM
To: 'rtestman@gplabs.com' <rtestman@gplabs.com>
Cc: 'mboatwright@gplabs.com' <mboatwright@gplabs.com>
Subject: Protocol AEA09 Continuing Review Follow Up

Hi Robert,

I hope this email finds you well. We have received the Continuing Review Report for AEA09. In November 2014 you provided the attached letter detailing why the remaining condition of approval had not yet been met. It is my understanding that this rationale is no longer accurate. I spoke with Jeff Atlas, he explained that the current issue is that the EPA wanted to see the results from AEA08 before allowing AEA09. Now that AEA08 is mostly complete, you intend to submit a final Protocol for AEA09 to the EPA and then to Schulman for full approval. Is this accurate?

If you could please provide us with a letter, much like the one attached, detailing the current reasoning why the remaining condition of approval is unmet. If you have any questions please feel free to reach out and contact me.

Thank You,
Danielle

Danielle (Martz) Correa, B.S. | Ongoing Review Coordinator
Schulman IRB |4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100 | FAX: 866-657-7917
DCorrea@sairb.com | Visit us at www.sairb.com

Megan Boatwright

From: Robert Testman
Sent: Friday, October 23, 2015 1:29 PM
To: Danielle Correa
Cc: Megan Boatwright
Subject: RE: Protocol AEA09 Continuing Review Follow Up
Attachments: AEA09 continuing approval letter 2015.pdf

Hi Danielle,

Please find attached an explanation letter for AEA09. Feel free to contact me if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Danielle Correa [mailto:DCorrea@sairb.com]
Sent: Wednesday, October 21, 2015 9:58 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Protocol AEA09 Continuing Review Follow Up

Hi Robert,

I hope this email finds you well. We have received the Continuing Review Report for AEA09. In November 2014 you provided the attached letter detailing why the remaining condition of approval had not yet been met. It is my understanding that this rationale is no longer accurate. I spoke with Jeff Atlas, he explained that the current issue is that the EPA wanted to see the results from AEA08 before allowing AEA09. Now that AEA08 is mostly complete, you intend to submit a final Protocol for AEA09 to the EPA and then to Schulman for full approval. Is this accurate?

If you could please provide us with a letter, much like the one attached, detailing the current reasoning why the remaining condition of approval is unmet. If you have any questions please feel free to reach out and contact me.

Thank You,
Danielle

Danielle (Martz) Correa, B.S. | Ongoing Review Coordinator
Schulman IRB |4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100 | FAX: 866-657-7917
DCorrea@sairb.com | Visit us at www.sairb.com

Golden Pacific
LABORATORIES

October 23, 2015

Danielle Correa
Schulman Associates IRB
4445 Lake Forest Drive
Suite 300
Cincinnati, Ohio 45242

RE: Study AEA09 status

Dear Danielle,

We have recently submitted the single site periodic and continuing review form for study AEA09 (GPL study 120463, Schulman IRB number 201307317). Subsequent to last year's review this study was placed on hold at the request of EPA pending their review of data from study AEA08 (GPL study 130503, Schulman IRB number 201307366). As you know the field and analytical work for study AEA08 has been completed. That data was provided to EPA and on August 27, 2015 EPA approved continuation of the referenced study (AEA09). We have made the EPA/HSRB requested changes to the protocol and sent it to the sponsor for final review prior to submission to Schulman to obtain full approval. Due to ongoing sponsor review we anticipate submitting the revised protocol in approximately 30 days. Please feel free to contact me with any questions.

Sincerely,

Robert Testman
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Tuesday, November 10, 2015 2:40 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**CONTINUING/PERIODIC REVIEW**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Re-Approval Letter	Nov 10, 2015

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.com

CONDITIONAL REAPPROVAL: 11/10/2015
EXPIRATION DATE: 11/09/2016

November 10, 2015

FROM:	Schulman IRB ("Schulman" or the "Board") — Board #3
TO:	Robert J. Testman
SUBJECT:	Conditional Reapproval
SPONSOR:	American Chemistry Council
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board received your Study Status Report form on the referenced protocol.

Please note that the study remains on Conditional Approval. The Board is pending receipt of a final version of the protocol to satisfy the condition of approval.

This letter is to inform you that the Board approved your site(s) to conduct this study for another twelve (12) months. If the study is expected to last beyond the approval period, you must request reapproval at least eight (8) weeks prior to the expiration date noted above. Your next report to the Board on the status of this study is due ten (10) months from the approval date or at the time the study closes, whichever is earlier. You can find the Schulman Study Status Report Form at www.sairb.com.

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

dc

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yyyy format.

Megan Boatwright

From: Robert Testman
Sent: Friday, February 19, 2016 10:52 AM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: Revised AEA09 Protocol
Attachments: AEA09 ICF.docx; AEATF Brush Roller Final Protocol 05Jan2016.docx

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical-based products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin;; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long

underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy, or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates Institutional Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Schulman Associates Institutional Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

PROTOCOL

05 January 2016

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

February 2016

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEA09

GPL Study Number

120463

Total Number of Pages: 145

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No: AEA09
GPL Study No: 120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date: February 2016

Proposed Experimental Termination Date: July 2016

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
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Field Location:	Fresno County, CA
Reviewing IRB:	Schulman Associates IRB, Inc. 1550 Sawgrass Corporate Parkway Suite 120 Sunrise, FL 33323 Phone: (954) 327-0778 Website: www.sairb.com

2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 360 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 360 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all personal protective equipment (PPE, i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable,

thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as

outlined in section 4 of the scenario design document. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is limited incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: (*954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its

risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish.

Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California Department of Pesticide Review (DPR) and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity

profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations, and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data available to EPA from the PHED, the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or isopropyl alcohol (IPA) will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own gender. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The subjects will be painting using equipment such as extension poles and ladders. There is a risk of injury from dropped equipment or falling. These risks will be reduced by continuous observation from the research team and assistance with supporting ladders.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 360 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 360 ppm and 600 ppm.
A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study for each preparation of the test substance including colorant.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantitation of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint

types. The table below lists the proposed limit of quantitation (LOQ) for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample
Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Subjects will be provided a smaller container (paint cup) and edger to use at their preference for brush painting. If subjects use the paint cup they will transfer paint from the secondary container to the paint cup. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue.

Subjects will be provided dry cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at ambient room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting

rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary the amount of active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).

Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 6 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 12 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. The ceiling exhaust fan will be operated continuously during each ME. Room airflow (ACH) will be measured and included in the final study report. Photographs of the painting rooms will be maintained in the raw data. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The AiAH will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Painters to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects

will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates. At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24 initially selected are required, randomized subject 25 will be contacted followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate painters (or 'workers') for the MEs. This includes the planned 18 surrogate painters needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Subject Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire

about the health of the subject. The investigator will answer any questions the subject may have. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 24 subjects have been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of

female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and Subject Self-Reporting Demographic Form
- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands, face, or neck (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies or sensitivities to latex paint, soaps, BIT, isopropyl alcohol or other chemical-based products.
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Other health conditions that make participation difficult or unsafe (e.g. broken bone)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential appliers of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of six will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment,

travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed, research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for

a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink. The on-site health professional will immediately be contacted for further medical management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer

dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same gender. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer dosimeter shirt will be tucked into the pants. A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation, and the subject will retain the key during their ME.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. A piece of inner dosimeter cloth will be placed underneath the painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on and ensure proper placement.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained

in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections. Ceiling ventilation fans will remain on while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be provided additional test substance until they have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks. Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects

to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same gender. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

   a. The researcher will help subjects take off the painter's hat plus underlying dosimeter and save them for analysis.

   b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

   c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse by pouring the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

   d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

   e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

   f. The researcher will help subjects take off the long underwear, and save it for analysis.

   g. When all samples have been collected, subjects will dress

again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat and underlying dosimeter cloth will be removed with the assistance of a researcher (study team member) of the same gender, placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing, sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™ filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same gender and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring

period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in "gross violation" or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air

changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.
5. Prepare field fortification samples.
6. Monitor temperature and humidity, ensure room vent fans are on during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site

(e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 ng/mL and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at $\leq$ -10° C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be added to the raw data
Purity:	to be added to the raw data
Date Received:	to be added to the raw data
Expiration Date:	to be added to the raw data

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The limit of quantitation (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the remaining samples. Any sample not bracketed by the standard curve concentrations will be re-diluted and re-analyzed unless it is below the LOQ when at the minimum method dilution.

Each analytical set will include two laboratory fortified matrix samples, a solvent blank and an unfortified matrix control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution

and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantitation

Chromatographic quantitation (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);

12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study, except study subject personal information, will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be maintained in a separate location at GPL and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts (Appendix H), and an executive summary of EPA's REDs for BIT

summarizing their risk assessment conclusions (Appendix H). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the quality assurance unit (QAU). The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Study Director and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.

9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.
13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with California DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing

to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

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19. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Robert J. Testman, M.B.A. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Megan T. Boatwright, B.S. Date
Field Coordinator (English)
Golden Pacific Laboratories, LLC

Kimon P. Acedo, B.S. Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Reviewed By:

Margaret A. Hamelin, B.S., RQAP Date
Quality Assurance
Golden Pacific Laboratories, LLC

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol*. Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012 Complies with			
OTC	Yes	LEED®09 CI	Yes
SCAQMD	Yes	LEED®09 NC	Yes
CARB	Yes	LEED®09 CS	Yes
CARB SCM2007	Yes	LEED®09 H	Yes
MPI #	53	NGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer
Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry
Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent
Flash Point: N/A
Finish: 0-5 units @ 85°
Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic
A86W00151
VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12
Volume Solids: 43 ± 2%
Weight Solids: 61 ± 2%
Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

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SUPERPAINT®
Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE. Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
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The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet.

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SHERWIN WILLIAMS.

SUPERPAINT®

Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

Desde el 01/12/2012, cumple con:			
OTC	Si	LEED® 09 CI	Si
SCAQMD	Si	LEED® 09 NC	Si
CARB	Si	LEED® 09 CS	Si
CARB SCM 2007	Si	LEED® 09 H	Si
MPI N.°	53	NGBS	Si

CARACTERÍSTICAS

SuperPaint Interior Latex Flat se utiliza en paneles y maderas vírgenes, imprimados o con pintura previa, así como en revoque imprimado, mampostería y metales. SuperPaint permite cubrir con una capa cualquier color en superficies lisas y ofrece un acabado duradero que se puede lavar y fregar.

Color: Disponible en la mayoría de los colores
Para optimizar la cobertura y la coloración, utilice siempre el imprimador P-Shade recomendado.

Rendimiento: 350-40 ft²/gal (7,2-8,1 m²/L) a 4 mils húmedo; 1,6 mils seco

Tiempo de secado a 77 °F (25 °C) y 50 % RH:
Tacto: 1 hora
Repintado: 4 horas
Los plazos de secado y repintado dependen de la temperatura, la humedad y el espesor de la capa.

Punto de inflamación: N/C

Acabado: 0-5 unidades a 85°

Tinturas con CCE:

Base	oz/gal	Fuerte
Extrablanco	0-6	125 %
Base profunda	4-12	100 %
Blanco de alta reflectividad	0-5	125 %

Tipo de vehículo: Acrílico vinilo
A86W00151

COV (salvo solventes exentos): <50 g/L; 0,42 lb/gal
Conforme al Código de Reglamentos Federales [CFR], Título 40, Artículo 59.406, y a las Regulaciones de Productos Orgánicos [SOR] 2009-264, art. 12

Sólidos por volumen: 43 ± 2 %

Sólidos por peso: 61 ± 2 %

Peso por galón: 12,1 lb (5,4 kg)

ESPECIFICACIONES

SuperPaint Interior Latex se puede aplicar directamente sobre revestimientos previos o sobre paneles de yeso sin pintar, revoque (curado con un pH menor a 9), mampostería (curada con un pH menor a 9), madera sin sangrado.

Panel de yeso
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Mampostería/bloques
(se pueden rellenar para obtener una superficie lisa o imprimar si se trata de un sustrato con un pH alto)
1 capa Loxon Block Surfacer
o
1 capa Loxon Concrete & Masonry Primer
2 capas SuperPaint Interior Latex

Revoque
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Madera
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex
Si la madera presenta sangrados (como taninos u orificios de nudos), aplique una capa de imprimador con Multi-Surface Primer.

Otros imprimadores podrían ser adecuados.

Cuando volver a pintar implique un cambio de color drástico, la presencia de una capa de imprimador mejorará el poder cubritivo del revestimiento de color definitivo.

PREPARACIÓN DE LA SUPERFICIE

¡ADVERTENCIA! La eliminación de la pintura vieja mediante lija, raspaje u otro medio podría generar polvo o vapores que contengan plomo. La exposición al polvo y vapores con plomo podría causar un daño cerebral u otros problemas de salud, especialmente en el caso de niños y embarazadas. Para controlar la exposición al plomo y otras sustancias peligrosas se necesita utilizar equipos de protección adecuados, como un respirador bien ajustado (aprobado por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) y una contención y limpieza correctos. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-LEAD (en los EE. UU.) o comuníquese con la autoridad sanitaria local.

Elimine de las superficies cualquier tipo de contaminación lavándolas con un limpiador adecuado, enjuague minuciosamente y deje que se sequen. La pintura descascarada o marcada se debería rasquetear y lijar hasta lograr una superficie sólida. Las superficies brillantes se deberían lijar hasta quitarles el brillo. Las manchas causadas por agua, humo, tinta, lápiz, grasa, etc. se deberían sellar utilizando el imprimador/sellador adecuado.

Panel de yeso
Llene las grietas y perforaciones con enduido/masilla y lije hasta que la superficie quede lisa. Los compuestos para juntas se deben curar y lijar hasta que la superficie quede lisa. Elimine todo el polvo producido al lijar.

Mampostería, concreto, cemento, bloques
Todas las superficies nuevas se deben curar según las recomendaciones del proveedor (normalmente, durante unos 30 días). Elimine todo tipo de agente desmoldante y de curado. Las superficies ásperas se deben empastar para obtener una superficie lisa. Si no pudiera esperar 30 días para comenzar a pintar, deje que la superficie se cure durante 7 días y luego imprima la superficie con Loxon Concrete & Masonry Primer.

SHERWIN WILLIAMS.

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SUPERPAINT®
Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

PREPARACIÓN DE LA SUPERFICIE

Revoque
El revoque sin pintar se debe curar y dejar endurecer. El revoque texturado, blando, poroso o granulado debería tratarse con una solución de 1 pinta (473 cm^3) de vinagre de uso doméstico y 1 galón (3,79 L) de agua. Repita hasta que la superficie esté dura, luego enjuague con agua limpia y deje que se seque.

Madera
Lije la madera expuesta para lograr una superficie indemne. Emparche todos los orificios e imperfecciones con masilla o enduido para madera y lije hasta que la superficie quede lisa.

Moho
Antes de pintar, elimine el moho con una solución de 1 parte de blanqueador líquido y 3 partes de agua. Aplique la solución y friegue el área mohosa. Deje trabajar la solución sobre la superficie durante 10 minutos. Enjuague minuciosamente con agua y deje secar la superficie antes de pintarla. Utilice gafas protectoras, guantes impermeables y vestimenta de protección. Enjuague sin demora cualquier resto de la mezcla que tenga contacto con su piel. No agregue detergentes ni amoníaco a la solución de blanqueador y agua.

Enmasillado
Los espacios en las paredes, cielorrasos, molduras de cornisas y otros contramarcos internos se pueden rellenar con la masilla adecuada después de imprimar la superficie.

APLICACIÓN

Aplicar a temperaturas superiores a 50 °F (10 °C).
No es necesario diluir.
Brocha
Utilice brochas de nailon/poliéster.
Rodillo
Utilice rodillos de felpa sintética de 3/8" a 3/4" (0,95 a 1,90 cm).
Pistola de pulverización sin aire
Presión ..... 2000 psi
Boquilla..... .017"-.021"

INFORMACIÓN SOBRE LIMPIEZA

Use jabón y agua tibia para limpiar derrames, salpicaduras, manos y herramientas inmediatamente después de utilizar el producto. Después de limpiar, haga correr alcohol mineral por el equipo de la pistola para evitar que se oxide. Siga las recomendaciones de seguridad del fabricante siempre que utilice alcoholes minerales.

PRECAUCIONES

Únicamente para uso en interiores.
Proteja contra el frío.
Sin reacción fotoquímica.

ETIQUETA DE PRECAUCIÓN
PRECAUCIÓN: contiene SÍLICE CRISTALINA. Utilice únicamente con una ventilación adecuada. Para evitar una exposición excesiva, abra las puertas y ventanas o utilice otros medios para garantizar la circulación de aire fresco durante la aplicación y el secado. Si le llora la vista, le duele la cabeza o sufre mareos, aumente la circulación de aire fresco, utilice protección respiratoria (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) o abandone el lugar. Deberá haber una ventilación adecuada cuando se lije o desgaste la película seca. Si no pudiera proporcionarse una ventilación adecuada, utilice una máscara antipartículas (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH). Siga las instrucciones del fabricante de la máscara. Evite el contacto con ojos y la piel. Lávese las manos después de usar el producto. Mantenga el recipiente cerrado cuando no lo esté utilizando. No transfiera el contenido a otros recipientes para almacenarlo. PRIMEROS AUXILIOS: En caso de contacto ocular, enjuáguese minuciosamente con una gran cantidad de agua. Consulte a su médico si la irritación persiste. En caso de ingerir el producto, llame de inmediato al Centro de Toxicología, una sala de emergencias hospitalaria o a un médico. EFECTOS RETARDADOS CAUSADOS POR UNA EXPOSICIÓN EXCESIVA PROLONGADA El desgaste o lijado de la película seca podría liberar sílice cristalino que, según se ha comprobado, puede provocar daños pulmonares y cáncer en caso de exposición prolongada. ADVERTENCIA: Este producto contiene sustancias químicas que, según el Estado de California, provocan cáncer y defectos congénitos u otros daños reproductivos. NO INGERIR. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.
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La información y recomendaciones en la Hoja de Datos del Producto se basan en las pruebas realizadas por The Sherwin-Williams Company o en representación de ella. La información y recomendaciones mencionadas están sujetas a cambios y corresponden al producto ofrecido al momento de su publicación. Consulte a un representante de Sherwin-Williams para obtener la Hoja de Datos del Producto más reciente.

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or, absorbed through skin. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles or face shield) long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaiminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

FIRST AID	
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latices, Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Car Care Products Including Car Washes, Car Waxes, And Silicone Emulsions, Home Care Cleaning Products Including Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	**5383-121**
EPA Establishment Number	**5383-NJ-1**

ACTIVE INGREDIENT:	**% Weight**
1,2-Benzisothiazolin-3(2H)-One	**19.18%**
INERT INGREDIENTS	**80.82%**
TOTAL	**100.0%**

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:
[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

®MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

APPLICATION RATE: Mergal®BIT 20 is an effective preservative for most aqueous applications. Mergal®BIT 20 is suggested for use in aqueous or water-containing products and systems, including industrial and institutional products to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% wt/wt of Mergal®BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of Mergal®BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below.

FOR FOOD-CONTACT PAPER AND PAPERBOARD COATINGS: Follow the FDA clearances cited below. Use of Mergal®BIT 20 must not exceed 0.21 mg/in^2 (0.0326 mg/cm^2) of finished paper and paperboard intended for contact with dry foods and 0.11 mg/in^2 (0.0168 mg/cm^2) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal®BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 -	Components for Adhesives
21 CFR 176.170 –	Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 –	Components of Paper and Paperboard in contact with dry food
21 CFR 176-300 –	Slimicides (in the manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 –	Rubber articles intended for repeated use: follow instructions in paragraph (c)(4)(1X)

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polymer and micellar/polymer waterfloods: Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical-based products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin;; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear

(long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy, or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates Institutional Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Schulman Associates Institutional Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Spanish Informed Consent Form with Subject's Bill of Rights here after translation of approved English version (p1)

Spanish Informed Consent Form with Subject's Bill of Rights here after translation of approved English version (p2)

Spanish Informed Consent Form with Subject's Bill of Rights here after translation of approved English version (p3)

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APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA09: Interior Latex Paint Application with Brush and Roller Scenario

Part I: *Interview questions*	Q/NQ
1. Do you have any skin conditions on your hands (psoriasis, eczema, etc.)? ☐Yes ☐ No	
2. Do you have difficulty breathing? Moderate or severe asthma or emphysema? ☐Yes ☐ No	
3. Do you have Cardiovascular disease? Have you ever had a myocardial infarct, stroke, or congestive heart failure? Do you have uncontrolled high blood pressure? ☐Yes ☐ No	
4. Do you have other health problems that might make it difficult to participate in this study as described? ☐Yes ☐ No	
5. Are you employed by or married to an employee of an AEATF company, GPL, a paint manufacturer or the ACC (interviewer to explain initials of various entities)? ☐Yes ☐ No	

Part II: *To be filled out by candidate*			
6. Name		9. Weight: lbs	
7. Address		10. Height: ft in	
		11. Shirt size: ☐ **S** ☐ **M** ☐ **L** ☐ **XL** ☐ **XXL** ☐ **XXXL**	
8. City, ST, Zip		12. Waist: ☐ 24-28 in ☐ 28-32 in ☐ 32-36 in	
13. Telephone(s)		☐ 36-40 in ☐ 40-44 in ☐ 44-50 in	
14. Age in years =	15. DOB:	16. Sex ☐ M ☐ F	
17. Resident in Fresno County? ☐ Yes ☐ No		18. Have you painted with a brush and roller in the past 5 years? ☐Yes ☐ No	
		19. Have you worked as a professional painter in the past 10 years? ☐Yes ☐ No	
20. Preferred Language: ☐ English ☐ Spanish		21. Reads: ☐ English ☐ Spanish	
22. Are you pregnant? ☐ NA ☐Yes ☐ No		23. Are you nursing a baby? ☐ NA ☐Yes ☐ No	
24. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No			
25. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐ No			
26. Are you bothered by rubbing alcohol or soap on your skin more than family or friends? ☐Yes ☐ No			
Interviewer ID age verification: ☐Yes ☐ No _____ _____ Subject Signature Date			

Language of interview: : ☐ English ☐ Spanish	Interviewer Name:
Interview date:	Interviewer Signature:

Spanish Subject Self-Reporting Demographic Form here after translation of approved English version

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
*for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	Cristobalite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	Calcium Carbonate		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	Titanium Dioxide		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.

SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

A87W151

SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

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SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable

CONDITIONS TO AVOID

None known.

INCOMPATIBILITY

None known.

HAZARDOUS DECOMPOSITION PRODUCTS

By fire: Carbon Dioxide, Carbon Monoxide

HAZARDOUS POLYMERIZATION

Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS

Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.

IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD

Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.

Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

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SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

HOJA DE DATOS SOBRE LA SEGURIDAD DEL MATERIAL

A86W151
12 00

FECHA DE PREPARACIÓN
30-dic-2014

SECCIÓN 1 — PRODUCTO Y COMPAÑÍA IDENTIFICATIÓN

NÚMERO DEL PRODUCTO
A86W151
NOMBRE DEL PRODUCTO
SUPERPAINT® Interior Flat Latex Wall Paint, Extra White
NOMBRE DEL FABRICANTE
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

NÚMEROS DE TELÉFONOS Y SITIOS WEB

Información sobre el producto	www.sherwin-williams.com
Información reguladora	(216) 566-2902 www.paintdocs.com
Emergencia médica	(216) 566-2917
Emergencia de transporte*	(800) 424-9300
**para una emergencia química SOLAMENTE (derrame, fuga, fuego, exposición o accidente)*	

SECCIÓN 2 — INGREDIENTES DEL PRODUCTO

% por peso	CAS No.	INGREDIENTE	UNIDADES	PRESION DE VAPOR
15	14808-60-7	Cuarzo		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,1 mg/m3 Resp. de Polvo	
1	14464-46-1	cristobalita		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,05 mg/m3 Resp. de Polvo	
2	1332-58-7	Kaolin		
		ACGIH TLV	No Disponible	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	13463-67-7	Dioxido de Titanio		
		ACGIH TLV	10 mg/m3 de Polvo	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECCIÓN 3 — EFECTOS POTENCIALES PARA LA SALUD

VÍAS DE EXPOSICIÓN
INHALACIÓN de vapor o de la niebla para la atomización.
Contacto del producto, del vapor o de la niebla para la atomización con los OJOS o la PIEL.
EFECTOS DE LA SOBREEXPOSICIÓN
OJOS: Irritación.
PIEL: Una exposición prolongada y repetida puede causar irritación.
INHALACIÓN: Irritación del sistema respiratorio superior.

En un recinto cerrado, los vapores en alta concentración pueden causar dolor de cabeza, náusea o mareo.
SEÑALES Y SÍNTOMAS DE LA SOBREEXPOSISCIÓN
La rojez, la picazón o la sensación de ardor indican exposición excesiva de los ojos o la piel.
CONDICIONES MÉDICAS EMPEORADAS POR LA SOBREEXPOSICIÓN
Ninguno generalmente reconocido.
CANCER INFORMATION
Vea la Sección 11.

HMIS Codes

Salud	1*
Inflamabilidad	0
Reactividad	0

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SECCIÓN 4 — PRIMEROS AUXILIOS

OJOS: Lávese los ojos durante 15 minutos usando mucha agua. Consulte con un médico.
PIEL: Lávese bien la parte afectada con agua y jabón.
Quítese la ropa contaminada y lávela antes de volverla a usar.
INHALACIÓN: Si le afecta, salga del lugar contaminado. Respire. Manténgase abrigado y tranquilo.
INGESTIÓN: No induza o vomito. Consulte inmediatamente con un médico.

SECCIÓN 5 — PROCEDIMIENTOS DE EXTINCIÓN

PUNTO DE INFLAMACIÓN	LEL	UEL	CLASIFICACIÓN DE INFLAMACIÓN
No corresponde	No corresponde	No corresponde	No corresponde

PRODUCTOS PARA COMBATIR EL FUEGO
Anhídrido carbónico, producto químico seco, espuma de alcohol
PELIGROS DE EXPLOSIÓN E INCENDIO INUSUALES
Los envases cerrados pueden reventar (debido al acumulamiento de presión) cuando expuestos a calor intenso.
En casos de emergencias, la exposición prolongada a productos de su descomposición puede causar un peligro a la salud. Puede ser que los síntomas no se manifiesten de inmediato. Obtenga atención médica.
PROCEDIMIENTOS ESPECIALES PARA COMBATIR EL FUEGO
Debe usarse equipos de protección total, incluyendo aparatos respiratorios autocontenidos.
La atomización de agua puede resultar ineficaz. Si se usa agua, es preferible usar boquillas de neblina. Se puede usar agua para enfriar los envases cerrados a modo de prevenir el aumento de presión y la posible autoignición o explosión cuando expuesto a calor extremado.

SECCIÓN 6 — ACCIÓN EN CASO DE ACCIDENTES

PASOS A SEGUIR EN CASO QUE OCURRA UN DERRAME O FUGA DE MATERIAL
Elimine todas las fuentes de ignición. Ventile el lugar.
Elimine con absorbente inerte.

SECCIÓN 7 — MANEJO SEGURO Y ALMACENAMIENTO

CATEGORÍA DE ALMACENAMIENTO DEPT. TRAVAJO
No corresponde
PRECAUCIONES QUE DEBEN TOMARSE DURANTE EL MANEJO Y ALMACENAMIENTO
Mantenga cerrado el envase cuando no se usa. Transfiéralo únicamente a envases aprobados colocando todas las etiquetas con las indicaciones apropiadas. No es para uso interno. Manténgalo fuera del alcance de los niños.

SECCIÓN 8 — PROTECCIÓN PERSONAL

PRECAUCIONES A TOMARSE DURANTE EL USO
Use solamente con ventilación adecuada.
Evite el contacto con la piel y los ojos. Evite respirar el vapor y la niebla producida por la atomización.
Lávese las manos después de usar.
Este recubrimiento puede contener materiales clasificados como "partículas molestosas" (listadas como "polvo" en la Sección 2) las cuales puede que estén presentes a niveles peligrosos únicamente durante el lijado o el pulido de película seca. Si la Sección 2 no menciona polvos específicos, los límites aplicables para los "polvos molestosos" son ACGIH TLV 10 mg/m3 (total de polvo), 3 mg/m3 (fracción respirable), OSHA PEL 15 mg/m3 (total de polvo), 5 mg/m3 (fracción respirable).
Remover la pintura vieja ya sea lijando, raspando, gastando o de cualquier otra manera creará polvo o gases que pueden contener plomo. La exposición al polvo o a los gases que contengan plomo puede causar daños al cerebro o causar otros efectos adversos a la salud, especialmente en personas menores de edad y mujeres embarazadas. Para controlar la exposición al plomo y a otras substancias peligrodas, será necesario el uso de equipos de protección tales como un respirador apropiado aprobado por NIOSH, como así también el uso de procedimientos correctos de contención y limpieza. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-5323 (en los EE.UU.) o consulte con una autoridad competente en temas de salud a nivel local.
VENTILACIÓN
El escape de ventilación local es preferible. El escape general es aceptable si la exposición a los materiales en la Sección 2 se mantiene debajo de los límites de exposición aplicables. Recurra a los Estándares de OSHA 1910.94, 1910.107, 1910.108.
PROTECCIÓN RESPIRATORIA
Si la exposición individual no puede ser controlada debajo de los límites aplicables por medio de la ventilación, use un respirador apropiado para vapor orgánico/partículas aprobado por NIOSH/MSHA para protección contra los materiales mencionados en la Sección 2.
Cuando lije o pula la película seca, use un respirador para polvo/niebla aprobado por NIOSH/MSHA para protección contra el polvo que pueda generarse de este producto, de la capa anterior de pintura o del abrasivo utilizado.
GUANTES DE PROTECCIÓN
Use guantes apropiados para protección contra los materiales de la Sección 2.
PROTECCIÓN DE LOS OJOS
Use anteojos de seguridad con protectores laterales sin perforación.

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SECCIÓN 9 — PROPIEDADES FISICAS Y QUIMICAS

PESO DEL PRODUCTO	12,05 lb/gal	1443 g/l
PESO ESPECÍFICO	1,45	
PUNTOS DE EBULLICIÓN	212 - 213 °F	100 - 100 °C
PUNTO DE FUSIÓN	No disponible	
% VOLÁTIL VOLUMEN	57%	
COEFICIENTE DE EVAPORACIÓN	Más lento que el éter	
DENSIDAD DE VAPOR	Más pesado que el aire	
SOLUBILIDAD EN AGUA	No disponible	
pH	9,3	

COV (Teorético)

0,35 lb/gal	42 g/l	Less Water and Federally Exempt Solventes
0,16 lb/gal	19 g/l	Emitido COV

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0,41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

SECCIÓN 10 — ESTABILIDAD Y REACTIVIDAD

ESTABILIDAD — Estable

CONDICIONES A EVITAR

Ninguno conocido.

INCOMPATIBILIDAD

Ninguno conocido.

PRODUCTOS DE DESCOMPOSICIÓN PELIGROSA

Por el fuego: Dióxido de carbono, monóxido de carbono

POLIMERIZACIÓN PELIGROSA

No ocurrirá.

SECCIÓN 11 — INFORMACIÓN TOXICOLOGICA

PELIGROS CRÓNICOS PARA LA SALUD

La silice cristalina (cuarzo, cristobalita) aparece en la lista IARC y NTP. La exposición por mucho tiempo a altos niveles de polvo de sílica, que ocurre solamente cuando se lija o pule la película seca, puede causar daño al pulmón (silicosis) y quizas cáncer.

La Agencia Internacional de Investigación del Cáncer reporta en su Monografía No. 93 que existen evidencias suficientes para afirmar que el dióxido de titanio provoca cáncer en ratas de laboratorio, pero que no hay evidencias de que provoque cáncer en los seres humanos y lo clasifica dentro del Grupo 2B. Además, el resumen de la agencia IARC concluye que "No se cree que exista una exposición significativa al dióxido de titanio durante el uso de productos donde el titanio se junta con otros materiales, como en el caso de la pintura."

INFORMACIÓN TOXICOLOGIA

CAS No.	INGREDIENTE			
14808-60-7	Cuarzo			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
14464-46-1	cristobalita			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
1332-58-7	Kaolin			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
13463-67-7	Dioxido de Titanio			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible

SECCIÓN 12 — INFORMACIÓN ECOLÓGICA

ECOTOXICOLÓGICA INFORMACIÓN

Ningunos datos disponibles.

SECCIÓN 13 — CONSIDERACIONES DE DESECHO

MÉTODO PARA EL DESCARTE DE RESIDUOS

El residuo de este producto no es peligroso tal como lo define la Ley de Conservación y Recuperación de Recursos ("RCRA") 40 CFR 261. Incinérelo en los lugares autorizados. No incinere envases cerrados. Descártelo de acuerdo con las regulaciones locales, estatales y federales concernientes a la polución.

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SECCIÓN 14 — INFORMACIÓN DE TRANSPORTE

Las descripciones de envío multimodal se proporcionan a título informativo, y no tienen en cuenta el tamaño de los recipientes. La presencia de una descripción de envío para un modo de transporte en particular (mar, aire, etc.) no indica que el producto esté envasado de forma adecuada para ese modo de transporte. La idoneidad de todos los envases se debe revisar antes de los envíos y el cumplimiento de todos los reglamentos pertinentes es responsabilidad exclusiva de la persona que ofrece el producto para su transporte. El personal que carga y descarga materiales o sustancias peligrosos debe contar con formación sobre todos los riesgos derivados de dichas sustancias y sobre las medidas necesarias en caso de emergencia.

US Ground (DOT)
No regulado.
Canada (TDG)
No regulado.
IMO
No regulado.
IATA/ICAO
No regulado.

SECCIÓN 15 — INFORMACIÓN REGLAMENTARIA

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICACIÓN

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

Ningún ingrediente en este producto está sujeto a la notificación por parte del proveedor bajo la ley SARA 313 (40 CFR 372.65C).

CALIFORNIA PROPOSITION 65
CUIDADO: Este producto contiene químicos que a conocimiento del estado de California puede causar cáncer defectos de nacimiento u otros daños reproductivos.

TSCA INFORMACIÓN
Todos los químicos en este producto estan en la lista o son exhonerado de la lista de inventario de TSCA.

SECCIÓN 16 — INFORMACIÓN MISCELÁNEA

La información anterior se refiere a este producto tal como ha sido recientemente formulado, y está basada en información disponible a la fecha. La adición de reductores u otros aditivos a este producto puede substancialmente alterar la composición y los peligros del producto. Debido a que las condiciones de uso están fuera de nuestro control, no damos ningún tipo de garantía, expresa o implícita, ni asumimos responsabilidad en conexión con el uso de cualquier parte de esta información.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

Spanish advertisement here after translation of approved English version

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

Spanish Subject Invitation to Participate Script here after translation of approved English version

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.

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Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:
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1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA09-BRS-01-PH	Brush and Roller Worker Sample, ME 01, Painter's Hat
AEA09-BRS-01-PH-ID	Brush and Roller Worker Sample, ME 01, Painter's Hat Dosimeter
AEA09-BRS-01-AR	Brush and Roller Worker Sample, ME 01, Air Sampling Tube
AEA09-BRS-01-RES-01	Brush and Roller Worker Sample, ME 01, RespiCon™ 100 µm
AEA09-BRS-01-RES-02	Brush and Roller Worker Sample, ME 01, RespiCon™ 10 µm
AEA09-BRS-01-RES-03	Brush and Roller Worker Sample, ME 01, RespiCon™ 2.5 µm
AEA09-BRS-01-HW-01	Brush and Roller Worker Sample, ME 01, Hand Wash
AEA09-BRS-01-FW-01	Brush and Roller Worker Sample, ME 01, Face and Neck Wipe
AEA09-BRS-01-ID-UA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-01-ID-LA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Arm
AEA09-BRS-01-ID-FT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Front Torso
AEA09-BRS-01-ID-RT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Rear Torso
AEA09-BRS-01-ID-UL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Leg
AEA09-BRS-01-ID-LL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Leg
AEA09-BRS-01-OD-UA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Arm
AEA09-BRS-01-OD-LA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-01-OD-FT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Front Torso
AEA09-BRS-01-OD-RT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Rear Torso
AEA09-BRS-01-OD-UL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Leg
AEA09-BRS-01-OD-LL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Leg
AEA09-BRS-02-PH	Brush and Roller Worker Sample, ME 02, Painter's Hat
AEA09-BRS-02-PH-ID	Brush and Roller Worker Sample, ME 02, Painter's Hat Dosimeter
AEA09-BRS-02-AR	Brush and Roller Worker Sample, ME 02, Air Sampling Tube
AEA09-BRS-02-RES-01	Brush and Roller Worker Sample, ME 02, RespiCon™ 100 µm
AEA09-BRS-02-RES-02	Brush and Roller Worker Sample, ME 02, RespiCon™ 10 µm
AEA09-BRS-02-RES-03	Brush and Roller Worker Sample, ME 02, RespiCon™ 2.5 µm
AEA09-BRS-02-HW-01	Brush and Roller Worker Sample, ME 02, Hand Wash
AEA09-BRS-02-FW-01	Brush and Roller Worker Sample, ME 02, Face and Neck Wipe
AEA09-BRS-02-ID-UA	Brush and Roller Worker Sample, ME 02, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-02-ID-LA	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Arm

Sample ID Number	Description
AEA09-BRS-02-ID-FT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Front Torso
AEA09-BRS-02-ID-RT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Rear Torso
AEA09-BRS-02-ID-UL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Upper Leg
AEA09-BRS-02-ID-LL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Leg
AEA09-BRS-02-OD-UA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Arm
AEA09-BRS-02-OD-LA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Arm
AEA09-BRS-02-OD-FT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Front Torso
AEA09-BRS-02-OD-RT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Rear Torso
AEA09-BRS-02-OD-UL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Leg
AEA09-BRS-02-OD-LL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Leg
AEA09-BRS-03-PH	Brush and Roller Worker Sample, ME 03, Painter's Hat
AEA09-BRS-03-PH-ID	Brush and Roller Worker Sample, ME 03, Painter's Hat Dosimeter
AEA09-BRS-03-AR	Brush and Roller Worker Sample, ME 03, Air Sampling Tube
AEA09-BRS-03-RES-01	Brush and Roller Worker Sample, ME 03, RespiCon™ 100 µm
AEA09-BRS-03-RES-02	Brush and Roller Worker Sample, ME 03, RespiCon™ 10 µm
AEA09-BRS-03-RES-03	Brush and Roller Worker Sample, ME 03, RespiCon™ 2.5 µm
AEA09-BRS-03-HW-01	Brush and Roller Worker Sample, ME 03, Hand Wash
AEA09-BRS-03-FW-01	Brush and Roller Worker Sample, ME 03, Face and Neck Wipe
AEA09-BRS-03-ID-UA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Arm
AEA09-BRS-03-ID-LA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Arm
AEA09-BRS-03-ID-FT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Front Torso
AEA09-BRS-03-ID-RT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Rear Torso
AEA09-BRS-03-ID-UL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Leg
AEA09-BRS-03-ID-LL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Leg
AEA09-BRS-03-OD-UA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Arm
AEA09-BRS-03-OD-LA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Arm
AEA09-BRS-03-OD-FT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-03-OD-RT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Rear Torso
AEA09-BRS-03-OD-UL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Leg
AEA09-BRS-03-OD-LL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Leg
AEA09-BRS-04-PH	Brush and Roller Worker Sample, ME 04, Painter's Hat
AEA09-BRS-04-PH-ID	Brush and Roller Worker Sample, ME 04, Painter's Hat Dosimeter
AEA09-BRS-04-AR	Brush and Roller Worker Sample, ME 04, Air Sampling Tube
AEA09-BRS-04-RES-01	Brush and Roller Worker Sample, ME 04, RespiCon™ 100 µm
AEA09-BRS-04-RES-02	Brush and Roller Worker Sample, ME 04, RespiCon™ 10 µm
AEA09-BRS-04-RES-03	Brush and Roller Worker Sample, ME 04, RespiCon™ 2.5 µm
AEA09-BRS-04-HW-01	Brush and Roller Worker Sample, ME 04, Hand Wash
AEA09-BRS-04-FW-01	Brush and Roller Worker Sample, ME 04, Face and Neck Wipe
AEA09-BRS-04-ID-UA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Arm
AEA09-BRS-04-ID-LA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Arm
AEA09-BRS-04-ID-FT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Front Torso
AEA09-BRS-04-ID-RT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Rear Torso
AEA09-BRS-04-ID-UL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Leg
AEA09-BRS-04-ID-LL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Leg
AEA09-BRS-04-OD-UA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Arm
AEA09-BRS-04-OD-LA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Arm
AEA09-BRS-04-OD-FT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Front Torso
AEA09-BRS-04-OD-RT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Rear Torso
AEA09-BRS-04-OD-UL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Leg
AEA09-BRS-04-OD-LL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Leg
AEA09-BRS-05-PH	Brush and Roller Worker Sample, ME 05, Painter's Hat
AEA09-BRS-05-PH-ID	Brush and Roller Worker Sample, ME 05, Painter's Hat Dosimeter
AEA09-BRS-05-AR	Brush and Roller Worker Sample, ME 05, Air Sampling Tube
AEA09-BRS-05-RES-01	Brush and Roller Worker Sample, ME 05, RespiCon™ 100 µm
AEA09-BRS-05-RES-02	Brush and Roller Worker Sample, ME 05, RespiCon™ 10 µm
AEA09-BRS-05-RES-03	Brush and Roller Worker Sample, ME 05, RespiCon™ 2.5 µm
AEA09-BRS-05-HW-01	Brush and Roller Worker Sample, ME 05, Hand Wash

Sample ID Number	Description
AEA09-BRS-05-FW-01	Brush and Roller Worker Sample, ME 05, Face and Neck Wipe
AEA09-BRS-05-ID-UA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Arm
AEA09-BRS-05-ID-LA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Arm
AEA09-BRS-05-ID-FT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Front Torso
AEA09-BRS-05-ID-RT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Rear Torso
AEA09-BRS-05-ID-UL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Leg
AEA09-BRS-05-ID-LL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Leg
AEA09-BRS-05-OD-UA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Arm
AEA09-BRS-05-OD-LA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Arm
AEA09-BRS-05-OD-FT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Front Torso
AEA09-BRS-05-OD-RT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Rear Torso
AEA09-BRS-05-OD-UL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Leg
AEA09-BRS-05-OD-LL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Leg
AEA09-BRS-06-PH	Brush and Roller Worker Sample, ME 06, Painter's Hat
AEA09-BRS-06-PH-ID	Brush and Roller Worker Sample, ME 06, Painter's Hat Dosimeter
AEA09-BRS-06-AR	Brush and Roller Worker Sample, ME 06, Air Sampling Tube
AEA09-BRS-06-RES-01	Brush and Roller Worker Sample, ME 06, RespiCon™ 100 µm
AEA09-BRS-06-RES-02	Brush and Roller Worker Sample, ME 06, RespiCon™ 10 µm
AEA09-BRS-06-RES-03	Brush and Roller Worker Sample, ME 06, RespiCon™ 2.5 µm
AEA09-BRS-06-HW-01	Brush and Roller Worker Sample, ME 06, Hand Wash
AEA09-BRS-06-FW-01	Brush and Roller Worker Sample, ME 06, Face and Neck Wipe
AEA09-BRS-06-ID-UA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Arm
AEA09-BRS-06-ID-LA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Arm
AEA09-BRS-06-ID-FT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Front Torso
AEA09-BRS-06-ID-RT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Rear Torso
AEA09-BRS-06-ID-UL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Leg
AEA09-BRS-06-ID-LL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-BRS-06-OD-UA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Arm
AEA09-BRS-06-OD-LA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Arm
AEA09-BRS-06-OD-FT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Front Torso
AEA09-BRS-06-OD-RT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Rear Torso
AEA09-BRS-06-OD-UL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Leg
AEA09-BRS-06-OD-LL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Leg
AEA09-BRS-07-PH	Brush and Roller Worker Sample, ME 07, Painter's Hat
AEA09-BRS-07-PH-ID	Brush and Roller Worker Sample, ME 07, Painter's Hat Dosimeter
AEA09-BRS-07-AR	Brush and Roller Worker Sample, ME 07, Air Sampling Tube
AEA09-BRS-07-RES-01	Brush and Roller Worker Sample, ME 07, RespiCon™ 100 µm
AEA09-BRS-07-RES-02	Brush and Roller Worker Sample, ME 07, RespiCon™ 10 µm
AEA09-BRS-07-RES-03	Brush and Roller Worker Sample, ME 07, RespiCon™ 2.5 µm
AEA09-BRS-07-HW-01	Brush and Roller Worker Sample, ME 07, Hand Wash
AEA09-BRS-07-FW-01	Brush and Roller Worker Sample, ME 07, Face and Neck Wipe
AEA09-BRS-07-ID-UA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Arm
AEA09-BRS-07-ID-LA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Arm
AEA09-BRS-07-ID-FT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Front Torso
AEA09-BRS-07-ID-RT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Rear Torso
AEA09-BRS-07-ID-UL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Leg
AEA09-BRS-07-ID-LL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Leg
AEA09-BRS-07-OD-UA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Arm
AEA09-BRS-07-OD-LA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Arm
AEA09-BRS-07-OD-FT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Front Torso
AEA09-BRS-07-OD-RT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Rear Torso
AEA09-BRS-07-OD-UL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Leg
AEA09-BRS-07-OD-LL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Leg
AEA09-BRS-08-PH	Brush and Roller Worker Sample, ME 08, Painter's Hat
AEA09-BRS-08-PH-ID	Brush and Roller Worker Sample, ME 08, Painter's Hat

Sample ID Number	Description
	Dosimeter
AEA09-BRS-08-AR	Brush and Roller Worker Sample, ME 08, Air Sampling Tube
AEA09-BRS-08-RES-01	Brush and Roller Worker Sample, ME 08, RespiCon™ 100 µm
AEA09-BRS-08-RES-02	Brush and Roller Worker Sample, ME 08, RespiCon™ 10 µm
AEA09-BRS-08-RES-03	Brush and Roller Worker Sample, ME 08, RespiCon™ 2.5 µm
AEA09-BRS-08-HW-01	Brush and Roller Worker Sample, ME 08, Hand Wash
AEA09-BRS-08-FW-01	Brush and Roller Worker Sample, ME 08, Face and Neck Wipe
AEA09-BRS-08-ID-UA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Arm
AEA09-BRS-08-ID-LA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Arm
AEA09-BRS-08-ID-FT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Front Torso
AEA09-BRS-08-ID-RT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Rear Torso
AEA09-BRS-08-ID-UL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Leg
AEA09-BRS-08-ID-LL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Leg
AEA09-BRS-08-OD-UA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Arm
AEA09-BRS-08-OD-LA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Arm
AEA09-BRS-08-OD-FT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Front Torso
AEA09-BRS-08-OD-RT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Rear Torso
AEA09-BRS-08-OD-UL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Leg
AEA09-BRS-08-OD-LL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Leg
AEA09-BRS-09-PH	Brush and Roller Worker Sample, ME 09, Painter's Hat
AEA09-BRS-09-PH-ID	Brush and Roller Worker Sample, ME 09, Painter's Hat Dosimeter
AEA09-BRS-09-AR	Brush and Roller Worker Sample, ME 09, Air Sampling Tube
AEA09-BRS-09-RES-01	Brush and Roller Worker Sample, ME 09, RespiCon™ 100 µm
AEA09-BRS-09-RES-02	Brush and Roller Worker Sample, ME 09, RespiCon™ 10 µm
AEA09-BRS-09-RES-03	Brush and Roller Worker Sample, ME 09, RespiCon™ 2.5 µm
AEA09-BRS-09-HW-01	Brush and Roller Worker Sample, ME 09, Hand Wash
AEA09-BRS-09-FW-01	Brush and Roller Worker Sample, ME 09, Face and Neck Wipe
AEA09-BRS-09-ID-UA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Arm
AEA09-BRS-09-ID-LA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Arm
AEA09-BRS-09-ID-FT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-09-ID-RT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Rear Torso
AEA09-BRS-09-ID-UL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Leg
AEA09-BRS-09-ID-LL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Leg
AEA09-BRS-09-OD-UA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Arm
AEA09-BRS-09-OD-LA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Arm
AEA09-BRS-09-OD-FT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Front Torso
AEA09-BRS-09-OD-RT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Rear Torso
AEA09-BRS-09-OD-UL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Leg
AEA09-BRS-09-OD-LL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Leg
AEA09-BRS-10-PH	Brush and Roller Worker Sample, ME 10, Painter's Hat
AEA09-BRS-10-PH-ID	Brush and Roller Worker Sample, ME 10, Painter's Hat Dosimeter
AEA09-BRS-10-AR	Brush and Roller Worker Sample, ME 10, Air Sampling Tube
AEA09-BRS-10-RES-01	Brush and Roller Worker Sample, ME 10, RespiCon™ 100 µm
AEA09-BRS-10-RES-02	Brush and Roller Worker Sample, ME 10, RespiCon™ 10 µm
AEA09-BRS-10-RES-03	Brush and Roller Worker Sample, ME 10, RespiCon™ 2.5 µm
AEA09-BRS-10-HW-01	Brush and Roller Worker Sample, ME 10, Hand Wash
AEA09-BRS-10-FW-01	Brush and Roller Worker Sample, ME 10, Face and Neck Wipe
AEA09-BRS-10-ID-UA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Arm
AEA09-BRS-10-ID-LA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Arm
AEA09-BRS-10-ID-FT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Front Torso
AEA09-BRS-10-ID-RT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Rear Torso
AEA09-BRS-10-ID-UL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Leg
AEA09-BRS-10-ID-LL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Leg
AEA09-BRS-10-OD-UA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Arm
AEA09-BRS-10-OD-LA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Arm
AEA09-BRS-10-OD-FT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Front Torso
AEA09-BRS-10-OD-RT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-10-OD-UL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Leg
AEA09-BRS-10-OD-LL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Leg
AEA09-BRS-11-PH	Brush and Roller Worker Sample, ME 11, Painter's Hat
AEA09-BRS-11-PH-ID	Brush and Roller Worker Sample, ME 11, Painter's Hat Dosimeter
AEA09-BRS-11-AR	Brush and Roller Worker Sample, ME 11, Air Sampling Tube
AEA09-BRS-11-RES-01	Brush and Roller Worker Sample, ME 11, RespiCon™ 100 µm
AEA09-BRS-11-RES-02	Brush and Roller Worker Sample, ME 11, RespiCon™ 10 µm
AEA09-BRS-11-RES-03	Brush and Roller Worker Sample, ME 11, RespiCon™ 2.5 µm
AEA09-BRS-11-HW-01	Brush and Roller Worker Sample, ME 11, Hand Wash
AEA09-BRS-11-FW-01	Brush and Roller Worker Sample, ME 11, Face and Neck Wipe
AEA09-BRS-11-ID-UA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Arm
AEA09-BRS-11-ID-LA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Arm
AEA09-BRS-11-ID-FT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Front Torso
AEA09-BRS-11-ID-RT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Rear Torso
AEA09-BRS-11-ID-UL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Leg
AEA09-BRS-11-ID-LL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Leg
AEA09-BRS-11-OD-UA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Arm
AEA09-BRS-11-OD-LA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Arm
AEA09-BRS-11-OD-FT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Front Torso
AEA09-BRS-11-OD-RT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Rear Torso
AEA09-BRS-11-OD-UL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Leg
AEA09-BRS-11-OD-LL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Leg
AEA09-BRS-12-PH	Brush and Roller Worker Sample, ME 12, Painter's Hat
AEA09-BRS-12-PH-ID	Brush and Roller Worker Sample, ME 12, Painter's Hat Dosimeter
AEA09-BRS-12-AR	Brush and Roller Worker Sample, ME 12, Air Sampling Tube
AEA09-BRS-12-RES-01	Brush and Roller Worker Sample, ME 12, RespiCon™ 100 µm
AEA09-BRS-12-RES-02	Brush and Roller Worker Sample, ME 12, RespiCon™ 10 µm
AEA09-BRS-12-RES-03	Brush and Roller Worker Sample, ME 12, RespiCon™ 2.5 µm
AEA09-BRS-12-HW-01	Brush and Roller Worker Sample, ME 12, Hand Wash
AEA09-BRS-12-FW-01	Brush and Roller Worker Sample, ME 12, Face and Neck Wipe

Sample ID Number	Description
AEA09-BRS-12-ID-UA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Arm
AEA09-BRS-12-ID-LA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Arm
AEA09-BRS-12-ID-FT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Front Torso
AEA09-BRS-12-ID-RT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Rear Torso
AEA09-BRS-12-ID-UL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Leg
AEA09-BRS-12-ID-LL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Leg
AEA09-BRS-12-OD-UA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Arm
AEA09-BRS-12-OD-LA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Arm
AEA09-BRS-12-OD-FT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Front Torso
AEA09-BRS-12-OD-RT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Rear Torso
AEA09-BRS-12-OD-UL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Leg
AEA09-BRS-12-OD-LL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Leg
AEA09-BRS-13-PH	Brush and Roller Worker Sample, ME 13, Painter's Hat
AEA09-BRS-13-PH-ID	Brush and Roller Worker Sample, ME 13, Painter's Hat Dosimeter
AEA09-BRS-13-AR	Brush and Roller Worker Sample, ME 13, Air Sampling Tube
AEA09-BRS-13-RES-01	Brush and Roller Worker Sample, ME 13, RespiCon™ 100 µm
AEA09-BRS-13-RES-02	Brush and Roller Worker Sample, ME 13, RespiCon™ 10 µm
AEA09-BRS-13-RES-03	Brush and Roller Worker Sample, ME 13, RespiCon™ 2.5 µm
AEA09-BRS-13-HW-01	Brush and Roller Worker Sample, ME 13, Hand Wash
AEA09-BRS-13-FW-01	Brush and Roller Worker Sample, ME 13, Face and Neck Wipe
AEA09-BRS-13-ID-UA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Arm
AEA09-BRS-13-ID-LA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Arm
AEA09-BRS-13-ID-FT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Front Torso
AEA09-BRS-13-ID-RT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Rear Torso
AEA09-BRS-13-ID-UL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Leg
AEA09-BRS-13-ID-LL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Leg
AEA09-BRS-13-OD-UA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Arm

Sample ID Number	Description
AEA09-BRS-13-OD-LA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Arm
AEA09-BRS-13-OD-FT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Front Torso
AEA09-BRS-13-OD-RT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Rear Torso
AEA09-BRS-13-OD-UL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Leg
AEA09-BRS-13-OD-LL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Leg
AEA09-BRS-14-PH	Brush and Roller Worker Sample, ME 14, Painter's Hat
AEA09-BRS-14-PH-ID	Brush and Roller Worker Sample, ME 14, Painter's Hat Dosimeter
AEA09-BRS-14-AR	Brush and Roller Worker Sample, ME 14, Air Sampling Tube
AEA09-BRS-14-RES-01	Brush and Roller Worker Sample, ME 14, RespiCon™ 100 µm
AEA09-BRS-14-RES-02	Brush and Roller Worker Sample, ME 14, RespiCon™ 10 µm
AEA09-BRS-14-RES-03	Brush and Roller Worker Sample, ME 14, RespiCon™ 2.5 µm
AEA09-BRS-14-HW-01	Brush and Roller Worker Sample, ME 14, Hand Wash
AEA09-BRS-14-FW-01	Brush and Roller Worker Sample, ME 14, Face and Neck Wipe
AEA09-BRS-14-ID-UA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Arm
AEA09-BRS-14-ID-LA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Arm
AEA09-BRS-14-ID-FT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Front Torso
AEA09-BRS-14-ID-RT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Rear Torso
AEA09-BRS-14-ID-UL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Leg
AEA09-BRS-14-ID-LL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Leg
AEA09-BRS-14-OD-UA	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Arm
AEA09-BRS-14-OD-LA	Brush and Roller Worker Sample, ME 14, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-14-OD-FT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Front Torso
AEA09-BRS-14-OD-RT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Rear Torso
AEA09-BRS-14-OD-UL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Leg
AEA09-BRS-14-OD-LL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Lower Leg
AEA09-BRS-15-PH	Brush and Roller Worker Sample, ME 15, Painter's Hat
AEA09-BRS-15-PH-ID	Brush and Roller Worker Sample, ME 15, Painter's Hat Dosimeter
AEA09-BRS-15-AR	Brush and Roller Worker Sample, ME 15, Air Sampling Tube

Sample ID Number	Description
AEA09-BRS-15-RES-01	Brush and Roller Worker Sample, ME 15, RespiCon™ 100 µm
AEA09-BRS-15-RES-02	Brush and Roller Worker Sample, ME 15, RespiCon™ 10 µm
AEA09-BRS-15-RES-03	Brush and Roller Worker Sample, ME 15, RespiCon™ 2.5 µm
AEA09-BRS-15-HW-01	Brush and Roller Worker Sample, ME 15, Hand Wash
AEA09-BRS-15-FW-01	Brush and Roller Worker Sample, ME 15, Face and Neck Wipe
AEA09-BRS-15-ID-UA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Arm
AEA09-BRS-15-ID-LA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Arm
AEA09-BRS-15-ID-FT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Front Torso
AEA09-BRS-15-ID-RT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Rear Torso
AEA09-BRS-15-ID-UL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Leg
AEA09-BRS-15-ID-LL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Leg
AEA09-BRS-15-OD-UA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Arm
AEA09-BRS-15-OD-LA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Arm
AEA09-BRS-15-OD-FT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Front Torso
AEA09-BRS-15-OD-RT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Rear Torso
AEA09-BRS-15-OD-UL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Leg
AEA09-BRS-15-OD-LL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Leg
AEA09-BRS-16-PH	Brush and Roller Worker Sample, ME 16, Painter's Hat
AEA09-BRS-16-PH-ID	Brush and Roller Worker Sample, ME 16, Painter's Hat Dosimeter
AEA09-BRS-16-AR	Brush and Roller Worker Sample, ME 16, Air Sampling Tube
AEA09-BRS-16-RES-01	Brush and Roller Worker Sample, ME 16, RespiCon™ 100 µm
AEA09-BRS-16-RES-02	Brush and Roller Worker Sample, ME 16, RespiCon™ 10 µm
AEA09-BRS-16-RES-03	Brush and Roller Worker Sample, ME 16, RespiCon™ 2.5 µm
AEA09-BRS-16-HW-01	Brush and Roller Worker Sample, ME 16, Hand Wash
AEA09-BRS-16-FW-01	Brush and Roller Worker Sample, ME 16, Face and Neck Wipe
AEA09-BRS-16-ID-UA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Arm
AEA09-BRS-16-ID-LA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Arm
AEA09-BRS-16-ID-FT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Front Torso
AEA09-BRS-16-ID-RT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-16-ID-UL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Leg
AEA09-BRS-16-ID-LL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Leg
AEA09-BRS-16-OD-UA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Arm
AEA09-BRS-16-OD-LA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Arm
AEA09-BRS-16-OD-FT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Front Torso
AEA09-BRS-16-OD-RT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Rear Torso
AEA09-BRS-16-OD-UL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Leg
AEA09-BRS-16-OD-LL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Leg
AEA09-BRS-17-PH	Brush and Roller Worker Sample, ME 17, Painter's Hat
AEA09-BRS-17-PH-ID	Brush and Roller Worker Sample, ME 17, Painter's Hat Dosimeter
AEA09-BRS-17-AR	Brush and Roller Worker Sample, ME 17, Air Sampling Tube
AEA09-BRS-17-RES-01	Brush and Roller Worker Sample, ME 17, RespiCon™ 100 µm
AEA09-BRS-17-RES-02	Brush and Roller Worker Sample, ME 17, RespiCon™ 10 µm
AEA09-BRS-17-RES-03	Brush and Roller Worker Sample, ME 17, RespiCon™ 2.5 µm
AEA09-BRS-17-HW-01	Brush and Roller Worker Sample, ME 17, Hand Wash
AEA09-BRS-17-FW-01	Brush and Roller Worker Sample, ME 17, Face and Neck Wipe
AEA09-BRS-17-ID-UA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Arm
AEA09-BRS-17-ID-LA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Arm
AEA09-BRS-17-ID-FT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Front Torso
AEA09-BRS-17-ID-RT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Rear Torso
AEA09-BRS-17-ID-UL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Leg
AEA09-BRS-17-ID-LL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Leg
AEA09-BRS-17-OD-UA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Arm
AEA09-BRS-17-OD-LA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Arm
AEA09-BRS-17-OD-FT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Front Torso
AEA09-BRS-17-OD-RT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Rear Torso
AEA09-BRS-17-OD-UL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Leg

Sample ID Number	Description
AEA09-BRS-17-OD-LL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Leg
AEA09-BRS-18-PH	Brush and Roller Worker Sample, ME 18, Painter's Hat
AEA09-BRS-18-PH-ID	Brush and Roller Worker Sample, ME 18, Painter's Hat Dosimeter
AEA09-BRS-18-AR	Brush and Roller Worker Sample, ME 18, Air Sampling Tube
AEA09-BRS-18-RES-01	Brush and Roller Worker Sample, ME 18, RespiCon™ 100 µm
AEA09-BRS-18-RES-02	Brush and Roller Worker Sample, ME 18, RespiCon™ 10 µm
AEA09-BRS-18-RES-03	Brush and Roller Worker Sample, ME 18, RespiCon™ 2.5 µm
AEA09-BRS-18-HW-01	Brush and Roller Worker Sample, ME 18, Hand Wash
AEA09-BRS-18-FW-01	Brush and Roller Worker Sample, ME 18, Face and Neck Wipe
AEA09-BRS-18-ID-UA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Arm
AEA09-BRS-18-ID-LA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Arm
AEA09-BRS-18-ID-FT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Front Torso
AEA09-BRS-18-ID-RT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Rear Torso
AEA09-BRS-18-ID-UL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Leg
AEA09-BRS-18-ID-LL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Leg
AEA09-BRS-18-OD-UA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Arm
AEA09-BRS-18-OD-LA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Arm
AEA09-BRS-18-OD-FT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Front Torso
AEA09-BRS-18-OD-RT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Rear Torso
AEA09-BRS-18-OD-UL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Leg
AEA09-BRS-18-OD-LL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-FF-01-PH-C1	Fortification Sample, ME 01, Painter's Hat, 1st Control
AEA09-FF-01-PH-C2	Fortification Sample, ME 01, Painter's Hat, 2nd Control
AEA09-FF-01-PH-L1	Fortification Sample, ME 01, Painter's Hat, 1st Low Level
AEA09-FF-01-PH-L2	Fortification Sample, ME 01, Painter's Hat, 2nd Low Level
AEA09-FF-01-PH-L3	Fortification Sample, ME 01, Painter's Hat, 3rd Low Level
AEA09-FF-01-PH-H1	Fortification Sample, ME 01, Painter's Hat, 1st High Level
AEA09-FF-01-PH-H2	Fortification Sample, ME 01, Painter's Hat, 2nd High Level
AEA09-FF-01-PH-H3	Fortification Sample, ME 01, Painter's Hat, 3rd High Level
AEA09-FF-01-AR-C1	Fortification Sample, ME 01, Air Sampling Tube, 1st Control
AEA09-FF-01-AR-C2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Control
AEA09-FF-01-AR-L1	Fortification Sample, ME 01, Air Sampling Tube, 1st Low Level
AEA09-FF-01-AR-L2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Low Level
AEA09-FF-01-AR-L3	Fortification Sample, ME 01, Air Sampling Tube, 3rd Low Level
AEA09-FF-01-AR-H1	Fortification Sample, ME 01, Air Sampling Tube, 1st High Level
AEA09-FF-01-AR-H2	Fortification Sample, ME 01, Air Sampling Tube, 2nd High Level
AEA09-FF-01-AR-H3	Fortification Sample, ME 01, Air Sampling Tube, 3rd High Level
AEA09-FF-01-RES-C1	Fortification Sample, ME 01, RespiCon, 1st Control
AEA09-FF-01-RES-C2	Fortification Sample, ME 01, RespiCon, 2nd Control
AEA09-FF-01-RES-L1	Fortification Sample, ME 01, RespiCon, 1st Low Level
AEA09-FF-01-RES-L2	Fortification Sample, ME 01, RespiCon, 2nd Low Level
AEA09-FF-01-RES-L3	Fortification Sample, ME 01, RespiCon, 3rd Low Level
AEA09-FF-01-RES-H1	Fortification Sample, ME 01, RespiCon, 1st High Level
AEA09-FF-01-RES-H2	Fortification Sample, ME 01, RespiCon, 2nd High Level
AEA09-FF-01-RES-H3	Fortification Sample, ME 01, RespiCon, 3rd High Level
AEA09-FF-01-HW-C1	Fortification Sample, ME 01, Hand Wash, 1st Control
AEA09-FF-01-HW-C2	Fortification Sample, ME 01, Hand Wash, 2nd Control
AEA09-FF-01-HW-L1	Fortification Sample, ME 01, Hand Wash, 1st Low Level
AEA09-FF-01-HW-L2	Fortification Sample, ME 01, Hand Wash, 2nd Low Level
AEA09-FF-01-HW-L3	Fortification Sample, ME 01, Hand Wash, 3rd Low Level
AEA09-FF-01-HW-H1	Fortification Sample, ME 01, Hand Wash, 1st High Level
AEA09-FF-01-HW-H2	Fortification Sample, ME 01, Hand Wash, 2nd High Level
AEA09-FF-01-HW-H3	Fortification Sample, ME 01, Hand Wash, 3rd High Level
AEA09-FF-01-FW-C1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Control
AEA09-FF-01-FW-C2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Control
AEA09-FF-01-FW-L1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Low Level
AEA09-FF-01-FW-L2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Low Level
AEA09-FF-01-FW-L3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd Low Level
AEA09-FF-01-FW-H1	Fortification Sample, ME 01, Face and Neck Wipe, 1st High Level
AEA09-FF-01-FW-H2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd High Level
AEA09-FF-01-FW-H3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd High Level

Sample ID Number	Description
AEA09-FF-01-ID-C1	Fortification Sample, ME 01, Inner Dosimeter, 1st Control
AEA09-FF-01-ID-C2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Control
AEA09-FF-01-ID-L1	Fortification Sample, ME 01, Inner Dosimeter, 1st Low Level
AEA09-FF-01-ID-L2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Low Level
AEA09-FF-01-ID-L3	Fortification Sample, ME 01, Inner Dosimeter, 3rd Low Level
AEA09-FF-01-ID-H1	Fortification Sample, ME 01, Inner Dosimeter, 1st High Level
AEA09-FF-01-ID-H2	Fortification Sample, ME 01, Inner Dosimeter, 2nd High Level
AEA09-FF-01-ID-H3	Fortification Sample, ME 01, Inner Dosimeter, 3rd High Level
AEA09-FF-01-OD-C1	Fortification Sample, ME 01, Outer Dosimeter, 1st Control
AEA09-FF-01-OD-C2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Control
AEA09-FF-01-OD-L1	Fortification Sample, ME 01, Outer Dosimeter, 1st Low Level
AEA09-FF-01-OD-L2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Low Level
AEA09-FF-01-OD-L3	Fortification Sample, ME 01, Outer Dosimeter, 3rd Low Level
AEA09-FF-01-OD-H1	Fortification Sample, ME 01, Outer Dosimeter, 1st High Level
AEA09-FF-01-OD-H2	Fortification Sample, ME 01, Outer Dosimeter, 2nd High Level
AEA09-FF-01-OD-H3	Fortification Sample, ME 01, Outer Dosimeter, 3rd High Level
AEA09-FF-02-PH-C1	Fortification Sample, ME 02, Painter's Hat, 1st Control
AEA09-FF-02-PH-C2	Fortification Sample, ME 02, Painter's Hat, 2nd Control
AEA09-FF-02-PH-L1	Fortification Sample, ME 02, Painter's Hat, 1st Low Level
AEA09-FF-02-PH-L2	Fortification Sample, ME 02, Painter's Hat, 2nd Low Level
AEA09-FF-02-PH-L3	Fortification Sample, ME 02, Painter's Hat, 3rd Low Level
AEA09-FF-02-PH-H1	Fortification Sample, ME 02, Painter's Hat, 1st High Level
AEA09-FF-02-PH-H2	Fortification Sample, ME 02, Painter's Hat, 2nd High Level
AEA09-FF-02-PH-H3	Fortification Sample, ME 02, Painter's Hat, 3rd High Level
AEA09-FF-02-AR-C1	Fortification Sample, ME 02, Air Sampling Tube, 1st Control
AEA09-FF-02-AR-C2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Control
AEA09-FF-02-AR-L1	Fortification Sample, ME 02, Air Sampling Tube, 1st Low Level
AEA09-FF-02-AR-L2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Low Level
AEA09-FF-02-AR-L3	Fortification Sample, ME 02, Air Sampling Tube, 3rd Low Level
AEA09-FF-02-AR-H1	Fortification Sample, ME 02, Air Sampling Tube, 1st High Level
AEA09-FF-02-AR-H2	Fortification Sample, ME 02, Air Sampling Tube, 2nd High Level
AEA09-FF-02-AR-H3	Fortification Sample, ME 02, Air Sampling Tube, 3rd High Level
AEA09-FF-02-RES-C1	Fortification Sample, ME 02, RespiCon, 1st Control
AEA09-FF-02-RES-C2	Fortification Sample, ME 02, RespiCon, 2nd Control
AEA09-FF-02-RES-L1	Fortification Sample, ME 02, RespiCon, 1st Low Level
AEA09-FF-02-RES-L2	Fortification Sample, ME 02, RespiCon, 2nd Low Level
AEA09-FF-02-RES-L3	Fortification Sample, ME 02, RespiCon, 3rd Low Level
AEA09-FF-02-RES-H1	Fortification Sample, ME 02, RespiCon, 1st High Level
AEA09-FF-02-RES-H2	Fortification Sample, ME 02, RespiCon, 2nd High Level
AEA09-FF-02-RES-H3	Fortification Sample, ME 02, RespiCon, 3rd High Level
AEA09-FF-02-HW-C1	Fortification Sample, ME 02, Hand Wash, 1st Control
AEA09-FF-02-HW-C2	Fortification Sample, ME 02, Hand Wash, 2nd Control
AEA09-FF-02-HW-L1	Fortification Sample, ME 02, Hand Wash, 1st Low Level
AEA09-FF-02-HW-L2	Fortification Sample, ME 02, Hand Wash, 2nd Low Level
AEA09-FF-02-HW-L3	Fortification Sample, ME 02, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-02-HW-H1	Fortification Sample, ME 02, Hand Wash, 1st High Level
AEA09-FF-02-HW-H2	Fortification Sample, ME 02, Hand Wash, 2nd High Level
AEA09-FF-02-HW-H3	Fortification Sample, ME 02, Hand Wash, 3rd High Level
AEA09-FF-02-FW-C1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Control
AEA09-FF-02-FW-C2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Control
AEA09-FF-02-FW-L1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Low Level
AEA09-FF-02-FW-L2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Low Level
AEA09-FF-02-FW-L3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd Low Level
AEA09-FF-02-FW-H1	Fortification Sample, ME 02, Face and Neck Wipe, 1st High Level
AEA09-FF-02-FW-H2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd High Level
AEA09-FF-02-FW-H3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd High Level
AEA09-FF-02-ID-C1	Fortification Sample, ME 02, Inner Dosimeter, 1st Control
AEA09-FF-02-ID-C2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Control
AEA09-FF-02-ID-L1	Fortification Sample, ME 02, Inner Dosimeter, 1st Low Level
AEA09-FF-02-ID-L2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Low Level
AEA09-FF-02-ID-L3	Fortification Sample, ME 02, Inner Dosimeter, 3rd Low Level
AEA09-FF-02-ID-H1	Fortification Sample, ME 02, Inner Dosimeter, 1st High Level
AEA09-FF-02-ID-H2	Fortification Sample, ME 02, Inner Dosimeter, 2nd High Level
AEA09-FF-02-ID-H3	Fortification Sample, ME 02, Inner Dosimeter, 3rd High Level
AEA09-FF-02-OD-C1	Fortification Sample, ME 02, Outer Dosimeter, 1st Control
AEA09-FF-02-OD-C2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Control
AEA09-FF-02-OD-L1	Fortification Sample, ME 02, Outer Dosimeter, 1st Low Level
AEA09-FF-02-OD-L2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Low Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-02-OD-H1	Fortification Sample, ME 02, Outer Dosimeter, 1st High Level
AEA09-FF-02-OD-H2	Fortification Sample, ME 02, Outer Dosimeter, 2nd High Level
AEA09-FF-02-OD-H3	Fortification Sample, ME 02, Outer Dosimeter, 3rd High Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-03-PH-C1	Fortification Sample, ME 03, Painter's Hat, 1st Control
AEA09-FF-03-PH-C2	Fortification Sample, ME 03, Painter's Hat, 2nd Control
AEA09-FF-03-PH-L1	Fortification Sample, ME 03, Painter's Hat, 1st Low Level
AEA09-FF-03-PH-L2	Fortification Sample, ME 03, Painter's Hat, 2nd Low Level
AEA09-FF-03-PH-L3	Fortification Sample, ME 03, Painter's Hat, 3rd Low Level
AEA09-FF-03-PH-H1	Fortification Sample, ME 03, Painter's Hat, 1st High Level
AEA09-FF-03-PH-H2	Fortification Sample, ME 03, Painter's Hat, 2nd High Level
AEA09-FF-03-PH-H3	Fortification Sample, ME 03, Painter's Hat, 3rd High Level
AEA09-FF-03-AR-C1	Fortification Sample, ME 03, Air Sampling Tube, 1st Control
AEA09-FF-03-AR-C2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Control
AEA09-FF-03-AR-L1	Fortification Sample, ME 03, Air Sampling Tube, 1st Low Level
AEA09-FF-03-AR-L2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Low Level
AEA09-FF-03-AR-L3	Fortification Sample, ME 03, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-AR-H1	Fortification Sample, ME 03, Air Sampling Tube, 1st High Level
AEA09-FF-03-AR-H2	Fortification Sample, ME 03, Air Sampling Tube, 2nd High Level
AEA09-FF-03-AR-H3	Fortification Sample, ME 03, Air Sampling Tube, 3rd High Level
AEA09-FF-03-RES-C1	Fortification Sample, ME 03, RespiCon, 1st Control
AEA09-FF-03-RES-C2	Fortification Sample, ME 03, RespiCon, 2nd Control
AEA09-FF-03-RES-L1	Fortification Sample, ME 03, RespiCon, 1st Low Level
AEA09-FF-03-RES-L2	Fortification Sample, ME 03, RespiCon, 2nd Low Level
AEA09-FF-03-RES-L3	Fortification Sample, ME 03, RespiCon, 3rd Low Level
AEA09-FF-03-RES-H1	Fortification Sample, ME 03, RespiCon, 1st High Level
AEA09-FF-03-RES-H2	Fortification Sample, ME 03, RespiCon, 2nd High Level
AEA09-FF-03-RES-H3	Fortification Sample, ME 03, RespiCon, 3rd High Level
AEA09-FF-03-HW-C1	Fortification Sample, ME 03, Hand Wash, 1st Control
AEA09-FF-03-HW-C2	Fortification Sample, ME 03, Hand Wash, 2nd Control
AEA09-FF-03-HW-L1	Fortification Sample, ME 03, Hand Wash, 1st Low Level
AEA09-FF-03-HW-L2	Fortification Sample, ME 03, Hand Wash, 2nd Low Level
AEA09-FF-03-HW-L3	Fortification Sample, ME 03, Hand Wash, 3rd Low Level
AEA09-FF-03-HW-H1	Fortification Sample, ME 03, Hand Wash, 1st High Level
AEA09-FF-03-HW-H2	Fortification Sample, ME 03, Hand Wash, 2nd High Level
AEA09-FF-03-HW-H3	Fortification Sample, ME 03, Hand Wash, 3rd High Level
AEA09-FF-03-FW-C1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Control
AEA09-FF-03-FW-C2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Control
AEA09-FF-03-FW-L1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Low Level
AEA09-FF-03-FW-L2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Low Level
AEA09-FF-03-FW-L3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd Low Level
AEA09-FF-03-FW-H1	Fortification Sample, ME 03, Face and Neck Wipe, 1st High Level
AEA09-FF-03-FW-H2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd High Level
AEA09-FF-03-FW-H3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd High Level
AEA09-FF-03-ID-C1	Fortification Sample, ME 03, Inner Dosimeter, 1st Control
AEA09-FF-03-ID-C2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Control
AEA09-FF-03-ID-L1	Fortification Sample, ME 03, Inner Dosimeter, 1st Low Level
AEA09-FF-03-ID-L2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Low Level
AEA09-FF-03-ID-L3	Fortification Sample, ME 03, Inner Dosimeter, 3rd Low Level
AEA09-FF-03-ID-H1	Fortification Sample, ME 03, Inner Dosimeter, 1st High Level
AEA09-FF-03-ID-H2	Fortification Sample, ME 03, Inner Dosimeter, 2nd High Level
AEA09-FF-03-ID-H3	Fortification Sample, ME 03, Inner Dosimeter, 3rd High Level
AEA09-FF-03-OD-C1	Fortification Sample, ME 03, Outer Dosimeter, 1st Control
AEA09-FF-03-OD-C2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Control
AEA09-FF-03-OD-L1	Fortification Sample, ME 03, Outer Dosimeter, 1st Low Level
AEA09-FF-03-OD-L2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Low Level
AEA09-FF-03-OD-L3	Fortification Sample, ME 03, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description

AEA09-FF-03-OD-H1	Fortification Sample, ME 03, Outer Dosimeter, 1st High Level
AEA09-FF-03-OD-H2	Fortification Sample, ME 03, Outer Dosimeter, 2nd High Level
AEA09-FF-03-OD-H3	Fortification Sample, ME 03, Outer Dosimeter, 3rd High Level
AEA09-FF-04-PH-C1	Fortification Sample, ME 04, Painter's Hat, 1st Control
AEA09-FF-04-PH-C2	Fortification Sample, ME 04, Painter's Hat, 2nd Control
AEA09-FF-04-PH-L1	Fortification Sample, ME 04, Painter's Hat, 1st Low Level
AEA09-FF-04-PH-L2	Fortification Sample, ME 04, Painter's Hat, 2nd Low Level
AEA09-FF-04-PH-L3	Fortification Sample, ME 04, Painter's Hat, 3rd Low Level
AEA09-FF-04-PH-H1	Fortification Sample, ME 04, Painter's Hat, 1st High Level
AEA09-FF-04-PH-H2	Fortification Sample, ME 04, Painter's Hat, 2nd High Level
AEA09-FF-04-PH-H3	Fortification Sample, ME 04, Painter's Hat, 3rd High Level
AEA09-FF-04-AR-C1	Fortification Sample, ME 04, Air Sampling Tube, 1st Control
AEA09-FF-04-AR-C2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Control
AEA09-FF-04-AR-L1	Fortification Sample, ME 04, Air Sampling Tube, 1st Low Level
AEA09-FF-04-AR-L2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Low Level
AEA09-FF-04-AR-L3	Fortification Sample, ME 04, Air Sampling Tube, 3rd Low Level
AEA09-FF-04-AR-H1	Fortification Sample, ME 04, Air Sampling Tube, 1st High Level
AEA09-FF-04-AR-H2	Fortification Sample, ME 04, Air Sampling Tube, 2nd High Level
AEA09-FF-04-AR-H3	Fortification Sample, ME 04, Air Sampling Tube, 3rd High Level
AEA09-FF-04-RES-C1	Fortification Sample, ME 04, RespiCon, 1st Control
AEA09-FF-04-RES-C2	Fortification Sample, ME 04, RespiCon, 2nd Control
AEA09-FF-04-RES-L1	Fortification Sample, ME 04, RespiCon, 1st Low Level
AEA09-FF-04-RES-L2	Fortification Sample, ME 04, RespiCon, 2nd Low Level
AEA09-FF-04-RES-L3	Fortification Sample, ME 04, RespiCon, 3rd Low Level
AEA09-FF-04-RES-H1	Fortification Sample, ME 04, RespiCon, 1st High Level
AEA09-FF-04-RES-H2	Fortification Sample, ME 04, RespiCon, 2nd High Level
AEA09-FF-04-RES-H3	Fortification Sample, ME 04, RespiCon, 3rd High Level
AEA09-FF-04-HW-C1	Fortification Sample, ME 04, Hand Wash, 1st Control
AEA09-FF-04-HW-C2	Fortification Sample, ME 04, Hand Wash, 2nd Control
AEA09-FF-04-HW-L1	Fortification Sample, ME 04, Hand Wash, 1st Low Level
AEA09-FF-04-HW-L2	Fortification Sample, ME 04, Hand Wash, 2nd Low Level
AEA09-FF-04-HW-L3	Fortification Sample, ME 04, Hand Wash, 3rd Low Level
AEA09-FF-04-HW-H1	Fortification Sample, ME 04, Hand Wash, 1st High Level
AEA09-FF-04-HW-H2	Fortification Sample, ME 04, Hand Wash, 2nd High Level
AEA09-FF-04-HW-H3	Fortification Sample, ME 04, Hand Wash, 3rd High Level
AEA09-FF-04-FW-C1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Control
AEA09-FF-04-FW-C2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Control
AEA09-FF-04-FW-L1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Low Level
AEA09-FF-04-FW-L2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Low Level
AEA09-FF-04-FW-L3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd Low Level
AEA09-FF-04-FW-H1	Fortification Sample, ME 04, Face and Neck Wipe, 1st High Level
AEA09-FF-04-FW-H2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd High Level

Sample ID Number	Description
AEA09-FF-04-FW-H3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd High Level
AEA09-FF-04-ID-C1	Fortification Sample, ME 04, Inner Dosimeter, 1st Control
AEA09-FF-04-ID-C2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Control
AEA09-FF-04-ID-L1	Fortification Sample, ME 04, Inner Dosimeter, 1st Low Level
AEA09-FF-04-ID-L2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Low Level
AEA09-FF-04-ID-L3	Fortification Sample, ME 04, Inner Dosimeter, 3rd Low Level
AEA09-FF-04-ID-H1	Fortification Sample, ME 04, Inner Dosimeter, 1st High Level
AEA09-FF-04-ID-H2	Fortification Sample, ME 04, Inner Dosimeter, 2nd High Level
AEA09-FF-04-ID-H3	Fortification Sample, ME 04, Inner Dosimeter, 3rd High Level
AEA09-FF-04-OD-C1	Fortification Sample, ME 04, Outer Dosimeter, 1st Control
AEA09-FF-04-OD-C2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Control
AEA09-FF-04-OD-L1	Fortification Sample, ME 04, Outer Dosimeter, 1st Low Level
AEA09-FF-04-OD-L2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Low Level
AEA09-FF-04-OD-L3	Fortification Sample, ME 04, Outer Dosimeter, 3rd Low Level
AEA09-FF-04-OD-H1	Fortification Sample, ME 04, Outer Dosimeter, 1st High Level
AEA09-FF-04-OD-H2	Fortification Sample, ME 04, Outer Dosimeter, 2nd High Level
AEA09-FF-04-OD-H3	Fortification Sample, ME 04, Outer Dosimeter, 3rd High Level
AEA09-FF-05-PH-C1	Fortification Sample, ME 05, Painter's Hat, 1st Control
AEA09-FF-05-PH-C2	Fortification Sample, ME 05, Painter's Hat, 2nd Control
AEA09-FF-05-PH-L1	Fortification Sample, ME 05, Painter's Hat, 1st Low Level
AEA09-FF-05-PH-L2	Fortification Sample, ME 05, Painter's Hat, 2nd Low Level
AEA09-FF-05-PH-L3	Fortification Sample, ME 05, Painter's Hat, 3rd Low Level
AEA09-FF-05-PH-H1	Fortification Sample, ME 05, Painter's Hat, 1st High Level
AEA09-FF-05-PH-H2	Fortification Sample, ME 05, Painter's Hat, 2nd High Level
AEA09-FF-05-PH-H3	Fortification Sample, ME 05, Painter's Hat, 3rd High Level
AEA09-FF-05-AR-C1	Fortification Sample, ME 05, Air Sampling Tube, 1st Control
AEA09-FF-05-AR-C2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Control
AEA09-FF-05-AR-L1	Fortification Sample, ME 05, Air Sampling Tube, 1st Low Level
AEA09-FF-05-AR-L2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Low Level
AEA09-FF-05-AR-L3	Fortification Sample, ME 05, Air Sampling Tube, 3rd Low Level
AEA09-FF-05-AR-H1	Fortification Sample, ME 05, Air Sampling Tube, 1st High Level
AEA09-FF-05-AR-H2	Fortification Sample, ME 05, Air Sampling Tube, 2nd High Level
AEA09-FF-05-AR-H3	Fortification Sample, ME 05, Air Sampling Tube, 3rd High Level
AEA09-FF-05-RES-C1	Fortification Sample, ME 05, RespiCon, 1st Control
AEA09-FF-05-RES-C2	Fortification Sample, ME 05, RespiCon, 2nd Control
AEA09-FF-05-RES-L1	Fortification Sample, ME 05, RespiCon, 1st Low Level
AEA09-FF-05-RES-L2	Fortification Sample, ME 05, RespiCon, 2nd Low Level
AEA09-FF-05-RES-L3	Fortification Sample, ME 05, RespiCon, 3rd Low Level
AEA09-FF-05-RES-H1	Fortification Sample, ME 05, RespiCon, 1st High Level
AEA09-FF-05-RES-H2	Fortification Sample, ME 05, RespiCon, 2nd High Level
AEA09-FF-05-RES-H3	Fortification Sample, ME 05, RespiCon, 3rd High Level
AEA09-FF-05-HW-C1	Fortification Sample, ME 05, Hand Wash, 1st Control
AEA09-FF-05-HW-C2	Fortification Sample, ME 05, Hand Wash, 2nd Control
AEA09-FF-05-HW-L1	Fortification Sample, ME 05, Hand Wash, 1st Low Level
AEA09-FF-05-HW-L2	Fortification Sample, ME 05, Hand Wash, 2nd Low Level
AEA09-FF-05-HW-L3	Fortification Sample, ME 05, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-05-HW-H1	Fortification Sample, ME 05, Hand Wash, 1st High Level
AEA09-FF-05-HW-H2	Fortification Sample, ME 05, Hand Wash, 2nd High Level
AEA09-FF-05-HW-H3	Fortification Sample, ME 05, Hand Wash, 3rd High Level
AEA09-FF-05-FW-C1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Control
AEA09-FF-05-FW-C2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Control
AEA09-FF-05-FW-L1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Low Level
AEA09-FF-05-FW-L2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Low Level
AEA09-FF-05-FW-L3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd Low Level
AEA09-FF-05-FW-H1	Fortification Sample, ME 05, Face and Neck Wipe, 1st High Level
AEA09-FF-05-FW-H2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd High Level
AEA09-FF-05-FW-H3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd High Level
AEA09-FF-05-ID-C1	Fortification Sample, ME 05, Inner Dosimeter, 1st Control
AEA09-FF-05-ID-C2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Control
AEA09-FF-05-ID-L1	Fortification Sample, ME 05, Inner Dosimeter, 1st Low Level
AEA09-FF-05-ID-L2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Low Level
AEA09-FF-05-ID-L3	Fortification Sample, ME 05, Inner Dosimeter, 3rd Low Level
AEA09-FF-05-ID-H1	Fortification Sample, ME 05, Inner Dosimeter, 1st High Level
AEA09-FF-05-ID-H2	Fortification Sample, ME 05, Inner Dosimeter, 2nd High Level
AEA09-FF-05-ID-H3	Fortification Sample, ME 05, Inner Dosimeter, 3rd High Level
AEA09-FF-05-OD-C1	Fortification Sample, ME 05, Outer Dosimeter, 1st Control
AEA09-FF-05-OD-C2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Control
AEA09-FF-05-OD-L1	Fortification Sample, ME 05, Outer Dosimeter, 1st Low Level
AEA09-FF-05-OD-L2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Low Level
AEA09-FF-05-OD-L3	Fortification Sample, ME 05, Outer Dosimeter, 3rd Low Level
AEA09-FF-05-OD-H1	Fortification Sample, ME 05, Outer Dosimeter, 1st High Level
AEA09-FF-05-OD-H2	Fortification Sample, ME 05, Outer Dosimeter, 2nd High Level
AEA09-FF-05-OD-H3	Fortification Sample, ME 05, Outer Dosimeter, 3rd High Level
AEA09-FF-06-PH-C1	Fortification Sample, ME 06, Painter's Hat, 1st Control
AEA09-FF-06-PH-C2	Fortification Sample, ME 06, Painter's Hat, 2nd Control
AEA09-FF-06-PH-L1	Fortification Sample, ME 06, Painter's Hat, 1st Low Level
AEA09-FF-06-PH-L2	Fortification Sample, ME 06, Painter's Hat, 2nd Low Level
AEA09-FF-06-PH-L3	Fortification Sample, ME 06, Painter's Hat, 3rd Low Level
AEA09-FF-06-PH-H1	Fortification Sample, ME 06, Painter's Hat, 1st High Level
AEA09-FF-06-PH-H2	Fortification Sample, ME 06, Painter's Hat, 2nd High Level
AEA09-FF-06-PH-H3	Fortification Sample, ME 06, Painter's Hat, 3rd High Level
AEA09-FF-06-AR-C1	Fortification Sample, ME 06, Air Sampling Tube, 1st Control
AEA09-FF-06-AR-C2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Control
AEA09-FF-06-AR-L1	Fortification Sample, ME 06, Air Sampling Tube, 1st Low Level
AEA09-FF-06-AR-L2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Low Level
AEA09-FF-06-AR-L3	Fortification Sample, ME 06, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-AR-H1	Fortification Sample, ME 06, Air Sampling Tube, 1st High Level
AEA09-FF-06-AR-H2	Fortification Sample, ME 06, Air Sampling Tube, 2nd High Level
AEA09-FF-06-AR-H3	Fortification Sample, ME 06, Air Sampling Tube, 3rd High Level
AEA09-FF-06-RES-C1	Fortification Sample, ME 06, RespiCon, 1st Control
AEA09-FF-06-RES-C2	Fortification Sample, ME 06, RespiCon, 2nd Control
AEA09-FF-06-RES-L1	Fortification Sample, ME 06, RespiCon, 1st Low Level
AEA09-FF-06-RES-L2	Fortification Sample, ME 06, RespiCon, 2nd Low Level
AEA09-FF-06-RES-L3	Fortification Sample, ME 06, RespiCon, 3rd Low Level
AEA09-FF-06-RES-H1	Fortification Sample, ME 06, RespiCon, 1st High Level
AEA09-FF-06-RES-H2	Fortification Sample, ME 06, RespiCon, 2nd High Level
AEA09-FF-06-RES-H3	Fortification Sample, ME 06, RespiCon, 3rd High Level
AEA09-FF-06-HW-C1	Fortification Sample, ME 06, Hand Wash, 1st Control
AEA09-FF-06-HW-C2	Fortification Sample, ME 06, Hand Wash, 2nd Control
AEA09-FF-06-HW-L1	Fortification Sample, ME 06, Hand Wash, 1st Low Level
AEA09-FF-06-HW-L2	Fortification Sample, ME 06, Hand Wash, 2nd Low Level
AEA09-FF-06-HW-L3	Fortification Sample, ME 06, Hand Wash, 3rd Low Level
AEA09-FF-06-HW-H1	Fortification Sample, ME 06, Hand Wash, 1st High Level
AEA09-FF-06-HW-H2	Fortification Sample, ME 06, Hand Wash, 2nd High Level
AEA09-FF-06-HW-H3	Fortification Sample, ME 06, Hand Wash, 3rd High Level
AEA09-FF-06-FW-C1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Control
AEA09-FF-06-FW-C2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Control
AEA09-FF-06-FW-L1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Low Level
AEA09-FF-06-FW-L2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Low Level
AEA09-FF-06-FW-L3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd Low Level
AEA09-FF-06-FW-H1	Fortification Sample, ME 06, Face and Neck Wipe, 1st High Level
AEA09-FF-06-FW-H2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd High Level
AEA09-FF-06-FW-H3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd High Level
AEA09-FF-06-ID-C1	Fortification Sample, ME 06, Inner Dosimeter, 1st Control
AEA09-FF-06-ID-C2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Control
AEA09-FF-06-ID-L1	Fortification Sample, ME 06, Inner Dosimeter, 1st Low Level
AEA09-FF-06-ID-L2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Low Level
AEA09-FF-06-ID-L3	Fortification Sample, ME 06, Inner Dosimeter, 3rd Low Level
AEA09-FF-06-ID-H1	Fortification Sample, ME 06, Inner Dosimeter, 1st High Level
AEA09-FF-06-ID-H2	Fortification Sample, ME 06, Inner Dosimeter, 2nd High Level
AEA09-FF-06-ID-H3	Fortification Sample, ME 06, Inner Dosimeter, 3rd High Level
AEA09-FF-06-OD-C1	Fortification Sample, ME 06, Outer Dosimeter, 1st Control
AEA09-FF-06-OD-C2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Control
AEA09-FF-06-OD-L1	Fortification Sample, ME 06, Outer Dosimeter, 1st Low Level
AEA09-FF-06-OD-L2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Low Level
AEA09-FF-06-OD-L3	Fortification Sample, ME 06, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-OD-H1	Fortification Sample, ME 06, Outer Dosimeter, 1st High Level
AEA09-FF-06-OD-H2	Fortification Sample, ME 06, Outer Dosimeter, 2nd High Level
AEA09-FF-06-OD-H3	Fortification Sample, ME 06, Outer Dosimeter, 3rd High Level
AEA09-FF-07-PH-C1	Fortification Sample, ME 07, Painter's Hat, 1st Control
AEA09-FF-07-PH-C2	Fortification Sample, ME 07, Painter's Hat, 2nd Control
AEA09-FF-07-PH-L1	Fortification Sample, ME 07, Painter's Hat, 1st Low Level
AEA09-FF-07-PH-L2	Fortification Sample, ME 07, Painter's Hat, 2nd Low Level
AEA09-FF-07-PH-L3	Fortification Sample, ME 07, Painter's Hat, 3rd Low Level
AEA09-FF-07-PH-H1	Fortification Sample, ME 07, Painter's Hat, 1st High Level
AEA09-FF-07-PH-H2	Fortification Sample, ME 07, Painter's Hat, 2nd High Level
AEA09-FF-07-PH-H3	Fortification Sample, ME 07, Painter's Hat, 3rd High Level
AEA09-FF-07-AR-C1	Fortification Sample, ME 07, Air Sampling Tube, 1st Control
AEA09-FF-07-AR-C2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Control
AEA09-FF-07-AR-L1	Fortification Sample, ME 07, Air Sampling Tube, 1st Low Level
AEA09-FF-07-AR-L2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Low Level
AEA09-FF-07-AR-L3	Fortification Sample, ME 07, Air Sampling Tube, 3rd Low Level
AEA09-FF-07-AR-H1	Fortification Sample, ME 07, Air Sampling Tube, 1st High Level
AEA09-FF-07-AR-H2	Fortification Sample, ME 07, Air Sampling Tube, 2nd High Level
AEA09-FF-07-AR-H3	Fortification Sample, ME 07, Air Sampling Tube, 3rd High Level
AEA09-FF-07-RES-C1	Fortification Sample, ME 07, RespiCon, 1st Control
AEA09-FF-07-RES-C2	Fortification Sample, ME 07, RespiCon, 2nd Control
AEA09-FF-07-RES-L1	Fortification Sample, ME 07, RespiCon, 1st Low Level
AEA09-FF-07-RES-L2	Fortification Sample, ME 07, RespiCon, 2nd Low Level
AEA09-FF-07-RES-L3	Fortification Sample, ME 07, RespiCon, 3rd Low Level
AEA09-FF-07-RES-H1	Fortification Sample, ME 07, RespiCon, 1st High Level
AEA09-FF-07-RES-H2	Fortification Sample, ME 07, RespiCon, 2nd High Level
AEA09-FF-07-RES-H3	Fortification Sample, ME 07, RespiCon, 3rd High Level
AEA09-FF-07-HW-C1	Fortification Sample, ME 07, Hand Wash, 1st Control
AEA09-FF-07-HW-C2	Fortification Sample, ME 07, Hand Wash, 2nd Control
AEA09-FF-07-HW-L1	Fortification Sample, ME 07, Hand Wash, 1st Low Level
AEA09-FF-07-HW-L2	Fortification Sample, ME 07, Hand Wash, 2nd Low Level
AEA09-FF-07-HW-L3	Fortification Sample, ME 07, Hand Wash, 3rd Low Level
AEA09-FF-07-HW-H1	Fortification Sample, ME 07, Hand Wash, 1st High Level
AEA09-FF-07-HW-H2	Fortification Sample, ME 07, Hand Wash, 2nd High Level
AEA09-FF-07-HW-H3	Fortification Sample, ME 07, Hand Wash, 3rd High Level
AEA09-FF-07-FW-C1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Control
AEA09-FF-07-FW-C2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Control
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Low Level
AEA09-FF-07-FW-L3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd Low Level
AEA09-FF-07-FW-H1	Fortification Sample, ME 07, Face and Neck Wipe, 1st High Level

Sample ID Number	Description
AEA09-FF-07-FW-H2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd High Level
AEA09-FF-07-FW-H3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd High Level
AEA09-FF-07-ID-C1	Fortification Sample, ME 07, Inner Dosimeter, 1st Control
AEA09-FF-07-ID-C2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Control
AEA09-FF-07-ID-L1	Fortification Sample, ME 07, Inner Dosimeter, 1st Low Level
AEA09-FF-07-ID-L2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Low Level
AEA09-FF-07-ID-L3	Fortification Sample, ME 07, Inner Dosimeter, 3rd Low Level
AEA09-FF-07-ID-H1	Fortification Sample, ME 07, Inner Dosimeter, 1st High Level
AEA09-FF-07-ID-H2	Fortification Sample, ME 07, Inner Dosimeter, 2nd High Level
AEA09-FF-07-ID-H3	Fortification Sample, ME 07, Inner Dosimeter, 3rd High Level
AEA09-FF-07-OD-C1	Fortification Sample, ME 07, Outer Dosimeter, 1st Control
AEA09-FF-07-OD-C2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Control
AEA09-FF-07-OD-L1	Fortification Sample, ME 07, Outer Dosimeter, 1st Low Level
AEA09-FF-07-OD-L2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Low Level
AEA09-FF-07-OD-L3	Fortification Sample, ME 07, Outer Dosimeter, 3rd Low Level
AEA09-FF-07-OD-H1	Fortification Sample, ME 07, Outer Dosimeter, 1st High Level
AEA09-FF-07-OD-H2	Fortification Sample, ME 07, Outer Dosimeter, 2nd High Level
AEA09-FF-07-OD-H3	Fortification Sample, ME 07, Outer Dosimeter, 3rd High Level
AEA09-FF-08-PH-C1	Fortification Sample, ME 08, Painter's Hat, 1st Control
AEA09-FF-08-PH-C2	Fortification Sample, ME 08, Painter's Hat, 2nd Control
AEA09-FF-08-PH-L1	Fortification Sample, ME 08, Painter's Hat, 1st Low Level
AEA09-FF-08-PH-L2	Fortification Sample, ME 08, Painter's Hat, 2nd Low Level
AEA09-FF-08-PH-L3	Fortification Sample, ME 08, Painter's Hat, 3rd Low Level
AEA09-FF-08-PH-H1	Fortification Sample, ME 08, Painter's Hat, 1st High Level
AEA09-FF-08-PH-H2	Fortification Sample, ME 08, Painter's Hat, 2nd High Level
AEA09-FF-08-PH-H3	Fortification Sample, ME 08, Painter's Hat, 3rd High Level
AEA09-FF-08-AR-C1	Fortification Sample, ME 08, Air Sampling Tube, 1st Control
AEA09-FF-08-AR-C2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Control
AEA09-FF-08-AR-L1	Fortification Sample, ME 08, Air Sampling Tube, 1st Low Level
AEA09-FF-08-AR-L2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Low Level
AEA09-FF-08-AR-L3	Fortification Sample, ME 08, Air Sampling Tube, 3rd Low Level
AEA09-FF-08-AR-H1	Fortification Sample, ME 08, Air Sampling Tube, 1st High Level
AEA09-FF-08-AR-H2	Fortification Sample, ME 08, Air Sampling Tube, 2nd High Level
AEA09-FF-08-AR-H3	Fortification Sample, ME 08, Air Sampling Tube, 3rd High Level
AEA09-FF-08-RES-C1	Fortification Sample, ME 08, RespiCon, 1st Control
AEA09-FF-08-RES-C2	Fortification Sample, ME 08, RespiCon, 2nd Control
AEA09-FF-08-RES-L1	Fortification Sample, ME 08, RespiCon, 1st Low Level
AEA09-FF-08-RES-L2	Fortification Sample, ME 08, RespiCon, 2nd Low Level
AEA09-FF-08-RES-L3	Fortification Sample, ME 08, RespiCon, 3rd Low Level
AEA09-FF-08-RES-H1	Fortification Sample, ME 08, RespiCon, 1st High Level
AEA09-FF-08-RES-H2	Fortification Sample, ME 08, RespiCon, 2nd High Level
AEA09-FF-08-RES-H3	Fortification Sample, ME 08, RespiCon, 3rd High Level
AEA09-FF-08-HW-C1	Fortification Sample, ME 08, Hand Wash, 1st Control
AEA09-FF-08-HW-C2	Fortification Sample, ME 08, Hand Wash, 2nd Control

Sample ID Number	Description
AEA09-FF-08-HW-L1	Fortification Sample, ME 08, Hand Wash, 1st Low Level
AEA09-FF-08-HW-L2	Fortification Sample, ME 08, Hand Wash, 2nd Low Level
AEA09-FF-08-HW-L3	Fortification Sample, ME 08, Hand Wash, 3rd Low Level
AEA09-FF-08-HW-H1	Fortification Sample, ME 08, Hand Wash, 1st High Level
AEA09-FF-08-HW-H2	Fortification Sample, ME 08, Hand Wash, 2nd High Level
AEA09-FF-08-HW-H3	Fortification Sample, ME 08, Hand Wash, 3rd High Level
AEA09-FF-08-FW-C1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Control
AEA09-FF-08-FW-C2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Control
AEA09-FF-08-FW-L1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Low Level
AEA09-FF-08-FW-L2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Low Level
AEA09-FF-08-FW-L3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd Low Level
AEA09-FF-08-FW-H1	Fortification Sample, ME 08, Face and Neck Wipe, 1st High Level
AEA09-FF-08-FW-H2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd High Level
AEA09-FF-08-FW-H3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd High Level
AEA09-FF-08-ID-C1	Fortification Sample, ME 08, Inner Dosimeter, 1st Control
AEA09-FF-08-ID-C2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Control
AEA09-FF-08-ID-L1	Fortification Sample, ME 08, Inner Dosimeter, 1st Low Level
AEA09-FF-08-ID-L2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Low Level
AEA09-FF-08-ID-L3	Fortification Sample, ME 08, Inner Dosimeter, 3rd Low Level
AEA09-FF-08-ID-H1	Fortification Sample, ME 08, Inner Dosimeter, 1st High Level
AEA09-FF-08-ID-H2	Fortification Sample, ME 08, Inner Dosimeter, 2nd High Level
AEA09-FF-08-ID-H3	Fortification Sample, ME 08, Inner Dosimeter, 3rd High Level
AEA09-FF-08-OD-C1	Fortification Sample, ME 08, Outer Dosimeter, 1st Control
AEA09-FF-08-OD-C2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Control
AEA09-FF-08-OD-L1	Fortification Sample, ME 08, Outer Dosimeter, 1st Low Level
AEA09-FF-08-OD-L2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Low Level
AEA09-FF-08-OD-L3	Fortification Sample, ME 08, Outer Dosimeter, 3rd Low Level
AEA09-FF-08-OD-H1	Fortification Sample, ME 08, Outer Dosimeter, 1st High Level
AEA09-FF-08-OD-H2	Fortification Sample, ME 08, Outer Dosimeter, 2nd High Level
AEA09-FF-08-OD-H3	Fortification Sample, ME 08, Outer Dosimeter, 3rd High Level
AEA09-FF-09-PH-C1	Fortification Sample, ME 09, Painter's Hat, 1st Control
AEA09-FF-09-PH-C2	Fortification Sample, ME 09, Painter's Hat, 2nd Control
AEA09-FF-09-PH-L1	Fortification Sample, ME 09, Painter's Hat, 1st Low Level
AEA09-FF-09-PH-L2	Fortification Sample, ME 09, Painter's Hat, 2nd Low Level
AEA09-FF-09-PH-L3	Fortification Sample, ME 09, Painter's Hat, 3rd Low Level
AEA09-FF-09-PH-H1	Fortification Sample, ME 09, Painter's Hat, 1st High Level
AEA09-FF-09-PH-H2	Fortification Sample, ME 09, Painter's Hat, 2nd High Level
AEA09-FF-09-PH-H3	Fortification Sample, ME 09, Painter's Hat, 3rd High Level
AEA09-FF-09-AR-C1	Fortification Sample, ME 09, Air Sampling Tube, 1st Control
AEA09-FF-09-AR-C2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Control

Sample ID Number	Description
AEA09-FF-09-AR-L1	Fortification Sample, ME 09, Air Sampling Tube, 1st Low Level
AEA09-FF-09-AR-L2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Low Level
AEA09-FF-09-AR-L3	Fortification Sample, ME 09, Air Sampling Tube, 3rd Low Level
AEA09-FF-09-AR-H1	Fortification Sample, ME 09, Air Sampling Tube, 1st High Level
AEA09-FF-09-AR-H2	Fortification Sample, ME 09, Air Sampling Tube, 2nd High Level
AEA09-FF-09-AR-H3	Fortification Sample, ME 09, Air Sampling Tube, 3rd High Level
AEA09-FF-09-RES-C1	Fortification Sample, ME 09, RespiCon, 1st Control
AEA09-FF-09-RES-C2	Fortification Sample, ME 09, RespiCon, 2nd Control
AEA09-FF-09-RES-L1	Fortification Sample, ME 09, RespiCon, 1st Low Level
AEA09-FF-09-RES-L2	Fortification Sample, ME 09, RespiCon, 2nd Low Level
AEA09-FF-09-RES-L3	Fortification Sample, ME 09, RespiCon, 3rd Low Level
AEA09-FF-09-RES-H1	Fortification Sample, ME 09, RespiCon, 1st High Level
AEA09-FF-09-RES-H2	Fortification Sample, ME 09, RespiCon, 2nd High Level
AEA09-FF-09-RES-H3	Fortification Sample, ME 09, RespiCon, 3rd High Level
AEA09-FF-09-HW-C1	Fortification Sample, ME 09, Hand Wash, 1st Control
AEA09-FF-09-HW-C2	Fortification Sample, ME 09, Hand Wash, 2nd Control
AEA09-FF-09-HW-L1	Fortification Sample, ME 09, Hand Wash, 1st Low Level
AEA09-FF-09-HW-L2	Fortification Sample, ME 09, Hand Wash, 2nd Low Level
AEA09-FF-09-HW-L3	Fortification Sample, ME 09, Hand Wash, 3rd Low Level
AEA09-FF-09-HW-H1	Fortification Sample, ME 09, Hand Wash, 1st High Level
AEA09-FF-09-HW-H2	Fortification Sample, ME 09, Hand Wash, 2nd High Level
AEA09-FF-09-HW-H3	Fortification Sample, ME 09, Hand Wash, 3rd High Level
AEA09-FF-09-FW-C1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Control
AEA09-FF-09-FW-C2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Control
AEA09-FF-09-FW-L1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Low Level
AEA09-FF-09-FW-L2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Low Level
AEA09-FF-09-FW-L3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd Low Level
AEA09-FF-09-FW-H1	Fortification Sample, ME 09, Face and Neck Wipe, 1st High Level
AEA09-FF-09-FW-H2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd High Level
AEA09-FF-09-FW-H3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd High Level
AEA09-FF-09-ID-C1	Fortification Sample, ME 09, Inner Dosimeter, 1st Control
AEA09-FF-09-ID-C2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Control
AEA09-FF-09-ID-L1	Fortification Sample, ME 09, Inner Dosimeter, 1st Low Level
AEA09-FF-09-ID-L2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Low Level
AEA09-FF-09-ID-L3	Fortification Sample, ME 09, Inner Dosimeter, 3rd Low Level
AEA09-FF-09-ID-H1	Fortification Sample, ME 09, Inner Dosimeter, 1st High Level
AEA09-FF-09-ID-H2	Fortification Sample, ME 09, Inner Dosimeter, 2nd High Level
AEA09-FF-09-ID-H3	Fortification Sample, ME 09, Inner Dosimeter, 3rd High Level
AEA09-FF-09-OD-C1	Fortification Sample, ME 09, Outer Dosimeter, 1st Control
AEA09-FF-09-OD-C2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Control

Sample ID Number	Description
AEA09-FF-09-OD-L1	Fortification Sample, ME 09, Outer Dosimeter, 1st Low Level
AEA09-FF-09-OD-L2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Low Level
AEA09-FF-09-OD-L3	Fortification Sample, ME 09, Outer Dosimeter, 3rd Low Level
AEA09-FF-09-OD-H1	Fortification Sample, ME 09, Outer Dosimeter, 1st High Level
AEA09-FF-09-OD-H2	Fortification Sample, ME 09, Outer Dosimeter, 2nd High Level
AEA09-FF-09-OD-H3	Fortification Sample, ME 09, Outer Dosimeter, 3rd High Level
AEA09-FF-10-PH-C1	Fortification Sample, ME 10, Painter's Hat, 1st Control
AEA09-FF-10-PH-C2	Fortification Sample, ME 10, Painter's Hat, 2nd Control
AEA09-FF-10-PH-L1	Fortification Sample, ME 10, Painter's Hat, 1st Low Level
AEA09-FF-10-PH-L2	Fortification Sample, ME 10, Painter's Hat, 2nd Low Level
AEA09-FF-10-PH-L3	Fortification Sample, ME 10, Painter's Hat, 3rd Low Level
AEA09-FF-10-PH-H1	Fortification Sample, ME 10, Painter's Hat, 1st High Level
AEA09-FF-10-PH-H2	Fortification Sample, ME 10, Painter's Hat, 2nd High Level
AEA09-FF-10-PH-H3	Fortification Sample, ME 10, Painter's Hat, 3rd High Level
AEA09-FF-10-AR-C1	Fortification Sample, ME 10, Air Sampling Tube, 1st Control
AEA09-FF-10-AR-C2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Control
AEA09-FF-10-AR-L1	Fortification Sample, ME 10, Air Sampling Tube, 1st Low Level
AEA09-FF-10-AR-L2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Low Level
AEA09-FF-10-AR-L3	Fortification Sample, ME 10, Air Sampling Tube, 3rd Low Level
AEA09-FF-10-AR-H1	Fortification Sample, ME 10, Air Sampling Tube, 1st High Level
AEA09-FF-10-AR-H2	Fortification Sample, ME 10, Air Sampling Tube, 2nd High Level
AEA09-FF-10-AR-H3	Fortification Sample, ME 10, Air Sampling Tube, 3rd High Level
AEA09-FF-10-RES-C1	Fortification Sample, ME 10, RespiCon, 1st Control
AEA09-FF-10-RES-C2	Fortification Sample, ME 10, RespiCon, 2nd Control
AEA09-FF-10-RES-L1	Fortification Sample, ME 10, RespiCon, 1st Low Level
AEA09-FF-10-RES-L2	Fortification Sample, ME 10, RespiCon, 2nd Low Level
AEA09-FF-10-RES-L3	Fortification Sample, ME 10, RespiCon, 3rd Low Level
AEA09-FF-10-RES-H1	Fortification Sample, ME 10, RespiCon, 1st High Level
AEA09-FF-10-RES-H2	Fortification Sample, ME 10, RespiCon, 2nd High Level
AEA09-FF-10-RES-H3	Fortification Sample, ME 10, RespiCon, 3rd High Level
AEA09-FF-10-HW-C1	Fortification Sample, ME 10, Hand Wash, 1st Control
AEA09-FF-10-HW-C2	Fortification Sample, ME 10, Hand Wash, 2nd Control
AEA09-FF-10-HW-L1	Fortification Sample, ME 10, Hand Wash, 1st Low Level
AEA09-FF-10-HW-L2	Fortification Sample, ME 10, Hand Wash, 2nd Low Level
AEA09-FF-10-HW-L3	Fortification Sample, ME 10, Hand Wash, 3rd Low Level
AEA09-FF-10-HW-H1	Fortification Sample, ME 10, Hand Wash, 1st High Level
AEA09-FF-10-HW-H2	Fortification Sample, ME 10, Hand Wash, 2nd High Level
AEA09-FF-10-HW-H3	Fortification Sample, ME 10, Hand Wash, 3rd High Level
AEA09-FF-10-FW-C1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Control
AEA09-FF-10-FW-C2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Control
AEA09-FF-10-FW-L1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Low Level
AEA09-FF-10-FW-L2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Low Level
AEA09-FF-10-FW-L3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-10-FW-H1	Fortification Sample, ME 10, Face and Neck Wipe, 1st High Level
AEA09-FF-10-FW-H2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd High Level
AEA09-FF-10-FW-H3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd High Level
AEA09-FF-10-ID-C1	Fortification Sample, ME 10, Inner Dosimeter, 1st Control
AEA09-FF-10-ID-C2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Control
AEA09-FF-10-ID-L1	Fortification Sample, ME 10, Inner Dosimeter, 1st Low Level
AEA09-FF-10-ID-L2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Low Level
AEA09-FF-10-ID-L3	Fortification Sample, ME 10, Inner Dosimeter, 3rd Low Level
AEA09-FF-10-ID-H1	Fortification Sample, ME 10, Inner Dosimeter, 1st High Level
AEA09-FF-10-ID-H2	Fortification Sample, ME 10, Inner Dosimeter, 2nd High Level
AEA09-FF-10-ID-H3	Fortification Sample, ME 10, Inner Dosimeter, 3rd High Level
AEA09-FF-10-OD-C1	Fortification Sample, ME 10, Outer Dosimeter, 1st Control
AEA09-FF-10-OD-C2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Control
AEA09-FF-10-OD-L1	Fortification Sample, ME 10, Outer Dosimeter, 1st Low Level
AEA09-FF-10-OD-L2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Low Level
AEA09-FF-10-OD-L3	Fortification Sample, ME 10, Outer Dosimeter, 3rd Low Level
AEA09-FF-10-OD-H1	Fortification Sample, ME 10, Outer Dosimeter, 1st High Level
AEA09-FF-10-OD-H2	Fortification Sample, ME 10, Outer Dosimeter, 2nd High Level
AEA09-FF-10-OD-H3	Fortification Sample, ME 10, Outer Dosimeter, 3rd High Level
AEA09-FF-11-PH-C1	Fortification Sample, ME 11, Painter's Hat, 1st Control
AEA09-FF-11-PH-C2	Fortification Sample, ME 11, Painter's Hat, 2nd Control
AEA09-FF-11-PH-L1	Fortification Sample, ME 11, Painter's Hat, 1st Low Level
AEA09-FF-11-PH-L2	Fortification Sample, ME 11, Painter's Hat, 2nd Low Level
AEA09-FF-11-PH-L3	Fortification Sample, ME 11, Painter's Hat, 3rd Low Level
AEA09-FF-11-PH-H1	Fortification Sample, ME 11, Painter's Hat, 1st High Level
AEA09-FF-11-PH-H2	Fortification Sample, ME 11, Painter's Hat, 2nd High Level
AEA09-FF-11-PH-H3	Fortification Sample, ME 11, Painter's Hat, 3rd High Level
AEA09-FF-11-AR-C1	Fortification Sample, ME 11, Air Sampling Tube, 1st Control
AEA09-FF-11-AR-C2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Control
AEA09-FF-11-AR-L1	Fortification Sample, ME 11, Air Sampling Tube, 1st Low Level
AEA09-FF-11-AR-L2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Low Level
AEA09-FF-11-AR-L3	Fortification Sample, ME 11, Air Sampling Tube, 3rd Low Level
AEA09-FF-11-AR-H1	Fortification Sample, ME 11, Air Sampling Tube, 1st High Level
AEA09-FF-11-AR-H2	Fortification Sample, ME 11, Air Sampling Tube, 2nd High Level
AEA09-FF-11-AR-H3	Fortification Sample, ME 11, Air Sampling Tube, 3rd High Level
AEA09-FF-11-RES-C1	Fortification Sample, ME 11, RespiCon, 1st Control
AEA09-FF-11-RES-C2	Fortification Sample, ME 11, RespiCon, 2nd Control
AEA09-FF-11-RES-L1	Fortification Sample, ME 11, RespiCon, 1st Low Level
AEA09-FF-11-RES-L2	Fortification Sample, ME 11, RespiCon, 2nd Low Level
AEA09-FF-11-RES-L3	Fortification Sample, ME 11, RespiCon, 3rd Low Level
AEA09-FF-11-RES-H1	Fortification Sample, ME 11, RespiCon, 1st High Level
AEA09-FF-11-RES-H2	Fortification Sample, ME 11, RespiCon, 2nd High Level
AEA09-FF-11-RES-H3	Fortification Sample, ME 11, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-11-HW-C1	Fortification Sample, ME 11, Hand Wash, 1st Control
AEA09-FF-11-HW-C2	Fortification Sample, ME 11, Hand Wash, 2nd Control
AEA09-FF-11-HW-L1	Fortification Sample, ME 11, Hand Wash, 1st Low Level
AEA09-FF-11-HW-L2	Fortification Sample, ME 11, Hand Wash, 2nd Low Level
AEA09-FF-11-HW-L3	Fortification Sample, ME 11, Hand Wash, 3rd Low Level
AEA09-FF-11-HW-H1	Fortification Sample, ME 11, Hand Wash, 1st High Level
AEA09-FF-11-HW-H2	Fortification Sample, ME 11, Hand Wash, 2nd High Level
AEA09-FF-11-HW-H3	Fortification Sample, ME 11, Hand Wash, 3rd High Level
AEA09-FF-11-FW-C1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Control
AEA09-FF-11-FW-C2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Control
AEA09-FF-11-FW-L1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Low Level
AEA09-FF-11-FW-L2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Low Level
AEA09-FF-11-FW-L3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd Low Level
AEA09-FF-11-FW-H1	Fortification Sample, ME 11, Face and Neck Wipe, 1st High Level
AEA09-FF-11-FW-H2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd High Level
AEA09-FF-11-FW-H3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd High Level
AEA09-FF-11-ID-C1	Fortification Sample, ME 11, Inner Dosimeter, 1st Control
AEA09-FF-11-ID-C2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Control
AEA09-FF-11-ID-L1	Fortification Sample, ME 11, Inner Dosimeter, 1st Low Level
AEA09-FF-11-ID-L2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Low Level
AEA09-FF-11-ID-L3	Fortification Sample, ME 11, Inner Dosimeter, 3rd Low Level
AEA09-FF-11-ID-H1	Fortification Sample, ME 11, Inner Dosimeter, 1st High Level
AEA09-FF-11-ID-H2	Fortification Sample, ME 11, Inner Dosimeter, 2nd High Level
AEA09-FF-11-ID-H3	Fortification Sample, ME 11, Inner Dosimeter, 3rd High Level
AEA09-FF-11-OD-C1	Fortification Sample, ME 11, Outer Dosimeter, 1st Control
AEA09-FF-11-OD-C2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Control
AEA09-FF-11-OD-L1	Fortification Sample, ME 11, Outer Dosimeter, 1st Low Level
AEA09-FF-11-OD-L2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Low Level
AEA09-FF-11-OD-L3	Fortification Sample, ME 11, Outer Dosimeter, 3rd Low Level
AEA09-FF-11-OD-H1	Fortification Sample, ME 11, Outer Dosimeter, 1st High Level
AEA09-FF-11-OD-H2	Fortification Sample, ME 11, Outer Dosimeter, 2nd High Level
AEA09-FF-11-OD-H3	Fortification Sample, ME 11, Outer Dosimeter, 3rd High Level
AEA09-FF-12-PH-C1	Fortification Sample, ME 12, Painter's Hat, 1st Control
AEA09-FF-12-PH-C2	Fortification Sample, ME 12, Painter's Hat, 2nd Control
AEA09-FF-12-PH-L1	Fortification Sample, ME 12, Painter's Hat, 1st Low Level
AEA09-FF-12-PH-L2	Fortification Sample, ME 12, Painter's Hat, 2nd Low Level
AEA09-FF-12-PH-L3	Fortification Sample, ME 12, Painter's Hat, 3rd Low Level
AEA09-FF-12-PH-H1	Fortification Sample, ME 12, Painter's Hat, 1st High Level
AEA09-FF-12-PH-H2	Fortification Sample, ME 12, Painter's Hat, 2nd High Level
AEA09-FF-12-PH-H3	Fortification Sample, ME 12, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-AR-C1	Fortification Sample, ME 12, Air Sampling Tube, 1st Control
AEA09-FF-12-AR-C2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Control
AEA09-FF-12-AR-L1	Fortification Sample, ME 12, Air Sampling Tube, 1st Low Level
AEA09-FF-12-AR-L2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Low Level
AEA09-FF-12-AR-L3	Fortification Sample, ME 12, Air Sampling Tube, 3rd Low Level
AEA09-FF-12-AR-H1	Fortification Sample, ME 12, Air Sampling Tube, 1st High Level
AEA09-FF-12-AR-H2	Fortification Sample, ME 12, Air Sampling Tube, 2nd High Level
AEA09-FF-12-AR-H3	Fortification Sample, ME 12, Air Sampling Tube, 3rd High Level
AEA09-FF-12-RES-C1	Fortification Sample, ME 12, RespiCon, 1st Control
AEA09-FF-12-RES-C2	Fortification Sample, ME 12, RespiCon, 2nd Control
AEA09-FF-12-RES-L1	Fortification Sample, ME 12, RespiCon, 1st Low Level
AEA09-FF-12-RES-L2	Fortification Sample, ME 12, RespiCon, 2nd Low Level
AEA09-FF-12-RES-L3	Fortification Sample, ME 12, RespiCon, 3rd Low Level
AEA09-FF-12-RES-H1	Fortification Sample, ME 12, RespiCon, 1st High Level
AEA09-FF-12-RES-H2	Fortification Sample, ME 12, RespiCon, 2nd High Level
AEA09-FF-12-RES-H3	Fortification Sample, ME 12, RespiCon, 3rd High Level
AEA09-FF-12-HW-C1	Fortification Sample, ME 12, Hand Wash, 1st Control
AEA09-FF-12-HW-C2	Fortification Sample, ME 12, Hand Wash, 2nd Control
AEA09-FF-12-HW-L1	Fortification Sample, ME 12, Hand Wash, 1st Low Level
AEA09-FF-12-HW-L2	Fortification Sample, ME 12, Hand Wash, 2nd Low Level
AEA09-FF-12-HW-L3	Fortification Sample, ME 12, Hand Wash, 3rd Low Level
AEA09-FF-12-HW-H1	Fortification Sample, ME 12, Hand Wash, 1st High Level
AEA09-FF-12-HW-H2	Fortification Sample, ME 12, Hand Wash, 2nd High Level
AEA09-FF-12-HW-H3	Fortification Sample, ME 12, Hand Wash, 3rd High Level
AEA09-FF-12-FW-C1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Control
AEA09-FF-12-FW-C2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Control
AEA09-FF-12-FW-L1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Low Level
AEA09-FF-12-FW-L2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Low Level
AEA09-FF-12-FW-L3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd Low Level
AEA09-FF-12-FW-H1	Fortification Sample, ME 12, Face and Neck Wipe, 1st High Level
AEA09-FF-12-FW-H2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd High Level
AEA09-FF-12-FW-H3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd High Level
AEA09-FF-12-ID-C1	Fortification Sample, ME 12, Inner Dosimeter, 1st Control
AEA09-FF-12-ID-C2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Control
AEA09-FF-12-ID-L1	Fortification Sample, ME 12, Inner Dosimeter, 1st Low Level
AEA09-FF-12-ID-L2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Low Level
AEA09-FF-12-ID-L3	Fortification Sample, ME 12, Inner Dosimeter, 3rd Low Level
AEA09-FF-12-ID-H1	Fortification Sample, ME 12, Inner Dosimeter, 1st High Level
AEA09-FF-12-ID-H2	Fortification Sample, ME 12, Inner Dosimeter, 2nd High Level
AEA09-FF-12-ID-H3	Fortification Sample, ME 12, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-OD-C1	Fortification Sample, ME 12, Outer Dosimeter, 1st Control
AEA09-FF-12-OD-C2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Control
AEA09-FF-12-OD-L1	Fortification Sample, ME 12, Outer Dosimeter, 1st Low Level
AEA09-FF-12-OD-L2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Low Level
AEA09-FF-12-OD-L3	Fortification Sample, ME 12, Outer Dosimeter, 3rd Low Level
AEA09-FF-12-OD-H1	Fortification Sample, ME 12, Outer Dosimeter, 1st High Level
AEA09-FF-12-OD-H2	Fortification Sample, ME 12, Outer Dosimeter, 2nd High Level
AEA09-FF-12-OD-H3	Fortification Sample, ME 12, Outer Dosimeter, 3rd High Level
AEA09-FF-13-PH-C1	Fortification Sample, ME 13, Painter's Hat, 1st Control
AEA09-FF-13-PH-C2	Fortification Sample, ME 13, Painter's Hat, 2nd Control
AEA09-FF-13-PH-L1	Fortification Sample, ME 13, Painter's Hat, 1st Low Level
AEA09-FF-13-PH-L2	Fortification Sample, ME 13, Painter's Hat, 2nd Low Level
AEA09-FF-13-PH-L3	Fortification Sample, ME 13, Painter's Hat, 3rd Low Level
AEA09-FF-13-PH-H1	Fortification Sample, ME 13, Painter's Hat, 1st High Level
AEA09-FF-13-PH-H2	Fortification Sample, ME 13, Painter's Hat, 2nd High Level
AEA09-FF-13-PH-H3	Fortification Sample, ME 13, Painter's Hat, 3rd High Level
AEA09-FF-13-AR-C1	Fortification Sample, ME 13, Air Sampling Tube, 1st Control
AEA09-FF-13-AR-C2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Control
AEA09-FF-13-AR-L1	Fortification Sample, ME 13, Air Sampling Tube, 1st Low Level
AEA09-FF-13-AR-L2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Low Level
AEA09-FF-13-AR-L3	Fortification Sample, ME 13, Air Sampling Tube, 3rd Low Level
AEA09-FF-13-AR-H1	Fortification Sample, ME 13, Air Sampling Tube, 1st High Level
AEA09-FF-13-AR-H2	Fortification Sample, ME 13, Air Sampling Tube, 2nd High Level
AEA09-FF-13-AR-H3	Fortification Sample, ME 13, Air Sampling Tube, 3rd High Level
AEA09-FF-13-RES-C1	Fortification Sample, ME 13, RespiCon, 1st Control
AEA09-FF-13-RES-C2	Fortification Sample, ME 13, RespiCon, 2nd Control
AEA09-FF-13-RES-L1	Fortification Sample, ME 13, RespiCon, 1st Low Level
AEA09-FF-13-RES-L2	Fortification Sample, ME 13, RespiCon, 2nd Low Level
AEA09-FF-13-RES-L3	Fortification Sample, ME 13, RespiCon, 3rd Low Level
AEA09-FF-13-RES-H1	Fortification Sample, ME 13, RespiCon, 1st High Level
AEA09-FF-13-RES-H2	Fortification Sample, ME 13, RespiCon, 2nd High Level
AEA09-FF-13-RES-H3	Fortification Sample, ME 13, RespiCon, 3rd High Level
AEA09-FF-13-HW-C1	Fortification Sample, ME 13, Hand Wash, 1st Control
AEA09-FF-13-HW-C2	Fortification Sample, ME 13, Hand Wash, 2nd Control
AEA09-FF-13-HW-L1	Fortification Sample, ME 13, Hand Wash, 1st Low Level
AEA09-FF-13-HW-L2	Fortification Sample, ME 13, Hand Wash, 2nd Low Level
AEA09-FF-13-HW-L3	Fortification Sample, ME 13, Hand Wash, 3rd Low Level
AEA09-FF-13-HW-H1	Fortification Sample, ME 13, Hand Wash, 1st High Level
AEA09-FF-13-HW-H2	Fortification Sample, ME 13, Hand Wash, 2nd High Level
AEA09-FF-13-HW-H3	Fortification Sample, ME 13, Hand Wash, 3rd High Level
AEA09-FF-13-FW-C1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Control
AEA09-FF-13-FW-C2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Control
AEA09-FF-13-FW-L1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Low Level
AEA09-FF-13-FW-L2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Low Level
AEA09-FF-13-FW-L3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-13-FW-H1	Fortification Sample, ME 13, Face and Neck Wipe, 1st High Level
AEA09-FF-13-FW-H2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd High Level
AEA09-FF-13-FW-H3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd High Level
AEA09-FF-13-ID-C1	Fortification Sample, ME 13, Inner Dosimeter, 1st Control
AEA09-FF-13-ID-C2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Control
AEA09-FF-13-ID-L1	Fortification Sample, ME 13, Inner Dosimeter, 1st Low Level
AEA09-FF-13-ID-L2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Low Level
AEA09-FF-13-ID-L3	Fortification Sample, ME 13, Inner Dosimeter, 3rd Low Level
AEA09-FF-13-ID-H1	Fortification Sample, ME 13, Inner Dosimeter, 1st High Level
AEA09-FF-13-ID-H2	Fortification Sample, ME 13, Inner Dosimeter, 2nd High Level
AEA09-FF-13-ID-H3	Fortification Sample, ME 13, Inner Dosimeter, 3rd High Level
AEA09-FF-13-OD-C1	Fortification Sample, ME 13, Outer Dosimeter, 1st Control
AEA09-FF-13-OD-C2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Control
AEA09-FF-13-OD-L1	Fortification Sample, ME 13, Outer Dosimeter, 1st Low Level
AEA09-FF-13-OD-L2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Low Level
AEA09-FF-13-OD-L3	Fortification Sample, ME 13, Outer Dosimeter, 3rd Low Level
AEA09-FF-13-OD-H1	Fortification Sample, ME 13, Outer Dosimeter, 1st High Level
AEA09-FF-13-OD-H2	Fortification Sample, ME 13, Outer Dosimeter, 2nd High Level
AEA09-FF-13-OD-H3	Fortification Sample, ME 13, Outer Dosimeter, 3rd High Level
AEA09-FF-14-PH-C1	Fortification Sample, ME 14, Painter's Hat, 1st Control
AEA09-FF-14-PH-C2	Fortification Sample, ME 14, Painter's Hat, 2nd Control
AEA09-FF-14-PH-L1	Fortification Sample, ME 14, Painter's Hat, 1st Low Level
AEA09-FF-14-PH-L2	Fortification Sample, ME 14, Painter's Hat, 2nd Low Level
AEA09-FF-14-PH-L3	Fortification Sample, ME 14, Painter's Hat, 3rd Low Level
AEA09-FF-14-PH-H1	Fortification Sample, ME 14, Painter's Hat, 1st High Level
AEA09-FF-14-PH-H2	Fortification Sample, ME 14, Painter's Hat, 2nd High Level
AEA09-FF-14-PH-H3	Fortification Sample, ME 14, Painter's Hat, 3rd High Level
AEA09-FF-14-AR-C1	Fortification Sample, ME 14, Air Sampling Tube, 1st Control
AEA09-FF-14-AR-C2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Control
AEA09-FF-14-AR-L1	Fortification Sample, ME 14, Air Sampling Tube, 1st Low Level
AEA09-FF-14-AR-L2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Low Level
AEA09-FF-14-AR-L3	Fortification Sample, ME 14, Air Sampling Tube, 3rd Low Level
AEA09-FF-14-AR-H1	Fortification Sample, ME 14, Air Sampling Tube, 1st High Level
AEA09-FF-14-AR-H2	Fortification Sample, ME 14, Air Sampling Tube, 2nd High Level
AEA09-FF-14-AR-H3	Fortification Sample, ME 14, Air Sampling Tube, 3rd High Level
AEA09-FF-14-RES-C1	Fortification Sample, ME 14, RespiCon, 1st Control
AEA09-FF-14-RES-C2	Fortification Sample, ME 14, RespiCon, 2nd Control
AEA09-FF-14-RES-L1	Fortification Sample, ME 14, RespiCon, 1st Low Level
AEA09-FF-14-RES-L2	Fortification Sample, ME 14, RespiCon, 2nd Low Level
AEA09-FF-14-RES-L3	Fortification Sample, ME 14, RespiCon, 3rd Low Level
AEA09-FF-14-RES-H1	Fortification Sample, ME 14, RespiCon, 1st High Level
AEA09-FF-14-RES-H2	Fortification Sample, ME 14, RespiCon, 2nd High Level
AEA09-FF-14-RES-H3	Fortification Sample, ME 14, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-14-HW-C1	Fortification Sample, ME 14, Hand Wash, 1st Control
AEA09-FF-14-HW-C2	Fortification Sample, ME 14, Hand Wash, 2nd Control
AEA09-FF-14-HW-L1	Fortification Sample, ME 14, Hand Wash, 1st Low Level
AEA09-FF-14-HW-L2	Fortification Sample, ME 14, Hand Wash, 2nd Low Level
AEA09-FF-14-HW-L3	Fortification Sample, ME 14, Hand Wash, 3rd Low Level
AEA09-FF-14-HW-H1	Fortification Sample, ME 14, Hand Wash, 1st High Level
AEA09-FF-14-HW-H2	Fortification Sample, ME 14, Hand Wash, 2nd High Level
AEA09-FF-14-HW-H3	Fortification Sample, ME 14, Hand Wash, 3rd High Level
AEA09-FF-14-FW-C1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Control
AEA09-FF-14-FW-C2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Control
AEA09-FF-14-FW-L1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Low Level
AEA09-FF-14-FW-L2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Low Level
AEA09-FF-14-FW-L3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd Low Level
AEA09-FF-14-FW-H1	Fortification Sample, ME 14, Face and Neck Wipe, 1st High Level
AEA09-FF-14-FW-H2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd High Level
AEA09-FF-14-FW-H3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd High Level
AEA09-FF-14-ID-C1	Fortification Sample, ME 14, Inner Dosimeter, 1st Control
AEA09-FF-14-ID-C2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Control
AEA09-FF-14-ID-L1	Fortification Sample, ME 14, Inner Dosimeter, 1st Low Level
AEA09-FF-14-ID-L2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Low Level
AEA09-FF-14-ID-L3	Fortification Sample, ME 14, Inner Dosimeter, 3rd Low Level
AEA09-FF-14-ID-H1	Fortification Sample, ME 14, Inner Dosimeter, 1st High Level
AEA09-FF-14-ID-H2	Fortification Sample, ME 14, Inner Dosimeter, 2nd High Level
AEA09-FF-14-ID-H3	Fortification Sample, ME 14, Inner Dosimeter, 3rd High Level
AEA09-FF-14-OD-C1	Fortification Sample, ME 14, Outer Dosimeter, 1st Control
AEA09-FF-14-OD-C2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Control
AEA09-FF-14-OD-L1	Fortification Sample, ME 14, Outer Dosimeter, 1st Low Level
AEA09-FF-14-OD-L2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Low Level
AEA09-FF-14-OD-L3	Fortification Sample, ME 14, Outer Dosimeter, 3rd Low Level
AEA09-FF-14-OD-H1	Fortification Sample, ME 14, Outer Dosimeter, 1st High Level
AEA09-FF-14-OD-H2	Fortification Sample, ME 14, Outer Dosimeter, 2nd High Level
AEA09-FF-14-OD-H3	Fortification Sample, ME 14, Outer Dosimeter, 3rd High Level
AEA09-FF-15-PH-C1	Fortification Sample, ME 15, Painter's Hat, 1st Control
AEA09-FF-15-PH-C2	Fortification Sample, ME 15, Painter's Hat, 2nd Control
AEA09-FF-15-PH-L1	Fortification Sample, ME 15, Painter's Hat, 1st Low Level
AEA09-FF-15-PH-L2	Fortification Sample, ME 15, Painter's Hat, 2nd Low Level
AEA09-FF-15-PH-L3	Fortification Sample, ME 15, Painter's Hat, 3rd Low Level
AEA09-FF-15-PH-H1	Fortification Sample, ME 15, Painter's Hat, 1st High Level
AEA09-FF-15-PH-H2	Fortification Sample, ME 15, Painter's Hat, 2nd High Level
AEA09-FF-15-PH-H3	Fortification Sample, ME 15, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-AR-C1	Fortification Sample, ME 15, Air Sampling Tube, 1st Control
AEA09-FF-15-AR-C2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Control
AEA09-FF-15-AR-L1	Fortification Sample, ME 15, Air Sampling Tube, 1st Low Level
AEA09-FF-15-AR-L2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Low Level
AEA09-FF-15-AR-L3	Fortification Sample, ME 15, Air Sampling Tube, 3rd Low Level
AEA09-FF-15-AR-H1	Fortification Sample, ME 15, Air Sampling Tube, 1st High Level
AEA09-FF-15-AR-H2	Fortification Sample, ME 15, Air Sampling Tube, 2nd High Level
AEA09-FF-15-AR-H3	Fortification Sample, ME 15, Air Sampling Tube, 3rd High Level
AEA09-FF-15-RES-C1	Fortification Sample, ME 15, RespiCon, 1st Control
AEA09-FF-15-RES-C2	Fortification Sample, ME 15, RespiCon, 2nd Control
AEA09-FF-15-RES-L1	Fortification Sample, ME 15, RespiCon, 1st Low Level
AEA09-FF-15-RES-L2	Fortification Sample, ME 15, RespiCon, 2nd Low Level
AEA09-FF-15-RES-L3	Fortification Sample, ME 15, RespiCon, 3rd Low Level
AEA09-FF-15-RES-H1	Fortification Sample, ME 15, RespiCon, 1st High Level
AEA09-FF-15-RES-H2	Fortification Sample, ME 15, RespiCon, 2nd High Level
AEA09-FF-15-RES-H3	Fortification Sample, ME 15, RespiCon, 3rd High Level
AEA09-FF-15-HW-C1	Fortification Sample, ME 15, Hand Wash, 1st Control
AEA09-FF-15-HW-C2	Fortification Sample, ME 15, Hand Wash, 2nd Control
AEA09-FF-15-HW-L1	Fortification Sample, ME 15, Hand Wash, 1st Low Level
AEA09-FF-15-HW-L2	Fortification Sample, ME 15, Hand Wash, 2nd Low Level
AEA09-FF-15-HW-L3	Fortification Sample, ME 15, Hand Wash, 3rd Low Level
AEA09-FF-15-HW-H1	Fortification Sample, ME 15, Hand Wash, 1st High Level
AEA09-FF-15-HW-H2	Fortification Sample, ME 15, Hand Wash, 2nd High Level
AEA09-FF-15-HW-H3	Fortification Sample, ME 15, Hand Wash, 3rd High Level
AEA09-FF-15-FW-C1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Control
AEA09-FF-15-FW-C2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Control
AEA09-FF-15-FW-L1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Low Level
AEA09-FF-15-FW-L2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Low Level
AEA09-FF-15-FW-L3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd Low Level
AEA09-FF-15-FW-H1	Fortification Sample, ME 15, Face and Neck Wipe, 1st High Level
AEA09-FF-15-FW-H2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd High Level
AEA09-FF-15-FW-H3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd High Level
AEA09-FF-15-ID-C1	Fortification Sample, ME 15, Inner Dosimeter, 1st Control
AEA09-FF-15-ID-C2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Control
AEA09-FF-15-ID-L1	Fortification Sample, ME 15, Inner Dosimeter, 1st Low Level
AEA09-FF-15-ID-L2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Low Level
AEA09-FF-15-ID-L3	Fortification Sample, ME 15, Inner Dosimeter, 3rd Low Level
AEA09-FF-15-ID-H1	Fortification Sample, ME 15, Inner Dosimeter, 1st High Level
AEA09-FF-15-ID-H2	Fortification Sample, ME 15, Inner Dosimeter, 2nd High Level
AEA09-FF-15-ID-H3	Fortification Sample, ME 15, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-OD-C1	Fortification Sample, ME 15, Outer Dosimeter, 1st Control
AEA09-FF-15-OD-C2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Control
AEA09-FF-15-OD-L1	Fortification Sample, ME 15, Outer Dosimeter, 1st Low Level
AEA09-FF-15-OD-L2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Low Level
AEA09-FF-15-OD-L3	Fortification Sample, ME 15, Outer Dosimeter, 3rd Low Level
AEA09-FF-15-OD-H1	Fortification Sample, ME 15, Outer Dosimeter, 1st High Level
AEA09-FF-15-OD-H2	Fortification Sample, ME 15, Outer Dosimeter, 2nd High Level
AEA09-FF-15-OD-H3	Fortification Sample, ME 15, Outer Dosimeter, 3rd High Level
AEA09-FF-16-PH-C1	Fortification Sample, ME 16, Painter's Hat, 1st Control
AEA09-FF-16-PH-C2	Fortification Sample, ME 16, Painter's Hat, 2nd Control
AEA09-FF-16-PH-L1	Fortification Sample, ME 16, Painter's Hat, 1st Low Level
AEA09-FF-16-PH-L2	Fortification Sample, ME 16, Painter's Hat, 2nd Low Level
AEA09-FF-16-PH-L3	Fortification Sample, ME 16, Painter's Hat, 3rd Low Level
AEA09-FF-16-PH-H1	Fortification Sample, ME 16, Painter's Hat, 1st High Level
AEA09-FF-16-PH-H2	Fortification Sample, ME 16, Painter's Hat, 2nd High Level
AEA09-FF-16-PH-H3	Fortification Sample, ME 16, Painter's Hat, 3rd High Level
AEA09-FF-16-AR-C1	Fortification Sample, ME 16, Air Sampling Tube, 1st Control
AEA09-FF-16-AR-C2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Control
AEA09-FF-16-AR-L1	Fortification Sample, ME 16, Air Sampling Tube, 1st Low Level
AEA09-FF-16-AR-L2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Low Level
AEA09-FF-16-AR-L3	Fortification Sample, ME 16, Air Sampling Tube, 3rd Low Level
AEA09-FF-16-AR-H1	Fortification Sample, ME 16, Air Sampling Tube, 1st High Level
AEA09-FF-16-AR-H2	Fortification Sample, ME 16, Air Sampling Tube, 2nd High Level
AEA09-FF-16-AR-H3	Fortification Sample, ME 16, Air Sampling Tube, 3rd High Level
AEA09-FF-16-RES-C1	Fortification Sample, ME 16, RespiCon, 1st Control
AEA09-FF-16-RES-C2	Fortification Sample, ME 16, RespiCon, 2nd Control
AEA09-FF-16-RES-L1	Fortification Sample, ME 16, RespiCon, 1st Low Level
AEA09-FF-16-RES-L2	Fortification Sample, ME 16, RespiCon, 2nd Low Level
AEA09-FF-16-RES-L3	Fortification Sample, ME 16, RespiCon, 3rd Low Level
AEA09-FF-16-RES-H1	Fortification Sample, ME 16, RespiCon, 1st High Level
AEA09-FF-16-RES-H2	Fortification Sample, ME 16, RespiCon, 2nd High Level
AEA09-FF-16-RES-H3	Fortification Sample, ME 16, RespiCon, 3rd High Level
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-HW-C2	Fortification Sample, ME 16, Hand Wash, 2nd Control
AEA09-FF-16-HW-L1	Fortification Sample, ME 16, Hand Wash, 1st Low Level
AEA09-FF-16-HW-L2	Fortification Sample, ME 16, Hand Wash, 2nd Low Level
AEA09-FF-16-HW-L3	Fortification Sample, ME 16, Hand Wash, 3rd Low Level
AEA09-FF-16-HW-H1	Fortification Sample, ME 16, Hand Wash, 1st High Level
AEA09-FF-16-HW-H2	Fortification Sample, ME 16, Hand Wash, 2nd High Level
AEA09-FF-16-HW-H3	Fortification Sample, ME 16, Hand Wash, 3rd High Level
AEA09-FF-16-FW-C1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Control
AEA09-FF-16-FW-C2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Control
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-FW-L1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Low Level
AEA09-FF-16-FW-L2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Low Level

Sample ID Number	Description
AEA09-FF-16-FW-L3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd Low Level
AEA09-FF-16-FW-H1	Fortification Sample, ME 16, Face and Neck Wipe, 1st High Level
AEA09-FF-16-FW-H2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd High Level
AEA09-FF-16-FW-H3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd High Level
AEA09-FF-16-ID-C1	Fortification Sample, ME 16, Inner Dosimeter, 1st Control
AEA09-FF-16-ID-C2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Control
AEA09-FF-16-ID-L1	Fortification Sample, ME 16, Inner Dosimeter, 1st Low Level
AEA09-FF-16-ID-L2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Low Level
AEA09-FF-16-ID-L3	Fortification Sample, ME 16, Inner Dosimeter, 3rd Low Level
AEA09-FF-16-ID-H1	Fortification Sample, ME 16, Inner Dosimeter, 1st High Level
AEA09-FF-16-ID-H2	Fortification Sample, ME 16, Inner Dosimeter, 2nd High Level
AEA09-FF-16-ID-H3	Fortification Sample, ME 16, Inner Dosimeter, 3rd High Level
AEA09-FF-16-OD-C1	Fortification Sample, ME 16, Outer Dosimeter, 1st Control
AEA09-FF-16-OD-C2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Control
AEA09-FF-16-OD-L1	Fortification Sample, ME 16, Outer Dosimeter, 1st Low Level
AEA09-FF-16-OD-L2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Low Level
AEA09-FF-16-OD-L3	Fortification Sample, ME 16, Outer Dosimeter, 3rd Low Level
AEA09-FF-16-OD-H1	Fortification Sample, ME 16, Outer Dosimeter, 1st High Level
AEA09-FF-16-OD-H2	Fortification Sample, ME 16, Outer Dosimeter, 2nd High Level
AEA09-FF-16-OD-H3	Fortification Sample, ME 16, Outer Dosimeter, 3rd High Level
AEA09-FF-17-PH-C1	Fortification Sample, ME 17, Painter's Hat, 1st Control
AEA09-FF-17-PH-C2	Fortification Sample, ME 17, Painter's Hat, 2nd Control
AEA09-FF-17-PH-L1	Fortification Sample, ME 17, Painter's Hat, 1st Low Level
AEA09-FF-17-PH-L2	Fortification Sample, ME 17, Painter's Hat, 2nd Low Level
AEA09-FF-17-PH-L3	Fortification Sample, ME 17, Painter's Hat, 3rd Low Level
AEA09-FF-17-PH-H1	Fortification Sample, ME 17, Painter's Hat, 1st High Level
AEA09-FF-17-PH-H2	Fortification Sample, ME 17, Painter's Hat, 2nd High Level
AEA09-FF-17-PH-H3	Fortification Sample, ME 17, Painter's Hat, 3rd High Level
AEA09-FF-17-AR-C1	Fortification Sample, ME 17, Air Sampling Tube, 1st Control
AEA09-FF-17-AR-C2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Control
AEA09-FF-17-AR-L1	Fortification Sample, ME 17, Air Sampling Tube, 1st Low Level
AEA09-FF-17-AR-L2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Low Level
AEA09-FF-17-AR-L3	Fortification Sample, ME 17, Air Sampling Tube, 3rd Low Level
AEA09-FF-17-AR-H1	Fortification Sample, ME 17, Air Sampling Tube, 1st High Level
AEA09-FF-17-AR-H2	Fortification Sample, ME 17, Air Sampling Tube, 2nd High Level
AEA09-FF-17-AR-H3	Fortification Sample, ME 17, Air Sampling Tube, 3rd High Level
AEA09-FF-17-RES-C1	Fortification Sample, ME 17, RespiCon, 1st Control
AEA09-FF-17-RES-C2	Fortification Sample, ME 17, RespiCon, 2nd Control
AEA09-FF-17-RES-L1	Fortification Sample, ME 17, RespiCon, 1st Low Level
AEA09-FF-17-RES-L2	Fortification Sample, ME 17, RespiCon, 2nd Low Level
AEA09-FF-17-RES-L3	Fortification Sample, ME 17, RespiCon, 3rd Low Level

Sample ID Number	Description
AEA09-FF-17-RES-H1	Fortification Sample, ME 17, RespiCon, 1st High Level
AEA09-FF-17-RES-H2	Fortification Sample, ME 17, RespiCon, 2nd High Level
AEA09-FF-17-RES-H3	Fortification Sample, ME 17, RespiCon, 3rd High Level
AEA09-FF-17-HW-C1	Fortification Sample, ME 17, Hand Wash, 1st Control
AEA09-FF-17-HW-C2	Fortification Sample, ME 17, Hand Wash, 2nd Control
AEA09-FF-17-HW-L1	Fortification Sample, ME 17, Hand Wash, 1st Low Level
AEA09-FF-17-HW-L2	Fortification Sample, ME 17, Hand Wash, 2nd Low Level
AEA09-FF-17-HW-L3	Fortification Sample, ME 17, Hand Wash, 3rd Low Level
AEA09-FF-17-HW-H1	Fortification Sample, ME 17, Hand Wash, 1st High Level
AEA09-FF-17-HW-H2	Fortification Sample, ME 17, Hand Wash, 2nd High Level
AEA09-FF-17-HW-H3	Fortification Sample, ME 17, Hand Wash, 3rd High Level
AEA09-FF-17-FW-C1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Control
AEA09-FF-17-FW-C2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Control
AEA09-FF-17-FW-L1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Low Level
AEA09-FF-17-FW-L2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Low Level
AEA09-FF-17-FW-L3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd Low Level
AEA09-FF-17-FW-H1	Fortification Sample, ME 17, Face and Neck Wipe, 1st High Level
AEA09-FF-17-FW-H2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd High Level
AEA09-FF-17-FW-H3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd High Level
AEA09-FF-17-ID-C1	Fortification Sample, ME 17, Inner Dosimeter, 1st Control
AEA09-FF-17-ID-C2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Control
AEA09-FF-17-ID-L1	Fortification Sample, ME 17, Inner Dosimeter, 1st Low Level
AEA09-FF-17-ID-L2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Low Level
AEA09-FF-17-ID-L3	Fortification Sample, ME 17, Inner Dosimeter, 3rd Low Level
AEA09-FF-17-ID-H1	Fortification Sample, ME 17, Inner Dosimeter, 1st High Level
AEA09-FF-17-ID-H2	Fortification Sample, ME 17, Inner Dosimeter, 2nd High Level
AEA09-FF-17-ID-H3	Fortification Sample, ME 17, Inner Dosimeter, 3rd High Level
AEA09-FF-17-OD-C1	Fortification Sample, ME 17, Outer Dosimeter, 1st Control
AEA09-FF-17-OD-C2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Control
AEA09-FF-17-OD-L1	Fortification Sample, ME 17, Outer Dosimeter, 1st Low Level
AEA09-FF-17-OD-L2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Low Level
AEA09-FF-17-OD-L3	Fortification Sample, ME 17, Outer Dosimeter, 3rd Low Level
AEA09-FF-17-OD-H1	Fortification Sample, ME 17, Outer Dosimeter, 1st High Level
AEA09-FF-17-OD-H2	Fortification Sample, ME 17, Outer Dosimeter, 2nd High Level
AEA09-FF-17-OD-H3	Fortification Sample, ME 17, Outer Dosimeter, 3rd High Level
AEA09-FF-18-PH-C1	Fortification Sample, ME 18, Painter's Hat, 1st Control
AEA09-FF-18-PH-C2	Fortification Sample, ME 18, Painter's Hat, 2nd Control
AEA09-FF-18-PH-L1	Fortification Sample, ME 18, Painter's Hat, 1st Low Level
AEA09-FF-18-PH-L2	Fortification Sample, ME 18, Painter's Hat, 2nd Low Level
AEA09-FF-18-PH-L3	Fortification Sample, ME 18, Painter's Hat, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-PH-H1	Fortification Sample, ME 18, Painter's Hat, 1st High Level
AEA09-FF-18-PH-H2	Fortification Sample, ME 18, Painter's Hat, 2nd High Level
AEA09-FF-18-PH-H3	Fortification Sample, ME 18, Painter's Hat, 3rd High Level
AEA09-FF-18-AR-C1	Fortification Sample, ME 18, Air Sampling Tube, 1st Control
AEA09-FF-18-AR-C2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Control
AEA09-FF-18-AR-L1	Fortification Sample, ME 18, Air Sampling Tube, 1st Low Level
AEA09-FF-18-AR-L2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Low Level
AEA09-FF-18-AR-L3	Fortification Sample, ME 18, Air Sampling Tube, 3rd Low Level
AEA09-FF-18-AR-H1	Fortification Sample, ME 18, Air Sampling Tube, 1st High Level
AEA09-FF-18-AR-H2	Fortification Sample, ME 18, Air Sampling Tube, 2nd High Level
AEA09-FF-18-AR-H3	Fortification Sample, ME 18, Air Sampling Tube, 3rd High Level
AEA09-FF-18-RES-C1	Fortification Sample, ME 18, RespiCon, 1st Control
AEA09-FF-18-RES-C2	Fortification Sample, ME 18, RespiCon, 2nd Control
AEA09-FF-18-RES-L1	Fortification Sample, ME 18, RespiCon, 1st Low Level
AEA09-FF-18-RES-L2	Fortification Sample, ME 18, RespiCon, 2nd Low Level
AEA09-FF-18-RES-L3	Fortification Sample, ME 18, RespiCon, 3rd Low Level
AEA09-FF-18-RES-H1	Fortification Sample, ME 18, RespiCon, 1st High Level
AEA09-FF-18-RES-H2	Fortification Sample, ME 18, RespiCon, 2nd High Level
AEA09-FF-18-RES-H3	Fortification Sample, ME 18, RespiCon, 3rd High Level
AEA09-FF-18-HW-C1	Fortification Sample, ME 18, Hand Wash, 1st Control
AEA09-FF-18-HW-C2	Fortification Sample, ME 18, Hand Wash, 2nd Control
AEA09-FF-18-HW-L1	Fortification Sample, ME 18, Hand Wash, 1st Low Level
AEA09-FF-18-HW-L2	Fortification Sample, ME 18, Hand Wash, 2nd Low Level
AEA09-FF-18-HW-L3	Fortification Sample, ME 18, Hand Wash, 3rd Low Level
AEA09-FF-18-HW-H1	Fortification Sample, ME 18, Hand Wash, 1st High Level
AEA09-FF-18-HW-H2	Fortification Sample, ME 18, Hand Wash, 2nd High Level
AEA09-FF-18-HW-H3	Fortification Sample, ME 18, Hand Wash, 3rd High Level
AEA09-FF-18-FW-C1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Control
AEA09-FF-18-FW-C2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Control
AEA09-FF-18-FW-L1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Low Level
AEA09-FF-18-FW-L2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Low Level
AEA09-FF-18-FW-L3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd Low Level
AEA09-FF-18-FW-H1	Fortification Sample, ME 18, Face and Neck Wipe, 1st High Level
AEA09-FF-18-FW-H2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd High Level
AEA09-FF-18-FW-H3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd High Level
AEA09-FF-18-ID-C1	Fortification Sample, ME 18, Inner Dosimeter, 1st Control
AEA09-FF-18-ID-C2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Control
AEA09-FF-18-ID-L1	Fortification Sample, ME 18, Inner Dosimeter, 1st Low Level
AEA09-FF-18-ID-L2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Low Level
AEA09-FF-18-ID-L3	Fortification Sample, ME 18, Inner Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-ID-H1	Fortification Sample, ME 18, Inner Dosimeter, 1st High Level
AEA09-FF-18-ID-H2	Fortification Sample, ME 18, Inner Dosimeter, 2nd High Level
AEA09-FF-18-ID-H3	Fortification Sample, ME 18, Inner Dosimeter, 3rd High Level
AEA09-FF-18-OD-C1	Fortification Sample, ME 18, Outer Dosimeter, 1st Control
AEA09-FF-18-OD-C2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Control
AEA09-FF-18-OD-L1	Fortification Sample, ME 18, Outer Dosimeter, 1st Low Level
AEA09-FF-18-OD-L2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Low Level
AEA09-FF-18-OD-L3	Fortification Sample, ME 18, Outer Dosimeter, 3rd Low Level
AEA09-FF-18-OD-H1	Fortification Sample, ME 18, Outer Dosimeter, 1st High Level
AEA09-FF-18-OD-H2	Fortification Sample, ME 18, Outer Dosimeter, 2nd High Level
AEA09-FF-18-OD-H3	Fortification Sample, ME 18, Outer Dosimeter, 3rd High Level

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Robert Testman
Sent: Monday, February 22, 2016 12:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol
Attachments: HSRB Final Report April 2014 meeting.docx; ny12-19.pdf; CDPR Review Response Email.pdf; CDPR letter 22Jan2014.pdf

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
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dguzman@sairb.com | Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
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Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
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(559)275-9091 (lab)
(949)939-3585 (cell)

June 25, 2014

EPA-HSRB-14-01

Robert Kavlock, Ph.D.
Interim EPA Science Advisor
Office of the Science Advisor
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: April 8-9, 2014 EPA Human Studies Review Board Meeting Report

Dear Dr. Kavlock,

The United States Environmental Protection Agency (EPA or Agency) requested that the Human Studies Review Board (HSRB) provide scientific and ethics reviews of two new scenario designs and associated protocols and two newly proposed protocols. The Board's responses to the related charge questions and their additional comments are enclosed in a final meeting report for the April 8-9, 2014, meeting. This letter indicates the key findings from the Board's reviews.

A New Scenario Design and Associated Protocol from the Antimicrobial Exposure Assessment Task Force (AEATF-II) Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Manual Pouring of Solid Formulation Antimicrobial Products (AEA07)

Science

- The Board concluded that this research, if modified in accordance with the suggestions made by the Agency and the Board, is likely to generate scientifically reliable data. The residential component of the research will be useful for assessing the exposure of those who pour solid formulation antimicrobial products into swimming pools using a wide range of techniques. The occupational component of this research will be useful for assessing exposures over a narrower but practical range of parameters.

Ethics

- The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Leighton, Sherman & Cohen, 2013) and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L.

A New Scenario Design and Associated Protocol from the AEATF-II Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Application of Latex Paint Containing an Antimicrobial Pesticide Product Using Brush and Roller Equipment (AEA09)

Science

- The Board agreed with the Agency's conclusion that, if modified according to Agency and HSRB recommendations, the proposed research to monitor dermal and inhalation exposure during application of latex paint containing an antimicrobial pesticide using brush and roller equipment is likely to produce scientifically reliable data. The Board also agreed that the modifications to the protocol suggested by the EPA (Leighton, Sherman & Cohen, 2014a) be accomplished before initiation of the study.

Ethics

- The documents submitted to the EPA and the HSRB do not fully meet the regulatory requirements. However, the Board concluded that the protocol submitted for review will likely meet the applicable requirements of 40 CFR part 26, subparts K and L, if: 1) it is modified in accordance with EPA (Leighton, Sherman, & Cohen, 2014a) and HSRB recommendations; 2) necessary approvals are obtained; and 3) additional documents are provided to the Agency for review.

A New Protocol from the AEATF-II Describing Proposed Research to Measure the Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (Known as BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipes and Wash Procedure (AEA08)

Science

- With the exception of one member, the Board concluded that the proposed research is likely to generate scientifically reliable data, useful for determining the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint and non-paint liquid solutions containing BIT, provided that the protocol is modified to address the issues raised by EPA and the HSRB.

Ethics

- The documents submitted to the EPA and the HSRB do not fully meet the regulatory requirements. Despite this, the Board concluded that this protocol will likely meet the applicable requirements of 40 CFR 26, subparts K and L if: 1) it is modified in accordance with EPA (Leighton, Sherman & Cohen, 2014b) and HSRB recommendations; 2) necessary approvals are obtained; and 3) additional documents are provided to the Agency for review.

A New Protocol from the U.S. Department of Agriculture Describing Proposed Research to Determine the Bite Protection Level of Repellent Treated Clothing for the United States Military

Science

- The Board concurred that the proposed protocol will likely generate scientifically reliable data for estimation of bite protection efficacy of impregnated clothing, if improvements in the overall study design enumerated by EPA (Sweeney & Sherman, 2014) and the Board are adequately considered.

Ethics

- The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Sweeney & Sherman, 2014) and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L.

Sincerely,

Rebecca T. Parkin, PhD, MPH
Chair
EPA Human Studies Review Board

NOTICE

This report has been written as part of the activities of the EPA Human Studies Review Board, a Federal advisory committee providing advice, information and recommendations on issues related to scientific and ethical aspects of human subjects research. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the view and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does the mention of trade names or commercial products constitute a recommendation for use. You may obtain further information about the EPA Human Studies Review Board from its website at http://www.epa.gov/osa/hsrb. You may also contact the HSRB Designated Federal Officer, via e-mail at ord-osa-hsrb@epa.gov

In preparing this document, the Board carefully considered all information provided and presented by the Agency presenters, as well as information presented by public commenters. This document addresses the information provided and presented within the structure of the charge by the Agency.

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD

Chair

Rebecca Parkin, PhD, MPH, Professorial Lecturer (EOH), Milken Institute School of Public Health, The George Washington University, Washington, DC

Vice Chair

*Jewell H. Halanych, M.D., Assistant Professor, Internal Medicine Residency Program, Montgomery Campus of the University of Alabama School of Medicine, Montgomery, AL

Members

Liza Dawson, Ph.D., Bioethicist, Research Ethics Team Leader, Division of AIDS National Institutes of Allergy & Infectious Diseases, Bethesda, MD

George Fernandez, PhD, Professor of Applied Statistics, Director of the University of Nevada-Reno Center for Research Design and Analysis, University of Nevada-Reno, Reno, NV

Kyle L. Galbraith, Ph.D., Manager, Human Subjects Protection, Carle Foundation Hospital, Urbana, IL

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William Popendorf, PhD, MPH, Professor Emeritus, Department of Biology, Utah State University, Logan, UT

Kenneth Ramos, M.D., Ph.D., PharmB, Associate Vice President, Precision Health Sciences, Professor of Medicine, Arizona Health Sciences Center, Tucson, AZ

Leonard Ritter, Ph.D., ATS, Professor Emeritus (Toxicology), School of Environmental Sciences, University of Guelph, Guelph, ON, Canada

Linda J. Young, PhD, Professor, Department of Statistics, Institute of Food and Agricultural Sciences, University of Florida, Gainesville, FL

Consultants

Sean Philpott-Jones, Ph.D., M.S. Bioethics; Director, Research Ethics; The Bioethics Program; Union Graduate College; Icahn School of Medicine at Mount Sinai; Schenectady, NY

Kendra L. Lawrence, Ph.D., BCE, Senior Technical Consultant, US Army Medical Material Development Activity, General Dynamics Information Technology, Fort Detrick, MD

Human Studies Review Board Staff

Jim Downing, Executive Director, Human Studies Review Board Staff, Office of the Science Advisor, United States Environmental Protection Agency, Washington, DC

*Not a participant at this meeting.

INTRODUCTION

On April 8 and 9, 2014, the United States Environmental Protection Agency's (EPA or Agency) Human Studies Review Board (HSRB) met to address the scientific and ethical charge questions related to two new scenario designs and associated protocols and two newly proposed protocols.

- A New Scenario Design and Associated Protocol from the Antimicrobial Exposure Assessment Task Force (AEATF-II) Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Manual Pouring of Solid Formulation Antimicrobial Products (AEA07)
- A New Scenario Design and Associated Protocol from the AEATF-II Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Application of Latex Paint Containing an Antimicrobial Pesticide Product Using Brush and Roller Equipment (AEA09)
- A New Protocol from the AEATF-II Describing Proposed Research to Measure the Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (Known as BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipes and Wash Procedure (AEA08)
- A New Protocol from the U.S. Department of Agriculture Describing Proposed Research to Determine the Bite Protection Level of Repellent Treated Clothing for the United States Military

REVIEW PROCESS

The Board conducted public face-to-face meetings in Arlington, Virginia, on April 8 and 9, 2014. Advance notice of the meeting was published in the *Federal Register* as "Human Studies Review Board; Notice of Public Meeting" (USEPA, 2014).

Following welcoming remarks from Agency officials, the Board heard presentations from EPA on each of the four protocols listed above. This Final Report of the meeting describes the discussion, recommendations and rationale in response to each charge question for each protocol. The Agency also made a presentation about the Repellency Awareness Graphic. The lead author of the HSRB Work Group on the Return of Individual Research Results described the group's workshop deliberations and report. Brief sections summarizing these latter two agenda items and the Board's discussions about them are included at the end of this meeting report.

For each protocol, Agency staff first presented their review of the science components of the proposal and the Board asked the Agency presenters clarifying questions about the science. The staff then described their review of the ethical aspects of the proposal and the Board asked clarifying questions about the ethical issues. The Board solicited public comments and next asked Agency staff to read the Charge Questions for the proposed protocol under consideration. The Board discussed the science question first and then the ethics question. Upon conclusion of the discussion of each question, the Chair called for a vote on a summary statement in response to that question.

For their evaluation and discussion, the Board considered materials presented at the meeting, oral comments, one letter from the public, and Agency background documents (*e.g.,* the proposed study protocols; AEATF governing documents; standard operating procedures and policies; institutional review board documentation; statistical methods and estimates); and the Agency's science and ethics reviews of the proposed protocols. A comprehensive list of background documents is available online at http://www.epa.gov/hsrb/.

CHARGE TO THE BOARD AND BOARD RESPONSE

A New Scenario Design and Associated Protocol from the Antimicrobial Exposure Assessment Task Force (AEATF-II) Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Manual Pouring of Solid Formulation Antimicrobial Products

Overview of the Scenario Design and Associated Protocol

AEATF-II's solid pour study (**AEA07**) is designed to measure dermal and inhalation exposures of workers and consumers when they manually pour solid antimicrobial products. The surrogate chemical for this study will be cyanuric acid (CYA). In this protocol, "pour" means either pour or scoop; scoops will be used in scenarios with larger containers. Two separate solid formulations are to be used; a powder and a granular product. Each formulation will be handled by the two sets of participants: workers and consumers. The research will be conducted in a warehouse in Concord, Ohio.

Four scenarios will be studied: occupational pouring of granules, occupational pouring of powders, residential [*i.e.;* consumer] pouring of granules, and residential pouring of powders. Each scenario will have 18 monitoring events (MEs) and three amounts of active ingredient handled (AaiH). The duration of pouring and the sizes and types of source and receiving containers will vary within each scenario. The same 18 worker participants will be studied in the two occupational scenarios, and the same 18 residential participants will be assessed in the two consumer scenarios. The occupational group will wear chemical resistant gloves while pouring a formulation into a mixing tank. The consumer group will not wear gloves as they pour the product into a swimming pool. Each ME will include measurement of dermal exposure by using inner and outer dosimeters, as well as hand and face washes. Breathing zone air concentrations for each ME will be measured using personal air monitors.

Participants for the study will be recruited from occupational and residential populations. The workers will be sought from experienced professional applicators (users), while the consumers will be recruited from residential groups with experience treating their swimming pools with solid formulations. The AEATF-II study is designed to represent real-world use of commercially available solid antimicrobial products. The study is intended to identify high-end levels of potential exposure. The Agency plans to use the resulting data in algorithms to estimate occupational and residential handlers' daily exposures from pouring or scooping solid antimicrobial products and to assess the related risks they would experience.

EPA's review of the proposed protocol was completed on September 10, 2013, and presented to the HSRB on April 8, 2014. The protocol was reviewed and approved by an independent human

subjects review committee, Shulman Associates IRB (SAIRB) of Sunrise, FL. The Agency made recommendations for improvements in both scientific and ethics aspects of the protocol.

Science

Charge to the Board

- Is this research likely to generate scientifically reliable data, useful for assessing the exposure of those who pour solid formulation antimicrobial pesticide products?

Board Response to the Charge

HSRB Recommendation

The Board concluded that this research, if modified in accordance with the suggestions made by the Agency and the Board, is likely to generate scientifically reliable data. The residential component of the research will be useful for assessing the exposure of those who pour solid formulation antimicrobial products into swimming pools using a wide range of techniques. The occupational component of this research will be useful for assessing exposures over a narrower but practical range of parameters.

HSRB Detailed Recommendations and Rationale

The Board agrees with the Agency's statement that revisions in the protocol need to be made regarding assigning specific AaiH, scoop sizes, and containers; requiring all subjects to wear particulate dust masks; and providing additional details about the airflow orientation. Furthermore, the AEATF-II will need to provide hand wash removal efficiency information to allow EPA to correct for incomplete residue removal from the hand sampling.

The Board expressed concerns with (1) the narrow range of use conditions proposed for all occupational users, in contrast to the wider range of product particle diameters, heights of "free-fall" while pouring, local air velocities, geometries of the receiving container, the subsequent time spent in the immediate vicinity of the pour, and the difference between new versus used gloves; (2) the potential for the occurrence of one or more identifiable random events (especially within the residential scenario)[1] that have the potential to overwhelm the underlying effect of proportionality over a 10-fold range in the residential AaiH; (3) the weak scientific justification offered to differentiate the studies being proposed to assess exposures while pouring solid antimicrobial products from studies already approved to assess exposures while pouring solid agricultural pesticides; (4) the inclusion of more research design features to enhance the likelihood of successful statistical tests of the results; and (5) the age and quality of toxicity studies used in support of the safety of a chemical or agent. Each of these five concerns is explained further below.

1. Most of these concerns are predicated upon factors generally known to affect a user's exposure and dose while pouring a solid (nonvolatile) product (*e.g.*, Popendorf, 2006, pp. 216-229). A summary of those factors is provided below.

[1] Such as a wet hand contacting the dry formulation while scooping or during a major spill.

- *The product's distribution of particle diameters.* Aerodynamic diameter influences the amount of airborne particles that are generated by a given action (*e.g.*, pouring from a given height), the settling velocity of these airborne particles, and (in combination with local air velocity as discussed below) the distance they travel before (or while) contributing to dermal (and airborne exposures), respectively. In typical indoor air (discussed below), particles larger than about 100 μm will fall a distance of one meter within about 1-4 meters of their source, meaning they will usually fall out of the air and land on a nearby surface (the floor if not before). Particles smaller than about 50 μm have a good chance of staying airborne for more than 10 meters. Sedimentation has almost no effect on particles 10 μm or less in diameter, and these small particles will behave similar to vapors.

- *The distance the product is allowed to "free fall"* from its pouring container to its receiving container. The amount of aerosol generated during a pouring operation is in some way proportional to the magnitude of the gravitational energy released when the poured material encounters either the bottom of the receiving container or the material already accumulating within that container. The protocol for occupational uses proposes a consistent free fall distance of about 18 inches by pouring the chemical through the top of a loading tank 36 inches tall and approximately half-full of circulating water. This distance is reasonable but may or may not represent a high-end exposure scenario for manual pouring. The range of free falls for the residential handlers is somewhat wider and will be replicated by allowing each person to stand, bend, or kneel on a deck surrounding a swimming pool and while pouring down to the water level.

- *The local horizontal air velocity*, *i.e.*, both its direction and speed. Horizontal air currents in typical mechanically ventilated rooms are generally in the range of 20 to 40 feet per minute (fpm) but can exceed 100 fpm.[2] Room air currents in a given location may also be vertical[3] and will usually have momentary vertical components due to turbulence. Particles will fall any time their settling velocity exceeds the local upward air speed; this process is called sedimentation. Thus, either some knowledge is needed of local air currents between the pour site and the person pouring or/and some steps need to be taken within the protocol to assure those conditions are varied among MEs.

- *The geometry of the receiving container*, in particular the height of its opening in relation to the user and any constraints like a lid. Receiving container geometry (in combination with the above factors) will affect the portions of a user's body on which most of the airborne particles will be deposited due to sedimentation and the magnitude of those depositions. While the height of receiving containers in industrial settings can easily range from floor level (or below) to above waist height, the protocol specifies a fixed height of approximately 36". Again, that height is reasonable but may or may not represent a high-end exposure scenario. However, the effect of a lid is more uncertain and thus problematic within the protocol. A partial lid will reduce the plume, but increase the likelihood of spillage and create a nearby large horizontal surface on which large diameter particles will collect via

[2] What some would call a "draft".
[3] Especially near a warm or hot source or where a horizontal air current encounters a vertical barrier.

sedimentation. The latter can increase real-world exposures whether or not the person who pours also cleans (*e.g.*, wipes or vacuums) those nearby surfaces.[4]

- *The subsequent time spent in the immediate vicinity of the pour* attending to some ancillary aspect of the pouring and mixing process. Time spent nearby (in combination with the above) will affect airborne exposures as well as the amount of airborne particles that will be deposited on the person due to sedimentation. The most common example is mixing while and immediately after pouring, but these are not included in this protocol. Industrial uses of biocides[5] usually require some form of mixing to assure suspension of the product. This mixing is most efficient if conducted during and immediately after the pouring step, and the same person who pours usually also monitors that mixing process. Another task is some, at least rudimentary, cleanup. More cleanup is likely to occur where the receiving container has a lid. Thus, the same person is usually in the near vicinity of the pour and is exposed to any particles still suspended in the air that can contribute to both their airborne and dermal exposures for several minutes.

- *The use of personal protective equipment (PPE);* in this case, gloves and respirators. The protocol justifies the consistent use of gloves by occupational handlers, no gloves by consumers, and, if modified, consistent use of respirators by all. However, new gloves provided to each participant are not the same as gloves previously used multiple times by the same person to handle the same solid formulated product. Past studies of handlers using their own gloves have shown significant hand exposures, on the order of 50% of their whole-body dose, presumably because of the accumulation of small amounts of material over time (Popendorf, et al., 1995).

The narrow range of use conditions proposed for the occupational scenario will make it difficult to extrapolate to other use conditions or to assure that the test conditions represent high-end exposures. Some use can be made of scientific principles that pertain to the factors that are listed above; however, most of these effects are more qualitative than quantitative. Among the known factors, it was encouraging to hear that information regarding the particle size distribution of the surrogate product will be provided. There are limits to the range of free-fall and receiving container geometries that can be replicated in a purposive diversity study. The Agency has already asked the sponsor to provide additional details about the airflow. At the time of the meeting, the protocol appeared to require the researchers to report a heating ventilation and air conditioning (HVAC) air exchange rate. Unless a case can be made for how the air exchange rate will be used, there does not seem to be a need within this protocol to have "a facilities maintenance engineer with HVAC training or an industrial hygienist will document the HVAC system (if there is one) in the warehouse and measure the air exchange rate" (Leighton, Sherman & Cohen, 2013, p. 13).

However, a few suggestions were made to either increase diversity or better replicate real-world occupational settings. At 20 to 40 fpm, the air velocity in indoor settings is typically too weak to sense but can be measured and is predominantly from one direction at any given location. The HSRB recommended that the Agency consider requiring steps within the protocol to add some

[4] In fact, such accumulations left unattended could become the largest component of long-term time-weighted average (TWA) dermal exposures which are beyond the purview of this protocol.
[5] As well as, most other solid formulations being poured, even in agricultural settings.

variability to the effect of ventilation in the indoor setting and thereby compensate the expected consistent air velocity at any one test location.[6]

The Board also suggested that the EPA consider adding a step into the occupational protocol that would cause the ME to spend some time in the immediate vicinity of the receiving container subsequent to the pour, *e.g.*, five minutes. While any time so spent would add realism, adding some rudimentary cleanup to the lip of the receiving container, its lid, and any inadvertent spillage would add even more realism. Applying this step to all or a random portion of MEs is another design option.[7]

The HSRB noted that because all occupational users will wear gloves these data cannot be used to estimate exposures to such users without gloves.[8] The issue of differences between new versus used gloves is less clear; it is not feasible to provide used gloves to the occupational handlers.[9] A simpler although less satisfying step would be to multiply the whole-body dermal exposures measured with new gloves by 2× (based on pre-rule published data, Popendorf *et al.*, 1995), which is also indicative of the probable magnitude of this issue.

2. The residential protocol is much more complex than the occupational protocol. It involves having some residential handlers pour their solid product straight from its container, others using a scoop, and a portion of both pouring first into a bucket, pre-dissolve it, then pouring the liquid mixture into the pool. Other than the protocol covering such a wide diversity of conditions that will limit its applicability to other more narrowly defined handling tasks, the proposed protocol seems likely to do a very good job of assessing exposures to consumers treating a swimming pool.

The fact that residential users will not wear gloves is understandable, but it heightens the probability for otherwise minor variations in application practices to create major variations in measured exposures. One notable example would be someone scooping biocide with a wet hand. It is well known that powders or granulars will stick to wet skin better than dry skin. It is more likely for someone to have wet hands around a pool than in an industrial setting. A wet hand holding a scoop inserted into a container is more likely to contact the product than if just pouring from its package. While no predicted value can be put on the relative increase in measured exposure that such an event would cause, it seems likely to exceed the 10× range between the low median AaiH (3.3 lb. in Group 1) and high median AaiH (38 lb. in Group 3). In contrast,

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[6] For example, if all tests are to be conducted in the same location within the warehouse, each ME could be instructed to work on a designed but different side of the receiving container. If such instructions are deemed too intrusive, then at least the equipment available to each ME can be pre-positioned on a different side of the receiving container. In either case, at least four different sides should be used.

[7] A potentially important suggestion was later made that when adding variability into purposive diversity studies of this nature, it is preferable to add it via a randomization structure by creating a list of the sequence of combinations of variables to be tested rather than allowing the probability of small numbers to operate haphazardly

[8] Apparently no labels for use without gloves are anticipated; so this point is moot.

[9] Future research might be conducted to assess naturally accumulated residues inside gloves used in real occupational settings. Other future research might be conducted into creating artificially contaminated gloves and into how much of the residues inside such gloves (whether created naturally or artificially) would transfer to wearers.

occupational users might have major spills, but their gloves should limit the excursions within their measured exposures. Given the stated goals of this study, no preventive steps against such occurrences is suggested, but one can anticipate that such an eventuality is likely to have a major effect on the subsequent tests for proportionality of unit exposure values with AaiH. The Board recommended that the observer of these MEs be instructed to watch very carefully for and note such occurrences, especially since a wet hand scooping inside a container may occur out of the observer's sight.

3. The Board also expressed some concern that the justification for conducting these studies appears more descriptive than scientific, and at best qualitative rather than quantitative. The question was asked, assuming that proprietary issues can be overcome, could this data-need be satisfied by using the new AHETF exposure data generated by pouring agricultural pesticides? Of particular interest are the conditions pertaining to prior pre-rule data from AHE39 and the previously reviewed protocols in AHE80 (Evans, Parsons & Sherman, 2010). AEATF-II cited five key differences between pouring solid antimicrobial products and pouring solid agricultural pesticides (Leighton, Sherman & Cohen, 2013, p. 21). However, most of these differences are either not serious, could be overcome, or/and are not rooted in science. For example, they state that agricultural granules are designed to be applied dry, directly to the soil surface and not mixed with water; this may be true for some, but many solid agricultural pesticides are poured into either an applicator bin or a tank of water. Another claim, agricultural granules are made up of carrier particles (such as clay, corn cob, or sand) to which the active ingredient is sorbed, but most antimicrobial granules do not contain an inert carrier. This claim is true for some but not for agricultural dry flowables, and the difference should be accounted for by their aerodynamic diameters (if they differ) and the known concentrations of their AIs. Their other justifications can be questioned similarly.

In contrast to the Agency's approach, a more scientific focus would be based on the use conditions outlined above (see item 1) or on a few other parameters such as the range of AaiH, the size of the pouring containers, and the use or not of scoops. Further discussion revealed that there are more scientific-based differences between the new AHETF data and that proposed herein. The agricultural containers in AHE39 were all 10 and 13 lb. bags and only half of those in AHE80 are within the 1 to 100 lb range of those proposed herein;[10] agricultural mixer/loaders rarely if ever use scoops that all the occupational biocide handlers will use; only 10 of AHE39's 25 MEs have an AaiH of 100 lb. or less (the range of interest to the AEATF). Thus, a valid scientific basis was found for conducting the proposed studies. In the end, the results of at least a portion of the two studies should be compared, and their differences and similarities used to provide further quantitative insight into the effects of use conditions.

4. In addition to the statistical issue of incorporating a randomization structure (noted in the next to last paragraph in item 1), an additional word of caution was offered. The statistical analysis of the gathered data will include modeling exposure as a linear function of AaiH handled. If data are collected at only three levels of AaiH handled, the choice of alternative models will be severely limited and difficult, if even possible, to assess if the anticipated linear model is found to be inappropriate. The power for testing the assumptions of proportionality will be relatively low. A design that included more levels of AaiH handled and fewer, if any,

[10] However, the size of bags is not regulated.

replicates at a given level of AaiH would allow the functional relationship between exposure and AaiH handled to be more fully explored and would provide greater power for testing the assumption of proportionality.

5. The Board commented that the acute dermal irritation studies and acute eye irritation studies (Shah, 2013a), upon which several decisions regarding the safety of human subjects were made, were conducted in 1981 (33 years ago) before Good Laboratory Practices (GLPs) were required by EPA. The notes to those studies indicate "Study not performed to GLP and no guideline is stated, but meets basic principles of a guideline study" (Shah, 2013a, pp. 4 and 6). The Board recommended that the age and quality (in terms of compliance with GLPs) of research be explicitly considered when submitting toxicity studies in support of the safety of a chemical or agent.

Ethics

Charge to the Board

- Is the research likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L?

Board Response to the Charge

HSRB Recommendation

The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Leighton, Sherman & Cohen, 2013) and the following HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L.

HSRB Detailed Recommendations and Rationale

The submitted documents assert that the revised study will be conducted in accordance with the ethical and regulatory standards of 40 CFR 26, Subparts K and L, as well as the requirements the US EPA's GLP Standards described at 40 CFR 160 (Shah, 2013b, p. 12). FIFRA §12(a)(2)(P) also applies.

The study sponsors have submitted all required materials and documents to the EPA and HSRB for review. Prior to this, the protocol was reviewed and approved by an independent human subjects review committee, Schulman Associates IRB (SAIRB) of Sunrise, FL. SAIRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and listed as active on the Office for Human Research Protections (OHRP) website (Reg. #IORG0000635).[11] Minutes of SAIRB meetings, a copy of their policies and procedures, and a list of IRB members were provided.

[11] OHRP is an office of the U.S. Department of Health and Human Services.

1. Except as noted below, the Board concurred with the conclusions and factual observations of the ethical strengths and weaknesses of the study, as detailed in the EPA's Ethics Review (Leighton, Sherman & Cohen, 2013, pp. 16-19). The proposed study is likely to meet the applicable ethical requirements for research involving human subjects, in accordance with the following criteria:

a. Risks to participants are commensurate with anticipated benefits to participants or society. Risks of study participation are six-fold: 1) allergic reaction or sensitivity to the test material; 2) allergic reaction or sensitivity to the surfactants used for hand and face/neck washing; 3) heat-related illness; 4) physical injury as a result of scripted activities; 5) psychological discomfort from undressing in the presence of a research technician; and 6) psychological stress and/or breach of confidentiality for pregnancy test results. These risks are minimized appropriately and are likely justified by the potential societal benefits, if the study is not duplicative of prior studies and produces useful data. There are no direct benefits to the participants.

- For the occupational portion of the study, only experienced handlers who are currently employed where they use powder or granule chemicals as part of their job and who consider themselves to be in good health will be enrolled. Similarly, for the consumer portion of the study, only participants who have experience handling and pouring powder or granular formulated pool maintenance chemicals and who consider themselves to be in good health will be recruited.
- The test material, cyanuric acid (1,3,5-triazine-2,4,6-triol), was chosen as a surrogate material because of its low toxicity and widespread use as a commonly used pool maintenance chemical. Current safety regulations do not require the use of gloves while pouring this product. While the Materials and Safety Data Sheet (MSDS) for cyanuric acid lists the use of chemical resistant gloves due to a potential for skin irritation, that reflects current industry practices that are meant purposefully to be overprotective, particularly for those working with large amounts of cyanuric acid in an occupational setting or those who have open cuts or sores on their hands. Participants with skin conditions or injuries to their hands (or face/neck) will be excluded.
- The study will exclude participants who have a history of sensitivity to the test material or to the surfactants used for the hand and face/neck washing. A Board member suggested adding a question to exclude persons with chronic respiratory illnesses or conditions.
- Subjects will be reminded about safe chemical handling practices and procedures, wearing appropriate PPE (including gloves in the occupational portion of the study), and will be monitored for any accidental or unintended product exposure of an extreme nature.
- Appropriate stopping measures are in place in the event of an injury or other adverse outcome.
- Risk of heat-related illness is minimized appropriately. Heat index will be monitored with an associated stopping rule. A medical professional will be on site to observe the workers and provide urgent care. Nearby medical facilities have been identified in case of emergency, and transportation to medical treatment will be provided, if needed.

- Minors and pregnant or lactating women are excluded from participation, with pregnancy either confirmed by over-the-counter pregnancy testing on the day of study or by opt-out. The potential stigma resulting from study exclusion due to pregnancy is appropriately minimized.

b. Voluntary and informed consent of all participants

- The Board respectfully disagrees with the Agency's conclusion that "no potential subjects are from a vulnerable population" (Leighton, Sherman & Cohen, 2013, p. 16). Rather, a better description is that the study is not actively recruiting participants that come from potentially vulnerable populations. There is a possibility that some participants in this study might be vulnerable, susceptible to coercion and undue influence. Despite this, the study protocol includes mechanisms designed to minimize coercive recruitment and enrollment.
- The informed consent materials, if changed as recommended by the EPA (Leighton, Sherman & Cohen, 2013) and by the HSRB below, will adequately inform the subjects of the risks, discomforts and benefits from participation and of their right to withdraw.
- Monetary compensation is not so high as to unduly influence participants.
- Faithful Spanish-language translations of the informed consent documents and recruitment materials were provided. Although there are minor concerns about the use of language in these document (including reading level), these are unlikely to interfere with the rights of non-English volunteers to give their voluntary and informed consent to participate in the study.

c. Equitable selection of study participants

- The study is designed to recruit an appropriately diverse population of participants who represent likely occupational and consumer (residential) users of the test material.
- The recruitment process has been carefully designed to assure that no subjects will be coerced or unduly induced into participating.

2. The Board recommended that the study protocol be modified to address the concerns noted in the EPA's Ethics Review (Leighton, Sherman & Cohen, 2013, pp. 16-19). In addition, the Board raised the following concerns:

a. The Board respectfully disagrees with the Agency's suggestion that the "Research-Related Injuries" section of the informed consent forms be revised to read as follows: "*If you experience an eye reaction, **skin reaction, respiratory irritation** or other adverse effect that you believe is related to your participation in the study, you should seek medical treatment and call the Study Director immediately at 1-877-298-7008*" (Leighton, Sherman & Cohen, 2013, p. 18). In fact, this revision does not go far enough. Study participants should be instructed to seek treatment and inform the Study Director of any eye reaction, skin reaction, respiratory irritation or other physical injury that occurs during or after participating in the study, regardless of whether or not the volunteer believes that it is related to the study.

b. It is not necessary or appropriate to state that cyanuric acid "does not require gloves or any other protective equipment to use" (Shah, 2013b, p. 31) on the occupational monitoring informed consent form. This may be confusing to participants, as they will be required to wear PPE during the study and will be given a copy of the MSDS to read, if requested. The study investigators should also consider how to handle the possibility that a participant in the consumer-monitoring phase of the study may ask to wear gloves.

c. Since study participants must self-report being in "good health," it should be clear what that term means. For example, since participants will be required to move 25-90 lbs. of product, some mention of those physical requirements should be made in reference to the health-related inclusion criterion.

d. With respect to the balance of risks and benefits, the submitted documents state that the risks of this study are "far lower than the risks of not being able to use effective antimicrobials for lack of information on the potential exposure to users" (Shah, 2013b, p. 26). This language includes assumptions about downstream consequences of decisions about conducting or not conducting specific research studies. The Board thus recommended that the study sponsor change this wording to read that "risks are reasonable in relation to the importance of understanding exposure patterns for consumers and occupational users of antimicrobials."

e. Participants in the study are allowed to take a short break if requested, either to use the bathroom or to have a cold drink. If the former, the researchers will conduct a hand wash to remove any product. Is the same true of the latter case, when a participant asks for a cold drink? Hand washes should also occur before any beverage consumption to reduce a participant's risk of accidental ingestion.

f. The study protocol should define the qualifications of the medical personnel needed and clarify this in the appropriate sections of the protocol.

g. The Board recommended that researchers complete a course in human subjects protections within three years of study initiation and completion.[12] Depending on when the study occurs, some investigators may exceed this recommended time limit.

A New Scenario Design and Associated Protocol from the AEATF-II Describing Proposed Research to Monitor Dermal and Inhalation Exposure During Application of Latex Paint Containing an Antimicrobial Pesticide Product Using Brush and Roller Equipment

Overview of the Scenario Design and Associated Protocol

The Antimicrobial Exposure Assessment Task Force (AEATF-II) proposes to measure dermal and inhalation exposures during the brush and roller application of interior latex paint, which contains an antimicrobial pesticide product (AEA09). The study participants will be recruited from the general (consumer) population, under the assumption that people who paint infrequently are more likely to experience greater exposures than professional painters.

[12] Within three years is generally considered "best practice" for training; e.g., see Section III D at http://mrmc.amedd.army.mil/assets/docs/orp/guidelinesForInvestigators.doc

The study will take place in a vacant building in Fresno, California. There will be 18 monitoring events (MEs), 6 for each of 3 chemical concentrations in the paint. The chemical to be used in this protocol is 1,2-Benzisothiazol-3(2H)-one (BIT). Study participants will apply about 2 gallons of paint using best-selling paint brushes and rollers. While opening and closing the paint can will be part of each ME, cleanup will not be included. Dermal exposures will be measured using inner and outer dosimeters, hand and face washes/wipes, and painter's hats. Additional exposures will be studied based on the results of gauze pads used to scrub participants' hands. During each ME, an OSHA Versatile Sampler (OVS) tube connected to a personal air sampling pump will be used to assess breathing zone inhalation exposures. Also, a three-stage Resp/Con Particle Sampler will be used to examine particles of 2.5, 10 and 100 μm.

The Agency plans to use the data from this study to estimate typical daily dermal and inhalation exposures among occupational and residential users of latex paint containing antimicrobial products, when applying them over a range of areas with a variety of paint rollers and brushes. The estimated exposures will be used to approximate risks to users of latex paint and similar products.

EPA's review of the proposed protocol was documented on March 14, 2014, and presented to the HSRB on April 8, 2014. The protocol was reviewed and conditionally approved by an independent human subjects review committee, Schulman Associates IRB (SAIRB) of Sunrise, FL.

Science

Charge to the Board

- Is this research likely to generate scientifically reliable data, useful for assessing the exposure of those who apply latex paint containing an antimicrobial pesticide using a brush or roller?

Board Response to the Charge

HSRB Recommendation

The Board agreed with the Agency's conclusion that, if modified according to Agency and HSRB recommendations, the proposed research to monitor dermal and inhalation exposure during application of latex paint containing an antimicrobial pesticide using brush and roller equipment is likely to produce scientifically reliable data. The Board also agreed that the modifications to the protocol suggested by the EPA (Leighton, Sherman & Cohen, 2014a, p. 2) be accomplished before initiation of the study.

HSRB Detailed Recommendations and Rationale

The Board made several recommendations, some bearing directly on the protocol for this study and others that should be considered for future studies of this nature.

1. Recommendations bearing directly on the protocol for this study

a. *Study design*: The Board recommended that the Agency reconsider the midpoint identified in this protocol. The middle concentration should be chosen to prevent high and low concentrations from having undue influence in fitting the regression to the data. Using only three dosage levels may not detect the true association between the dosage and exposure levels, and restricts the type of functions (such as quadratic and other complex lines) that can be fit to a straight line or a set of straight lines.. The HSRB recognized that adding more middle points could change the number of MEs but suggested that the Agency at least consider setting a midpoint that is more equidistant between the high and low concentrations.[13]

The study design uses what is termed "purposive diversity selection" as a means to assess the full range of variability by capturing many different activities/conditions in the fewest number of MEs (Shah, 2014a, p. 13). This is a good approach given the high cost of each monitoring event and limited sample size but the success of this approach depends on knowing in advance what factors have the greatest influence on variance in the outcome. The study identified three factors to achieve diversity: the date of application, the level of the active ingredient (AI) and the subject. The date of the application will likely have a relatively small contribution to variability. The level of AI in the paint is a controlled variable that clearly would influence the distribution of exposure (discussed above). The subject (careful or sloppy) is expected to have moderate influence on variance. These three factors are either purposively or randomly selected to achieve diversity in the outcome.

However, several other factors that potentially contribute to variance are discussed in the protocol including the roller and brush selection, wall finish, bucket size and the order that the monitoring events occur during the day. For example, if a subject participates in an ME that occurs in the morning versus late afternoon or on a Monday versus a Friday, this may contribute to variability just based on the scheduling. Additionally, the technicians monitoring the study may interact with the subjects differently for the same reason (how they feel at different times during the day or on different days of the week). These additional sources of variability are excluded by the purposive diversity selection. No justification is provided for why these other factors are standardized rather than being "purposively or randomly" included. Given that the primary exposure pathway for the brush and roller protocol is spatter and inadvertent contact with wet paint, factors such as roller nap thickness, paint type (density, sheen) and wall finish or texture could contribute significantly to variability in the outcome. Selecting the "best sellers" for painting tools can provide data representative of the central tendency but limits the range of the outcome. The HSRB recommended that either these additional factors be included in the purposive diversity selection process to "capture the range of exposure variation that is expected to exist" (Shah, 2014a, p. 7), or the statement that the protocol captures the range of variation be removed.

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[13] Another approach would be to distribute the same number of MEs (18) over six equally spaced dosages, thus having only three MEs per point instead of six MEs for each of three points, as in the proposed protocol. Increasing the number of AI dosages from three to six could improve the chance of detecting the true dosage-exposure association and increase the precision of exposure data estimates. Furthermore, following blinded dosage assignments to 18 MEs would avoid any placebo effects associated with the exposure measurements.

b. *Statistical modeling:* The main objective of this exposure study is to estimate the following summary statistics for exposure values after testing and confirming the expected log-normal distribution and the proportionality assumptions.

- AM = Modeled arithmetic mean = exp(LnGM) exp(½ Variance)
- GM = Modeled geometric mean = exp(LnGM)
- GSD = Modeled geometric standard deviation = exp(SD)
- P95 = Modeled 95th percentile = exp(LnGM) exp(Z95×SD)

However, if the data collected from this study fail to confirm the log-normal and proportionality assumptions, then the estimated summary statistics under-estimate (depending on the degree of non-linearity) the exposure summary statistics reported above. Therefore, if the study data reveal that association between dosage and exposure levels are significantly non-linear, evaluating for other non-linear dosage-response models such as log-logistic models (https://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_nlin_sect036.htm) and logistic models with 3 parameters (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2586183/pdf/nihms77514.pdf) are recommended for these exposure data. Also, the 95% confidence interval estimates for the arithmetic mean (P95) computed from the log-transformed data normally underestimate the error standard deviation, even after the back transformation.

Furthermore, as in similar studies, the Board encouraged the application of quantile regression models to estimate 95th percentile exposure estimates, in addition to reporting the arithmetic means.

Quantile regression methods model the relationship between dosage and the conditional quantiles of exposure; thus, it is especially useful in applications where extremes are important, such as in studies where upper quantiles of exposure levels are critical from a public health perspective (http://www2.sas.com/proceedings/sugi30/213-30.pdf).

c. *Exposure pathways:* The Brush and Roller protocol, as designed, focuses on non-volatile active ingredients in paints where the primary exposure pathway is physical contact with the paint through spatter, spills, and/or inadvertent contact with wet surfaces. The focus on non-volatile active ingredients was implied throughout the protocol and confirmed during the HSRB review meeting. This assumption can be verified with results from the personal air sampling during the ME. The protocol and justification for use of BIT (1,2-Benzisothiazol-3(2H)-one) should clearly define the "non- volatile" cutoff above which the current protocol will not be appropriate (*i.e.,* vapor pressures less than 0.1 mmHg). Otherwise, the assumption of a single representative surrogate of active ingredients breaks down because of the difference in physical chemical properties[14] which influence exposure pathways.

The protocol states that a painter's hat will be worn by all subjects and paint on the hat will be included in the characterization of whole body exposure. If the painter's hat is included as a surrogate surface, then a painter's sock/hood would be more representative. The shape of the hat and the brim on the hat change the contact area for exposure to spatter while a

[14] For example, vapor pressure, solubility, diffusivity and evaporation rate.

painter's sock/hood fits snug against the surface of the head with the added advantage of providing coverage on other parts of the face and neck (depending on how it is worn). Subjects are expected to wear their own socks and shoes. This could lead to an unanticipated expense to the subjects if they get paint on their shoes. Booties should be provided to prevent damage to subject's shoes, even if paint on the booties are not included as part of the external dosimeter.

d. *The test room design:* Test rooms for the Brush and Roller Protocol are designed to provide standardized conditions for the simulated painting events. *It is critical that these rooms be ventilated continuously during the MEs.* The protocol suggests turning off "ceiling ventilation fans" while ME is conducted (Shah, 2014b, p. 34). Exhaust fans should not be turned off during activity in the test rooms. Turning off fresh air ventilation during the MEs presents a real and unnecessary risk of symptoms related to exposure to bioeffluent (CO_2) and volatile constituents of the paint. California's Title 24 (California Energy Commission [CEC], 2008) and ASHRAE 62.2 (ASHRAE, 2013) both specify minimum required fresh air ventilation rates per occupant and/or unit floor area. The intent of both standards is to assure that the fresh air ventilation is sufficient to maintain acceptable indoor concentrations of occupant-generated pollutants – such as carbon dioxide – and acceptable indoor concentrations of pollutants emitted from building materials, furnishings, and the products used in buildings. The protocol should identify the appropriate minimum ventilation rate using either the CEC 2008 document or ASHRAE 2010 and design the test rooms to include an appropriately sized exhaust fan in each room to be operated continuously during the MEs. Given that the primary exposure pathway is expected to be physical contact with wet paint (spatter, spills and inadvertent contact), the fresh air ventilation is not expected to affect exposure to the antimicrobial surrogate. The exhausted air from the test room(s) should be vented outdoors.

e. *Additional test room issues:* Carryover of the surrogate antimicrobial chemical between experiments will be measured using both air samples collected in the rooms and surface wipes collected from the walls. It is unclear why the wall wipe samples are needed. If BIT is in the paint applied to the walls, and if the sampling method is effective, BIT will be detected in the wall wipes. The Board recommended that the protocol include some explanation of how these wall wipes will be used to understand exposures or define re-entry times because the exposure pathway for BIT in dry paint is not expected to contribute to the outcome.

The HSRB believes that industry data are available on typical drying times and/or re-entry times for painting; this information is expected to give a good estimate of how soon a room can be re-used for another ME. If this information is not available through industry partners, the protocol should include a verification task that characterizes the test rooms and the amount of time between experiments before re-use. This would entail painting the rooms with a finish coat of paint and monitoring room concentrations (not the user) over time to get a lucid understanding of clearance. That information can be used to determine how many test rooms are needed and the amount of time that should elapse between uses in each room.

The protocol should specify that the paint will be used in the consistency as received without further dilution.[15] The paint sheen should also be specified[16] because different sheen paints

[15] Note that if the paint is diluted it could increase the amount of spatter experienced during the ME.

could have different surface tensions resulting in different amounts of splatter for a given roller/brush/wall combination.

f. *Other comments:* The Board also noted that the study design seems to be based on the assumption that there will be a linear build-up of exposure by time. However, exposures will vary within the study period. There was concern that the measurements obtained will not reflect this variation and may not provide accurate exposure estimates. A member recommended that the Agency consider requiring measurements which will characterize exposure variations.

EPA has selected "best-selling" brushes and rollers for use in this study. Best selling items may be most representative, but they may not be the conservative choice since cheaper painting implements may drip more and lead to greater exposures. The Board recommended that the Agency clearly enumerate (and offer some rationale for) selection of both conservative and non-conservative factors embedded in the brush and roller study design.

Interpretation of the results of this study will be highly dependent upon results of a companion washing study (see review of AEA08 below). If the washing recovery study is not conducted in a scientifically sound manner, results of this study will not be useful. Therefore, this proposed protocol should not be approved or implemented until the companion washing study has been successfully implemented.

2. Recommendations for future studies of this nature

a. *Dermal No Observable Adverse Effects Levels (NOAELs)* or other toxicity parameters are routinely cited in evaluation of protocols that involve dermal exposure. The values are typically drawn from studies submitted in support of registration that are not generally available to HSRB members (except by FOIA processes that cannot be accommodated by the HSRB review timetable). Hence, the dermal toxicity study details are unknown. Traditionally, inadequate consideration has been given to the kinetics of dermal absorption in the design and conduct of dermal toxicity studies. Dermal absorption may be either flux or supply limited (Kissel, 2011). In the case of flux limitation, increasing skin loading will not produce an increase in absorbed dose; therefore, apparently increasing NOAELs will be misleading. Since the credibility of dermal toxicity values cannot be fairly evaluated in the absence of knowledge of experimental conditions, critical experimental details should be routinely provided in addition to toxicity outcomes.

b. *Worst case scenario:* There are no known data indicating whether consumer applicators (users) or professional applicators will get more paint on their skin. Thus, the justification for using consumer painters as a worse-case scenario is not supported by evidence. Among the justifications for using consumers is the statement within the Science and Ethics Review (Leighton, Sherman & Cohen, 2014a, p. 4[17]): *"This focus on consumer applicators is considered the more conservative approach, given that consumer painters are expected to be less skilled than professional painters. A less skilled painter is more likely to expose*

[16] The Board observed that the MSDS and the label in the protocol do not agree.
[17] Based on Shah, 2014a, p. 9.

themselves to the drips and paint spills."[18] An alternative opinion[19] is that professional painters are less concerned with personal contact with paint than are typical consumers, *i.e.*, they allow more paint to get on (and perhaps stay on) themselves. The lack of justification for using only consumer painters does not detract from the data's scientific reliability but is a weakness when extrapolating exposure measurements to professionals.

Ethics

Charge to the Board

- Is the research likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L?

Board Response to the Charge

HSRB Recommendation

The documents submitted to the EPA and the HSRB do not fully meet the regulatory requirements. However, the Board concluded that the protocol submitted for review will likely meet the applicable requirements of 40 CFR part 26, subparts K and L, if: 1) it is modified in accordance with EPA (Leighton, Sherman, & Cohen, 2014a) and HSRB recommendations; 2) necessary approvals are obtained; and 3) additional documents are provided to the Agency for review.

HSRB Detailed Recommendations and Rationale

The submitted documents indicate that the revised study will be conducted in accordance with the ethical and regulatory standards of 40 CFR 26, Subparts K and L, as well as the requirements the US EPA's FIFRA GLP Standards described at 40 CFR 160, and the California State EPA Department of Pesticide Regulation study monitoring (California Code of Regulations Title 3, Section 6710) (Testman, 2014, p. 48). FIFRA §12(a)(2)(P) also applies.

The protocol was reviewed by an independent human subjects review committee, Schulman Associates IRB (SAIRB) of Sunrise, FL, prior to submission. SAIRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). SAIRB is listed as an active IRB on the OHRP website (Reg. #IORG0000635). Minutes of SAIRB's meetings and a copy of SAIRB's policies and procedures were provided to the Agency. These documents indicate that SAIRB reviewed this protocol pursuant to the standards of the Common Rule (45 CFR Part 46, Subpart A).

However, at the time of the HSRB meeting, SAIRB had granted only "conditional approval" for the study, with full approval contingent upon review by the California Department of Pesticide

[18] Similar statements such as "*e.g.,* a slow fastidious painter may contact less paint than someone who is careless and sloppy" are also made (Leighton, Sherman, and Cohen, 2014a, p. 7).
[19] Based on the adage that "familiarity breeds complacency," regarded as folklore in occupational health professions.

Regulation (CDPR), EPA and this HSRB. Documents provided by SAIRB reflect only this conditional approval. Thus, the study sponsor was not in compliance with the requirements of 40 CFR 26.1125, which requires submission of "Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB." Submission of meeting minutes from SAIRB, documenting final approval and attendance are still required, together with documentation of IRB members' relationship with the study's sponsor.

As the study will take place in California, Title 3, Section 6710 of California's Code of Regulations also require review and approval by CDPR. Copies of communications between the study sponsor and CDPR and a copy of that department's approval were provided.

Except as noted below, the Board agreed with the conclusions and factual observations of the ethical strengths and weaknesses of the study, as detailed in the EPA's Ethics Review (Leighton, Sherman & Cohen, 2014a). The proposed study is likely to meet the applicable ethical requirements for research involving human subjects, in accordance with the following criteria:

a. Risks to participants are commensurate with anticipated benefits to participants or society. Six risks of study participation are identified by the HSRB reviewers: 1) reaction to latex paint or the active ingredient BIT that it contains; 2) discomfort from clothing and air pumps worn during the study; 3) irritation from alcohol wash and wipes; 4) heat stress from doing physical work while wearing two layers of clothing and a hat; 5) embarrassment from changing clothes in the presence of a researcher; and 6) surprise, embarrassment, or psychological stress from pregnancy testing and/or breach of confidentiality for pregnancy test results. These risks are minimized appropriately, are characterized as of low probability, and are justified by the potential societal benefits associated with data on dermal and inhalation exposure during application of latex paint containing BIT (1,2-Benzisothiazol-3(2H)-one), using a brush and roller. There are no direct benefits to the participants.

    - The test material, BIT, is an EPA-registered pesticide that is used in many household products including paint, laundry detergents, and household cleaners. Although it is considered to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer, for the purposes of this study it will be used in a latex paint formulation that is commercially available and in a manner that is consistent with the requirements of the EPA-approved label. Based on toxicological data currently available for BIT, coupled with appropriate exclusion criteria, and personal protective equipment, study participants are unlikely to be at risk of adverse side effects with exposure.
    - The study will exclude participants who have a history of sensitivity to the test material, latex or latex paint, or isopropyl alcohol. Subjects who report themselves to be in poor health or who have broken skin on the hands will also be excluded. Additional exclusion criteria, the justification for which is not explained and which may or may not be appropriate, include: severe respiratory disorders (*e.g.,* moderate or severe asthma, emphysema); cardiovascular disease (*e.g.,* history of myocardial infarcts, stroke, congestive heart failure, or uncontrolled high blood pressure); severe diabetes; or immunological suppression (e.g. undergoing chemotherapy, transplant patients).

- Appropriate stopping measures are in place in the event of an injury or other adverse outcome.
- Minors and pregnant or lactating women are excluded from taking part. Pregnancy is either confirmed by over-the-counter pregnancy testing on the day of study or by opt-out. Only volunteers whose test results show them to be non-pregnant will be allowed to participate. Potential stigma resulting from exclusion due to pregnancy is appropriately minimized. Testing is done in private and with the option of discrete withdrawal. Information regarding pregnancy test results will be kept confidential.

b. Voluntary and informed consent of all participants

- The Board respectfully disagrees with the Agency's conclusion that "no potential subjects are from a vulnerable population" (Leighton, Sherman & Cohen, 2014a, p. 11). Rather, a better description is that the study is not actively recruiting participants that come from potentially vulnerable populations. There is a possibility that some participants in this study might be vulnerable, susceptible to coercion and undue influence. The study protocol, however, includes several mechanisms designed to minimize coercive recruitment and enrollment.
- Research participants will be recruited through advertisements in English and Spanish in three local newspapers that will be seen by a diverse population of consumers likely to use the product, instead of in a workplace setting where there is potential for coercion or undue influence from an employer.
- The informed consent materials, if modified as recommended by the EPA (Leighton, Sherman & Cohen, 2014a) and the HSRB below, will adequately inform the subjects of the risks, discomforts and benefits from participation, and of their right to withdraw.
- Spanish translations of the informed consent documents and recruitment materials *were not provided*. The study sponsors have indicated that they will have these documents translated once SAIRB has fully approved the study. These documents must be submitted to EPA before the HSRB can confidently recommend that the protocol will likely meet the applicable requirements of 40 CFR part 26, subparts K and L. Additionally, SAIRB's Standing Operating Procedures do not include a description of how translated documents are validated; documentation of the process of validation should be provided to the Agency along with the translated materials.
- Monetary compensation is not so high as to unduly influence participants.

c. Equitable selection of study participants

- The protocol is designed to recruit participants from an appropriately diverse population who represent likely personal or commercial users of the test material.
- The recruitment process has been designed to assure that no subjects will be coerced or unduly induced into participating. However, recruitment through advertisements placed exclusively in local print media will draw literate subjects who may not represent the population of less-educated consumers who may use latex paint without reading the directions.

1. The Board recommended that the study protocol be modified to address the concerns noted in the EPA's Ethics Review (Leighton, Sherman & Cohen, 2014a), with one minor exception noted below:

a. EPA's Ethics Review called for the study's exclusions to be expanded from candidates known to be allergic to latex paint, soaps, or isopropyl alcohol "*to also exclude individuals who have allergies or sensitivities to BIT or other chemical-based products.*" The Board recommended the phrase "chemical-based products" be changed to "chemical products."

In addition, the Board raised the following concerns:

b. The HSRB respectfully disagrees with the statement that, "there is little incremental risk associated with [the study]" (Testman, 2014, p. 13). Despite the fact that the test materials are of low toxicity and that pesticide exposures are potentially higher during normal residential or commercial painting activities, there nevertheless is a risk associated with BIT exposure that would otherwise not exist outside of this intentional exposure study.

c. The provision for a researcher *of the same sex as the participant* being present when the participant changes clothes, while intended to minimize the potential embarrassment of being observed, may not have the intended effect for all participants. The research team should consider offering the participant a choice of researchers to observe them changing clothes.

d. In its description of the study, the protocol intermittently uses the term "applicators" to refer to the subjects who will be applying latex paint to walls and ceilings with brushes and rollers. The Board noted that the term "applicator" means an implement, such as a brush or roller, and recommended that subjects be referred to as "appliers" if specific reference to their role in applying paint is necessary.

e. The HSRB recommended that the consent form and protocol be modified as follows:

- Since study participants must self-report being in "good health," clear definitions of these terms should be in the protocol and in the informed consent document. Some of the exclusion criteria – severe respiratory disorders, cardiovascular disease, severe diabetes and immunological suppression – seem inappropriate given the physical requirements and risks of the study. Justification for these criteria should be provided, or the exclusion criteria revised. If these are appropriate exclusion criteria, ensuring that potential participants qualify for the study will require investigators to ask somewhat invasive questions about personal health status and medical history. The "Subject Invitation to Participate" script should thus include mention of these exclusion criteria, and the study enrollment section of the informed consent document should be revised to reflect the various exclusion criteria rather than simply state "we will ask you about your general health" (Testman, 2014, p. 63).

- *Study Procedures Point 10* on the consent form states that the researchers "may take pictures or video to show what happened in the study but those pictures will not show faces or tattoos in the final report" (Testman, 2014, p. 65). The Board recommended that

the phrase "faces or tattoos" be expanded to "faces, ears, tattoos, or other identifying features".

- *Study Procedures Point 12* on the consent form states that "The researcher will remove the painter's hat, air sampling pumps, and equipment" (Testman, 2014, p. 65). The words "from you" should be added to the end of this sentence. ("The researcher will remove the painter's hat, air sampling pumps, and equipment from you.")

- *Risks Point 1* on the consent form states "…if you think you may have gotten some of the paint in your eye…" (Testman, 2014, p. 66). The word "some" in this sentence should be replaced with the word "any".

- The last sentence of *Costs and Payment* states "…whether or not you are actually tested" (Testman, 2014, p. 68). The subject is not *tested*; the subject *participates in the test*. This phrase should be changed to "whether or not you actually take part."

- The last sentence of the first paragraph of *Confidentiality* states "any pictures of you in a report of this study will not show your face" (Testman, 2014, p. 68). This sentence should be expanded to "…will not show your face or other identifying features (such as piercings or tattoos)."

f. The HSRB recommended that researchers complete a course in human subjects protections within three years of study initiation and completion. Some investigators have or will (depending on when the study occurs) exceed this recommended time limit.

A New Protocol from the AEATF-II Describing Proposed Research to Measure the Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (Known as BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipes and Wash Procedure

Overview of the Proposed Protocol

The proposed removal efficiency study is pivotal to the conduct of the BIT exposure study (AEA09) reviewed above. The roller and brush latex paint study cannot proceed until this removal efficiency study (**AEA08**) has been carried out and the removal efficiency of BIT is considered to be adequate.

The proposed study is intended to assess the efficiency of a hand wash removal methodology; the method will then be used to monitor exposures of subjects after they apply a latex paint containing an antimicrobial (BIT), utilizing commercially available brushes and/or rollers. The AEATF II has stated that the primary objective of this study is to determine the removal efficiency of BIT in latex paint and in isopropyl alcohol (IPA) from human hands.

Study participants will be recruited from the general population of Fresno County, CA, and the surrounding area. Twenty-eight subjects will be qualified for the study; 8 will serve as alternates. Twenty individuals will be equally but randomly assigned to one of four study groups: two concentrations of BIT in latex paint and two concentrations of BIT in IPA.

The test subjects will have BIT-treated paint or BIT painted IPA applied to the surface of their right and left palms. The test substance will be allowed to dry on the subjects' hands for 45 minutes; the researchers will then perform a hand wash procedure similar to the hand wash procedure in the painting study (AEA09). The results of the paint portion of the efficiency study will be used to correct for any losses on the subjects' hands in the paint brush/roller exposure study. The results of the IPA portion of the efficiency study will be used to compare the differences in the efficiency between paint and a non-paint liquid. The IPA portion will also be available for future studies using non-paint liquids for hand wash sampling method corrections.

The Agency's review of the proposed protocol was completed on March 18, 2014, and presented to the HSRB on April 8, 2014. The protocol was reviewed and approved by an independent human subjects review committee, Shulman Associates IRB (SAIRB) of Sunrise, FL. The Agency made recommendations for improvements in both scientific and ethics aspects of the protocol.

Science

Charge to the Board

- Is this research likely to generate scientifically reliable data, useful for determining the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint and non-paint liquid solutions containing BIT?

Board Response to the Charge

HSRB Recommendation

- With the exception of one member, the Board concluded that the proposed research is likely to generate scientifically reliable data, useful for determining the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint and non-paint liquid solutions containing BIT, provided that the protocol is modified to address the issues raised by EPA and the HSRB.

HSRB Detailed Recommendations and Rationale

The Board carefully reviewed the protocol and determined that a number of methodological issues merit further attention and modification to ensure that the results of the study are useful for estimating exposure to BIT when present in commercial latex paints.

The HSRB noted that the sponsor proposed to apply BIT – either in paint or in IPA – to the palmar region of the hands, utilizing a glass capillary tube to spread the test material (paint or IPA). The Board expressed several concerns about this approach.

1. The HSRB was concerned that laboratory capillary tubes are rather fragile and typically have sharp ends. Even if the ends were heated and sealed, the Board remained concerned with the likely breakage of the glass tubes while the application of the test material was taking place.

2. Based on the information provided (Leighton, Sherman & Cohen, 2014b, pp. 4, 5 and 8), the proposed loading of paint (mL/cm2) appears to be excessive for many people's hands.[20] Reported dimensions for the human palm depend upon how they are defined and measured, but 8 × 10 cm (80 cm2) might be an average.[21] Noting that the test substance is not to be applied within a 2 cm edge around the palm that leaves a total area of approximately 4 × 6 cm or 24 cm2 for application of test material, approximately half of the 50 cm2 palm surface area estimated by the EPA reviewer.

3. Applying 500 µL (0.5 cm3) of latex paint to 24 cm2 (20 µL/cm2) will yield a layer of paint about 2 mm thick (or 1 mm thick to 50 cm2). This seems to be well in excess of the thickness expected of accidental paint blotches, smears, and small drops or spatter landing on the hands, face, or neck. Moreover, large deposits of that thickness are likely to be wiped (in fact, personal experience suggests that a 2 mm deposit thickness on a near-vertical skin surface if left unattended, is likely to ooze and potentially to drip). The 0.04 mm thick layer that would result from applying 100 µL (0.1 cm3) of BIT in IPA to 25 cm2 of skin (4 µL/cm2) seems at first glance to be less of a concern, but IPA's much lower viscosity could result in the same dripping unless the subject keeps the palms of their hands upright and horizontal.

Unfortunately, for users of recovery data, the effect of the thickness of the deposit in the real world can have a greater effect on recovery efficiency than the BIT concentration.[22] If one considers the process of adsorption and absorption on a molecular level, for molecules to contact the skin, they must be within some small distance (somewhat like a boundary layer) determined by the diffusion rate of the chemical within the deposit and residence time on the skin. In a high viscosity deposit (*e.g.*, paint or (in the extreme) detritus in a field setting), diffusion will be primarily molecular (versus convective diffusion), and such intermolecular processes occur over distances on the order of nm, not µm. Thus, the number of molecules (*i.e.*, the mass of the chemical) that will reach the skin will be proportionate to concentration within the deposit and to the thickness of the deposit, only if the thickness is less than the depth of such a pseudo-boundary layer. Molecules in a paint layer beyond such a pseudo-boundary layer will have no effect on skin retention or recovery. The same mechanisms will apply to IPA only at slightly larger distances in inverse proportion to its lower viscosity. In addition, the effects of convection and adherence of IPA to the skin would be increased if the subject were to move their hands enough to cause some flow along the skin. This leads to the suggestion that paint thickness beyond some limit (perhaps as small as 0.05 µm) will have no effect on chemical retention by the skin, and any additional paint applied to the skin beyond such a thickness will result in disproportionately higher recovery rates when the supporting paint matrix is removed. Note that 0.05 µm is $> 10^{-4}$ less than the calculated 2 mm think layer of paint in the proposed protocol and still $> 10^{-2}$ less than the calculated 0.04 mm think layer of IPA. Thus, the results of measuring recovery at a paint loading in the range of 20 $\mu L/cm^2$ seems likely to over-estimate the recovery at much lower levels of loading in the planned brush, roller, and later spray studies.

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[20] The same concern may also apply, but to a lesser extent, to IPA.

[21] *E.g.* , see http://www.theaveragebody.com/average_hand_size.php, http://en.wikipedia.org/wiki/Hand and/or http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2938623/

[22] The agency is referred to the Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held January 9 - 12, 2007 on the Review of Worker Exposure Assessment Methods.

4. It is important to recall that the palm of the hand is known to have among the lowest dermal permeability of any part of the body (Maibach, *et al.*, 1971; Wester, *et al.*, 1984; Baynes & Hodgson, 2004; Wester & Maibach, 2005). This knowledge suggests that limiting the recovery study to just the palm will bias the results toward a higher percent recovery. In addition, the palm is relatively smooth and easy to clean, which would also bias recovery results upwards. The Board recommended that dosing all or most of the entire hand be considered before the study design is finalized.

5. In addition to reasons to be concerned about the proposed total matrix volume in the washing study, there are also reasons to be concerned about the amount of AI to be employed. The washing study loads were selected to roughly match BIT skin loads in the brush and roller study anticipated to be roughly 1-10 $\mu g/cm^2$ based on a Pesticide Handler Exposure Database (PHED) painting study conducted with an unknown agent, which produced skin loads averaging 10.5 $\mu g/cm^2$ (Leighton, Sherman & Cohen, 2014b, p.4). EPA suggests that if actual loads in the washing protocol are a little lower, recoveries will be conservative in comparison to the brush and roller protocol. However, the 10.5 $\mu g/cm^2$ loading in the PHED painting study was achieved using paint containing 10,000 ppm of the target agent. BIT will be present in the brush and roller study paint at much lower levels, which suggests that loads will probably be much lower than the wash study design loads. This would lead to an expectation that the wash study recoveries will overestimate the brush and roller study recoveries, which could in turn lead to underestimation of exposures in the brush and roller study.

The Agency's attribution to Brouwer et al (2000) of "decreased removal efficiencies for low skin loadings" is consistent with the above logic (Leighton, Sherman & Cohen, 2014b, p. 8). However, the subsequent conclusion of the EPA review is that *"this [referring to a lower skin loading of 1.6 to 7.8 $\mu g/cm^2$ in this BIT proposal compared to 4.8 to 19.7 $\mu g/cm^2$ of BIT in the unreferenced research] would lead to a more conservative (protective) correction factor rather than less"* (Leighton, Sherman & Cohen, 2014b, p. 8) would only be true within certain constraints which probably are not true for this study.[23] The submitted protocol proposes to apply a skin loading of BIT lower than in the PHED paint study, but in a much thicker layer than was probably true for the rat study (not provided to the HSRB; see Boatwright, 2014, p. 91; Leighton, Sherman & Cohen, 2014b, p. 8)[24] and thicker than naturally occurs to painters. Therefore, in this study there will be less BIT actually reaching the skin, more BIT being recovered, and a less conservative protection factor than if a much lower loading of paint were tested.

Based on these points, the Board's recommendation is to test the recovery after applying the thinnest layer feasible based on the expected recovered dose and detection threshold. Second, it may be appropriate to keep the applied layer reasonably constant among subjects by varying the amount applied in proportion to the size of each person's palm area.

The desire for each subject to have a reasonably constant layer of paint is probably of less significance but was triggered by a series of statements near the top of p. 8 of Leighton, Sherman & Cohen (2014b) describing dermal absorption data in rats (MRID 46327901) and culminating

[23] The "probably" is needed because the Board was not given much information on the conditions of the prior BIT recovery study in PHED.
[24] Also, referred to in Boatwright, 2014, p. 91.

in *"This would imply that the 45 minute residence time proposed would be sufficiently long to allow the paint to dry yet not be substantially affected by dermal absorption over the anticipated 2 to 3 hour exposure time in the painting study."* The concern is that "substantially" could be viewed as misleading. An analysis of the reported data on rats shows that dermal absorption is fairly constant over the 72 hours at approximately 0.6±0.2%/hr (Boatright, 2014, p. 91). However, the results of the proposed recovery study will depend upon the combined effects of absorption and adsorption, and the adsorption data appear to follow first-order exponential kinetic equations with a half-life of about 10 hours.[25] So, if the resulting loading and recovery in the proposed study turn out to be the same as for this rat data, four times as much BIT would stay on or in the skin after 3 hours than after 45 minutes (about 11% versus 3%) which may be a *substantial* difference; the corresponding expected recoveries are 89% after 3 hours and 97% after 45 minutes.

A margin of exposure (MOE) for dermal exposure is reported based on a Lowest Observable Adverse Effect Level (LOAEL) from a 90-day rat study not available to the HSRB (Leighton, Sherman & Cohen, 2014b, p. 30). Hence, details (*e.g.,* vehicle, load, skin area exposed) of the dermal toxicity study are not available. Traditionally, inadequate consideration has been given to the kinetics of dermal absorption in the design and conduct of dermal toxicity studies. Dermal absorption may be either flux or supply limited (Kissel, 2011). In the case of flux limitation, increasing skin loading will not produce an increase in absorbed dose, and apparently increasing LOAELs or other toxicity parameters will be misleading. Since the credibility of dermal toxicity values cannot be fairly evaluated in the absence of knowledge of experimental conditions, critical experimental details should be routinely provided in addition to toxicity outcomes.

The extent of wetting will affect the degree of incapacitation that subjects experience for 45 minutes while the test substance is drying and the use of their hands will be at least limited if not denied. Clearly subjects should be instructed to take care of normal physiological needs before they get their hands wet.[26] The Board opined that it might be useful to carry out a small pilot test with simple, non-toxic, household items to better assess practical aspects of the proposal.

The Board was also concerned about the expectation that volunteers would be required to sit very still, with palms fully open and facing up for a period of 45 minutes following application of the test material to their palms to allow for drying before any washing occurred. The Board is of the view that trying to keep one's hand open for 45 minutes can become uncomfortable. The Board recommended providing the subjects with a simple tool (such as a brace) to help them keep their palms open; the form of an acceptable tool will be affected by the extent of the hand's surface that is wetted. The Board was concerned that compliance could be variable and poor.

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[25] The generic form of a model predicting skin retention is the sum of the linear absorption rate and exponential adsorption rate, as shown below. Recovery would be 1 minus retention.

$$\text{Retention} = [\text{avg. absorption rate} \times \text{time}] + [\text{final adsorbed fraction} \times (1 - e^{-\text{time/time coef}})]$$

The fit of the data provided within Leighton, Sherman & Cohen, 2014b, p. 8 yields the following coefficients that were used to anticipate the effects after 45 minutes and 3 hours.

$$\text{Retention} = [0.58\% \times \text{hours}] + [0.49\% \times (1 - e^{-\text{hours}/15})]$$

[26] Even something as simple as scratching an itch may not be allowed if their entire hand is wetted; leaving one or more finger tips untreated would be desirable but may not feasible.

The Board advised that better coordination is needed between the paint field exposure study and the laboratory BIT recovery study to assure that both studies use the same skin manipulation technique regarding scrubbing with gauze pads and rinsing (the procedure in the latter wherein "the subject rub[s] their fingers and palm together" (Leighton, Sherman & Cohen, 2014b, p. 4[27]), is not at all similar to the procedure utilized in the recovery efficiency study).

The HSRB noted that statistical issues, such as sample size and randomization, might need to be re-considered when developing a revised protocol that includes removal efficiency from both hands simultaneously (as in the painting study), rather than from the palms of two separate hands (as in the originally proposed efficiency removal study).

Although no hypothesis is stated explicitly, at least three are implied: (1) the removal efficiency for the dominant hand will be independent of that for the non-dominant hand. (2) the removal efficiency of BIT in latex paint will be the same as the removal efficiency of BIT in isopropyl alcohol. (3) BIT removal efficiencies will be the same at both BIT in latex paint concentration levels (120 and 600 ppm). If the first hypothesis is not true, then the subsequent analysis could have substantially less power than anticipated under the current design. If the third hypothesis is true, then data collected at 120 ppm would be combined with that collected at 600 ppm, and a correlation between the observations from the two hands would negatively impact the power.

An alternative approach would be to, for a given concentration, randomize BIT in latex paint to either the dominant or non-dominant hand and to use BIT in isopropyl alcohol at the same concentration on the other hand. This would be a split-plot design with concentration being the main unit treatment and latex paint/isopropyl alcohol being the subunit treatment. This would ensure independence between the observations made at 120 and 600 ppm, but still allow the third hypothesis to be tested. The foregoing statistical comments presume that each hand is treated separately. If a volunteer's two hands are treated as a single experimental unit, then other statistical considerations may be necessary.

Ethics

Charge to the Board

- Is the research likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L?

Board Response to the Charge

HSRB Recommendation

The documents submitted to the EPA and the HSRB do not fully meet the regulatory requirements. Despite this, the Board concluded that this protocol will likely meet the applicable requirements of 40 CFR 26, subparts K and L if: 1) it is modified in accordance with EPA (Leighton, Sherman & Cohen, 2014b) and HSRB recommendations; 2) necessary approvals are obtained; and 3) additional documents are provided to the Agency for review.

[27] Also, cited in Boatwright, 2014, p. 19.

HSRB Detailed Recommendations and Rationale

The submitted documents assert that the revised study will be conducted in accordance with the ethical and regulatory standards of 40 CFR 26, Subparts K and L, as well as the requirements the US EPA's GLP Standards described at 40 CFR 160 (Boatwright, 2014, p. 8). FIFRA §12(a)(2)(P) also applies.

An independent human subjects review committee, SAIRB of Sunrise, FL, reviewed the protocol prior to submission. Minutes of SAIRB meetings, a copy of their policies and procedures, and a list of IRB members were provided. SAIRB is fully accredited by AAHRPP and listed as active by OHRP (Reg. #IORG0000635). At the time of the HSRM meeting, SAIRB had only granted 'conditional approval' for the study, with full approval contingent upon review by the California Department of Pesticide Regulation (CDPR), EPA and HSRB. Because of this, the study sponsor was not in compliance with the requirements of 40 CFR 26.1125, which requires submission of "Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB."

As the study will take place in California, Title 3, Section 6710 of California's Code of Regulations also require review and approval by CDPR. Copies of communications between the study sponsor and CDPR, and a copy of that department's approval were provided.

1. Except as noted below, the Board agreed with the conclusions and factual observations of the ethical strengths and weaknesses of the study, as detailed in the EPA's Ethics Review (Leighton, Sherman & Cohen, 2014b). The proposed study is likely to meet the applicable ethical requirements for research involving human subjects, in accordance with the following criteria:

a. Risks to participants are commensurate with anticipated benefits to participants or society. Risks of study participation, as determined by the HSRB reviewers, are six-fold: 1) allergic reaction or sensitivity to the test material; 2) allergic reaction or sensitivity to the latex paint; 3) allergic reaction or sensitivity to the isopropyl alcohol used for BIT (1,2-Benzisothiazol-3(2H)-one) application and hand washing; 4) injury that occurs during application of test material using a glass capillary tube; 5) irritation from rubbing the skin during the hand washing procedure; and 6) psychological stress and/or breach of confidentiality for pregnancy test results. These risks are minimized appropriately and are justified by the potential societal benefits. There are no direct benefits to the participants.

   - The test material, BIT, is an EPA-registered pesticide that is used in many household products including paint, laundry detergents, and household cleaners. Although it is considered to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer, for the purposes of this study it will be used in a latex paint formulation that is commercially available and in a manner that is consistent with the requirements of the EPA-approved label.
   - The study will exclude participants who have a history of sensitivity to the test material, latex or latex paint, or isopropyl alcohol. Subjects who are in poor health (by self-report) or who have broken skin on the hands will also be excluded. Additional exclusion criteria, which may or may not be appropriate, include: severe respiratory disorders (*e.g.,*

moderate or severe asthma, emphysema); cardiovascular disease (*e.g.,* history of myocardial infarcts, stroke, congestive heart failure, or uncontrolled high blood pressure); severe diabetes; or immunological suppression (e.g. undergoing chemotherapy, transplant patients).

- Appropriate stopping measures are in place in the event of an injury or other adverse outcome.
- Hand irritation from the washing procedure, if it occurs, is likely to be minor and easily treated with over-the-counter medications.
- Minors and pregnant or lactating women are excluded from participation, with pregnancy either confirmed by over-the-counter pregnancy testing on the day of study or by opt-out. The potential stigma resulting from study exclusion due to pregnancy is appropriately minimized.

b. Voluntary and informed consent of all participants

- The Board respectfully disagrees with the Agency's conclusion that "no potential subjects are from a vulnerable population" (Leighton, Sherman & Cohen, 2014b, p. 11). Rather, a better description is that the study is not actively recruiting participants that come from potentially vulnerable populations. There is a possibility that some participants in this study might be vulnerable, susceptible to coercion and undue influence. Despite this, the study protocol includes several mechanisms designed to minimize coercive recruitment and enrollment.
- The informed consent materials, if changed as recommended by the EPA (Leighton, Sherman & Cohen, 2014b) and by the HSRB below, will adequately inform the subjects of the risks, discomforts and benefits from participation, and of their right to withdraw.
- Monetary compensation is not so high as to unduly influence participants.
- Spanish translations of the informed consent documents and recruitment materials *were not provided*. The study sponsors have indicated that they will translate the informed consent documents and requirement materials once full approval of SAIRB is obtained.

c. Equitable selection of study participants

Although the protocol does not specify painting experience as an eligibility criterion, the EPA review states that “the test subjects will be drawn from the same populations as the painting exposure study” (Leighton, Sherman & Cohen, 2014b, p. 22).

- The recruitment process has been carefully designed to assure that no subjects will be coerced or unduly induced into participating.

2. The Board recommended that the study protocol be modified to address the concerns noted in the EPA’s Ethics Review (Leighton, Sherman & Cohen, 2014b). Additionally, the Board raised the following concerns:

a. The HSRB recommended that the investigators not state that, "there is little incremental risk associated with [the study]" (Boatwright, 2014, p. 11). Despite the fact that the test materials are of low toxicity and that pesticide exposures are potentially higher during normal

residential or commercial painting activities, there nevertheless is a risk associated with BIT exposure that would otherwise not exist outside of this intentional exposure study.

b. Since study participants must self-report being in "good health," clear definitions of these terms need to be in the protocol and in the informed consent document.

c. The HSRB recommended that the informed consent document mention the potential discomfort that study participants might experience while sitting upright, arms on a table with palms up, for 45 minutes, together with steps that will be taken to minimize such potential discomfort.

d. Some of the exclusion criteria – severe respiratory disorders, cardiovascular disease, severe diabetes and immunological suppression – seem inappropriate given the physical requirements and risks of the study. Justification for these criteria should be provided, or the exclusion criteria revised. If these are appropriate exclusion criteria, ensuring that potential participants qualify for the study will require investigators to have clear definitions (*e.g.,* "broken skin") and ask somewhat invasive questions about personal health status and medical history. The "Subject Invitation to Participate" script should thus include mention of these exclusion criteria, and the study enrollment section of the informed consent document should be revised to reflect the various exclusion criteria rather than simply state "we will ask you about your general health" (Boatwright, 2014, p. 48).

e. The investigators will apply and spread the BIT/paint or BIT/IPA mixture using a glass capillary tube. These tubes can have rather rough ends or may shatter, potentially causing injury to the palms of study participants. This risk should be noted in the protocol and informed consent document. Alternatively, the investigators may want to consider alternate means of applying and spreading the test material that do not pose the same risk of injury.

f. The Board recommended that researchers complete a course in human subjects protections within three years of study initiation and completion. Some investigators have or will (depending on when the study occurs) exceed this recommended time limit.

A New Protocol from the U.S. Department of Agriculture Describing Proposed Research to Determine the Bite Protection Level of Repellent Treated Clothing for the United States Military

Overview of the Proposed Protocol

The sponsor's goal is to determine the mean level of bite protection (and 95% confidence intervals) for etofenprox-treated uniforms (specifically, U.S. Military Fire Resistant Army Combat Uniforms). Two materials ("coats" (referring to shirts and blouses) and "trousers" – or pants) will be studied in an untreated condition and in three conditions post-treatment with 1% repellent: fabric by weight: before any washings (0x), after 20 washings in hot water (20x), and after 50 washings (50x). Each study subject will be exposed to all four conditions and therefore serve as his/her own control. Each participant will put on a "sleeve" made from one of the two study materials (coat or trousers) in one of the four conditions and place his/her arm in a cage with one of two species of laboratory-raised mosquitoes (*Anopheles* or *Aedes*) for 15

minutes/hour up to 8 hours. The percent bite protection for each 15-minute test will be determined by counting and comparing the number of blood-fed female mosquitoes to the total number or mosquitoes placed in the cage for that test.

Eight people will be recruited into this study, based on calculations showing that little statistical power is gained with a larger number of study subjects; two alternates will be identified. Each participant will be tested 8 times; *i.e.,* four sleeve conditions for each of the two mosquito species. Thus, there will be 16 replicates for each fabric condition group.

Science

Charge to the Board

- Is the protocol "Laboratory Evaluation of Bite Protection From Repellent Impregnated Clothing for the United States Military" likely to generate scientifically reliable data, useful for estimating the level of mosquito bite protection provided by two different textiles treated with etofenprox?

Board Response to the Charge

HSRB Recommendation

- The Board concurred that the proposed protocol will likely generate scientifically reliable data for estimation of bite protection efficacy of impregnated clothing, if improvements in the overall study design enumerated by EPA (Sweeney & Sherman, 2014) and the Board are adequately considered.

HSRB Detailed Recommendations and Rationale

EPA's science review resulted in multiple comments. The Board reiterated several of EPA's recommendations:

- The HSRB agrees that the statistical analysis must be finalized prior to initiation of the study.

- The Board agrees that at least 20 qualified subjects should be identified and that participants be selected at random from that larger group.

- The HSRB is concerned that two alternate participants is an insufficient number due to potential for dropout.

- The Board agrees that the study should not be conducted until a product-specific fabric irritancy study is completed.

The HSRB made the following additional comments:

1. Statistical Design. The proposed protocol is generally well designed from a statistical standpoint. Because the desired scope of inference is beyond the subjects in this study, each subject should be treated as a random effect (not as a fixed effect).

Maintaining the sample size of 8 is a concern to the Board. This number does not allow for the possibility of dropouts; the HSRB recommended that additional participants be recruited so that a pool of alternates is available to ensure that the desired number of 8 completed tests is achieved. Questions were raised about how dropout data would be handled; *e.g.,* would it be analyzed or eliminated?

Furthermore, if one arm of each participant is used as a control, then double the sample size would be needed. To reduce the burden of testing on each participant, another option would be to have 16 participants on whom the tests for only one species are conducted.

Additionally, the number of participants by gender could be restricted, rather than left to chance, in the enrollment process.

If the treatment could be randomized instead of ordered by dose, the study design would be stronger. The Board asked the Agency to reconsider how the treatments will be assigned to participants.

2. Fabric sleeves. The Board believes that provision of a single sleeve size is inappropriate given the possible relationship between snugness of fit and bite protection. A range of sleeve sizes should be available corresponding to at least a portion of the uniform sizes available to soldiers; one-to-one correspondence is not required. However, each subject should be provided sleeves corresponding to their normal garment size. It is desirable to avoid rejecting either large subjects who cannot fit their arms into the "one sleeve size," or small subjects for whom the sleeves will be too loose. The Board heard that most soldiers do not wear their clothing tight; therefore, the HSRB recommended that the standard test conditions be as representative as possible of use conditions in the field. Characterization of the tightness of the sleeve should be recorded to enable comparing test outcomes and thereby gain insights for future protocols.

3. Dermal toxicity. An MOE of 235 was calculated based on a reported 50% Lethal Dose (LD_{50}) of > 2,100 mg/kg/day and an exposure of 9 mg/kg (based on 100% absorption of 635 mg of active ingredient (AI) from six sleeves).[28] This is declared adequate on the grounds that EPA's level of concern is an MOE of 100. Further attention is required to the following issues:

- The protocol from which the LD_{50} was estimated was not provided to the HSRB. If the experiments were conducted under flux limited conditions, the LD_{50} may be artificially high.

[28] The Board noted that 695 mg was indicated in the written materials, but 635 mg was presented during the Board meeting.

- 100% absorption of etofenprox is deemed conservative based on a reported bioavailability of 7%. The protocol from which the availability was estimated was not provided. It is unclear whether the 7% figure includes the agent in the treated skin at the end of the experiment. In addition, fractional absorption is dependent upon loading conditions. The Board recommended examining experimental conditions to determine whether the reported availability reflects flux limited conditions.

- Target MOE's of 100 typically represent 100x a NOAEL, not an LD_{50}. An explanation of this deviation needs to be provided.

4. Bite pressure. The Board noted that "bite pressure" is not clearly defined in this proposed protocol. The HSRB recommended that the term be clarified before the study begins.

5. Carryover. The proposed protocol assumes that each individual will conduct 8 two-arm trials on a single day. These studies would be conducted sequentially using each of two mosquito species. Each within-species protocol would be ordered as follows: untreated sleeves, 50x washed sleeves, 20x washed sleeves, 0x washed sleeves. This sequence minimizes, to the extent possible, carryover effects in within-species testing. However, the 0x sleeves from the first mosquito species will precede the untreated sleeve trials for the second species. Arms are to be washed in between, but the efficacy of washing is unknown. A more conservative strategy would be separation of species trials by sufficient time (days) to allow excretion of absorbed etofenprox.

6. *Additional comments*. The HSRB raised concerns about the possibility of treatment failure. One way to address this concern would be to test repellency effectiveness on one or two participants before the proposed study begins.

The scientific justification for conducting human research was articulated during the Board meeting but is not clearly documented. The Board recommended that the rationale for doing this research on humans be fully built and explicitly stated in the proposal.

Ethics

Charge to the Board

- Is the research likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L?

Board Response to the Charge

HSRB Recommendation

- The Board concluded that the protocol submitted for review, if modified in accordance with EPA (Sweeney & Sherman, 2014) and HSRB recommendations, is likely to meet the applicable requirements of 40 CFR 26, subparts K and L.

HSRB Detailed Recommendations and Rationale

The submitted documents assert that the study will be conducted in accordance with the ethical and regulatory standards of 40 CFR 26, Subparts K and L, as well as the requirements the US EPA's GLP Standards for FIFRA described at 40 CFR 160 (Bernier, 2014).

The protocol was reviewed and approved by Western IRB (WIRB) of Puyallup, WA, an independent human subjects review committee, prior to submission. WIRB is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). WIRB is listed as an active IRB on the OHRP website (Reg. # IORG0000432). Minutes of WIRB's meetings and a copy of WIRB's policies and procedures were provided to the Agency. These documents indicate that WIRB reviewed this protocol pursuant to the standards of the Common Rule (45 CFR Part 46, Subpart A).

1. Except as noted below, the Board concurred with the conclusions and factual observations of the ethical strengths and weaknesses of the study, as detailed in the EPA's Ethics Review (Sweeney & Sherman, 2014, pp. 2-5). The proposed study is likely to meet the applicable ethical requirements for research involving human subjects, in accordance with the following criteria:

a. Risks to participants are commensurate with anticipated benefits to participants or society. The HSRB identified four risks in the study protocol: 1) risk of exposure to biting arthropods, which includes discomfort from bites, subsequent itching, secondary infection from scratching, and allergic reaction; 2) risk from exposure to disease vectors; 3) risks from exposure to the test material, including allergic reaction to chemical repellents and latex from the outer glove; and 4) psychological stress from pregnancy testing and/or breach of confidentiality for pregnancy test results.

   These risks are minimized appropriately, are characterized as of low probability, and are justified by the potential societal benefits associated with data on repellent treatment for military clothing. There are no direct benefits to individual subjects.

   - Individuals who are hypersensitive to mosquito bites and those who are phobic about mosquitoes will be excluded from the study.

   - Participants will be informed that itching is likely to be the most significant discomfort they will experience. An over-the-counter topical steroid cream will be available for use immediately upon completion of the tests. Participants who become uncomfortable from itching may stop the test. A nurse familiar with the study protocol will be on call to assist if needed.

   - Mosquitoes used in the study will be exclusively from laboratory-bred colonies, and will be screened for disease vectors before use, making the risk of disease transmission negligible.

   - Only compounds with no clear association with allergic reactions will be tested. People who are known to be allergic to the test compound or to latex will be excluded from the

study. Only the forearm will be exposed. The potential risks to participants from test materials are minimized by exclusion of individuals who are sensitive to the test materials.

- Appropriate stopping measures are in place in the event of an injury or other adverse outcome.

- Minors and pregnant or lactating women are excluded from taking part. Pregnancy is either confirmed by over-the-counter pregnancy testing on the day of study or by opt-out. Only volunteers whose test results show them to be non-pregnant will be allowed to participate. Potential stigma resulting from exclusion due to pregnancy is appropriately minimized. Testing is done in private and with the option of discrete withdrawal. Information regarding pregnancy test results will be kept confidential.

b. Voluntary and informed consent of all participants

- The Board respectfully disagrees with the Agency's conclusion that "no potential subjects are from a vulnerable population" (Sweeney & Sherman, 2014, p. 22). Rather, a better description is that the study is not actively recruiting participants that come from potentially vulnerable populations. There is a possibility that some participants in this study might be vulnerable, susceptible to coercion and undue influence. The study protocol, however, includes several mechanisms designed to minimize coercive recruitment and enrollment.

- Research participants will be recruited through printed advertisements in English in the local Gainesville, FL, newspaper and posted on bulletin boards at the University of Florida. The ability to speak and read English is a requirement of participation, resulting in a generally literate subject population, typically less subject to coercion.

- The informed consent materials, if modified as recommended by the HSRB below, will adequately inform the subjects of the risks, discomforts and benefits from participation, and of their right to withdraw from the study at any time.

- Monetary compensation is not so high as to unduly influence participants.

c. Equitable selection of study participants

- The protocol is designed to recruit participants from an appropriately diverse population likely to represent the diversity of members of the military who are the intended users of the treated clothing, with a similar over-representation of younger individuals.

2. The Board recommended that the study protocol and informed consent document be modified to address the concerns noted in the EPA's Ethics Review (Sweeney & Sherman, 2014). In addition, the Board raised the following concerns:

a. Although a question about allergy/sensitivity to latex is listed on the enrollment questionnaire, latex allergy/sensitivity does not appear as an exclusion criterion in the recruitment interview script or consent document. Latex allergy/sensitivity should be included in all statements of exclusion criteria. Alternatively, the protocol could be modified to use nitrile gloves instead of latex.

b. The protocol currently calls for test sleeves to be made in a single size, despite the likely variation in arm size among participants and 34 different uniform sizes available to military personnel. The single sleeve size may both skew the results of the testing across participants of various arm sizes and it may also cause embarrassment to participants who attempt to put on sleeves that do not fit easily. The Board recommended that researchers include a question about shirt sleeve size in the recruitment interview and have test sleeves available in different sizes.

c. Currently, stopping rules depend on researchers' judgment on key criteria of subjects' attractiveness and sensitivity, and mosquitoes' biting pressure. (Bernier, 2014, p. 46). The Board recommended that the investigators articulate objective measures for stopping criteria.

d. The Board noted that clarification is needed in the consent form about a nurse being on call but not present at the study site.

e. Currently, partial (per sleeve) compensation is provided to participants who leave the study early for any reason. The HSRB recommended that, to prevent coercion or to compensate for dropping out or being excluded by the Principal Investigator (PI), full compensation be provided to all participants.

f. Language in the consent form indicating that laboratory mosquitoes pose no risk of transmitting disease needs to be modified. To address the unlikely possibility that any of the test mosquitoes is found to carry a disease, investigators should articulate a standard method and message for notifying participants of exposure.

g. It is recommended that researchers complete a course in human subjects protections within three years of study initiation and completion. Depending on when the study occurs, some investigators may exceed this recommended time limit.

Background Presentation on the Repellency Awareness Graphic and Possible Implications for the HSRB

Staff of EPA's Office of Pesticide Programs presented background and current information about the Repellency Awareness Graphic; it has been developed in response to public requests for clearer labeling of insect repellent products. Graphics were developed and pretested using focus group methods. The three final graphics show the number of hours which the skin-applied product will repel ticks and/or mosquitoes. Standardization of the graphic is expected to increase public understanding of product capabilities so they can more readily identify which products will meet their needs. The Agency's draft guidance for this graphic is out for public comment until November 13, 2014.

Board members asked several questions of clarification and raised some concerns. For example, one concern was how the Agency would use data from multiple studies to determine the number of hours displayed. Staff recognized that some companies will not have all of the data needed to complete the graphic for their product; they expect registrants to request a standardized protocol to obtain the necessary data. EPA staff would present the proposed protocol to the HSRB for review before studies would be approved. A question was asked about whether a standardized protocol would ensure best scientific practices or not.

Another concern was how a median Complete Protection Time (CPT) would be determined across mosquito and tick species. Furthermore, it was suggested that the lowest, rather than the median, CPT would be more conservative.

Report from the HSRB Work Group on the Return of Individual Research Results

A consultant to the Board provided information about the origin of the Work Group and summarized the group's report to the Board. He noted that in the 2009-2010 period the HSRB had received a protocol in which the sponsor included a draft letter to return study results to participants. On several occasions the HSRB had discussed return of research results, but determined that the topic merited in-depth discussion by a smaller group of Board members and representatives of study participants and their medical providers. A Work Group was formed to deliberate this issue; the workshop was held at EPA in January 2013. The Work Group membership, its process and report with an appendix are presented together in Appendix A.

As noted in the appended report, return of research results has been addressed for clinical studies and some community-based research but not for the types of laboratory or field studies within the HSRB's purview. The return of results is a timely, unresolved and evolving issue in the ethics profession.

The Work Group identified key ethical principles as the underpinnings of their deliberations: research participant's autonomy and right to know, and researchers' responsibilities to ensure trust and respect. The group discussed the potential impacts of results on participants and sponsors, as well as the HSRB and the Agency. The Work Group made three recommendations for the HSRB's consideration.

1. For many intentional exposure studies, individual results are unlikely to be clinically relevant. Despite this, study sponsors or investigators have an obligation to offer results to participants.
2. There is an absolute moral obligation to return aggregate results directly to all participants (*e.g.,* via a letter written in lay language), unless the participant declines of [sic] notification.
3. There is a presumptive moral obligation to return individual results in a way that is comprehensible, contextualized, relevant and useful if a study participant asks for them.

The Board asked clarifying questions and discussed the report. The HSRB agreed that the clinical setting is not a suitable framework for considering return of individual results to participants in intentional exposure studies. The question was raised as to whether actionable

exposure levels occur and whether the levels are always known to the participants. One Board member stated that the ethical principle of social justice points to always offering results.

Although the Board showed considerable interest in the report, there was insufficient time during this meeting to identify recommendations for the Agency. Furthermore, the recent release of the President's Bioethics Commission on Incidental Findings may inform the HSRB's deliberations and decisions; this report was not available for this meeting. The Board agreed to discuss the issue of returning individual results to study participants at a subsequent meeting.

References

ASHRAE (American Society of Heating, Refrigerating, and Air Conditioning Engineers). (2010). *ANSI (American National Standards Institute) /ASHRAE Standard 62.2-2013. Ventilation and Acceptable Indoor Air Quality* and Low-Rise Residential Buildings. Atlanta, GA: American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc. Available online at https://www.ashrae.org/standards-research--technology/standards--guidelines

Baynes, R.E. & Hodgson E. (2004). Absorption and distribution of toxicants. In Ch. 6. *A Textbook of Modern Toxicology, 3rd edition.* Hoboken, NJ: John Wiley & Sons, Inc. 557 p.

Bernier, U.R. (2014). *Volume 1: WIRB Approved Protocol and Approved Supplemental Documents: Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military*. [Unpublished document].. Washington, DC: United States Department of Agriculture. 210 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Boatwright, M.T. (2014). *Antimicrobial Exposure Assessment Task Force II (AEATF II) Removal Efficiency Study. Vol. 2. Primary Documentation: Study Protocol, Schulman Associates IRB (SAIRB) Preliminary Approval and Documentation, and CA Dept. of Pesticide Regulation (CDPR) Review and Response Documentation.* [Unpublished document]. Washington, DC: American Chemistry Council. 105 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

CEC (California Energy Commission). (2008). Administrative regulations: California code of regulations, Title 24, Part 1. In CEC, *2008 Building Energy Efficiency Standards for Residential and Nonresidential Buildings*. CEC-400-2008-001-CMF. Sacramento, CA: California Energy Commission.

Evans, J., Parsons, L., & Sherman, K. (2010). *Science and Ethics Review of AHETF Scenario Design and Protocol AHE80 for Exposure Monitoring of Workers during Open Pour Mixing and Loading of Wettable Powders in the United States.* [Unpublished document]. Washington, DC: United States Environmental Protection Agency. For the HSRB – 26 January 2011 meeting.

Kissel, J.C. (2011). The mismeasure of dermal absorption. *Journal of Exposure Science and Environmental Epidemiology,* 21(3), 302-309.

Leighton, T., Sherman, K., & Cohen, J. (2013). *Science and Ethics Review of AEATF II Solid Pour Scenario Design and Protocol for Exposure Monitoring*. [Unpublished document]. Washington, DC: United States Environmental Protection Agency. 58 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Leighton, T., Sherman, K., & Cohen, J. (2014a). *Science and Ethics Review of AEATF II Brush and Roller Painting Scenario Design and Protocol for Exposure Monitoring*. [Unpublished

document]. Washington, DC: United States Environmental Protection Agency. 57 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Leighton, T., Sherman, K., & Cohen, J. (2014b). *Science and Ethics Review of AEATF II Paint Hand Wash Removal Efficiency Protocol*. [Unpublished document]. Washington, DC: United States Environmental Protection Agency. 43 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Maibach, H.I., Milby, T.H., & Serat, W.F. (1971). Regional variation in percutaneous penetration in man. *Arch. Environ. Health,* 23, 208-213.

Popendorf, W., Selim, M., & Lewis, M. (1995). Exposure while applying industrial antimicrobial pesticides. *Amer. Indr. Hyg. Assoc. J.*, 56(10), 993-1001.

Popendorf, W. (2006). *Industrial Hygiene Control of Airborne Chemical Hazards*. Boca Raton, FL: CRC Press. 705 p.

Shah, H. (2013a). Study summaries for cyanuric acid. In *AEATF Supplemental Submission of tox study summaries for CYA.*[Unpublished document]. Washington, DC: American Chemistry Council. 8 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Shah, H. (2013b). *Pour Solid Study Submission. Vol. 2. Study Protocol, IIRB Approval Letter and Supporting Documents.*[Unpublished document]. Washington, DC: American Chemistry Council. 183 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Shah, H. (2014a). *Antimicrobial Exposure Assessment Task Force II (AEATF II) Brush and Roller Painting Study, Vol. 1. Scenario Design*. [Unpublished document]. Washington, DC: American Chemistry Council. 19 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Shah, H. (2014b). *Antimicrobial Exposure Assessment Task Force II (AEATF II) Brush and Roller Painting Study, Vol. 2. Primary Documentation: Study Protocol, Schulman Associates IRB (SAIRB) Preliminary Approval and Documentation and CA Dept. of Pesticide Regulation (CDPR) Review and Response Documentation*. [Unpublished document]. Washington, DC: American Chemistry Council. 19 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Sweeney, K.J., & Sherman, K. (2014). *Science and Ethics Review of USDA Protocol for Laboratory Evaluation of Bite Protection from Repellent-treated Clothing for the United States Military*. [Unpublished document]. Washington, DC: United States Environmental Protection Agency. 36 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

Testman, R.J. (2014). *Antimicrobial Exposure Assessment Task Force II (AEATF II) Brush and Roller Painting Study. Vol. 2. Primary Documentation: Study Protocol, Schulman Associates IRB (SAIRB) Preliminary Approval and Documentation and CA Dept. of Pesticide Regulation (CDPR) Review and Response Documentation.* [Unpublished document].

Washington, DC: American Chemistry Council. 150 p. Retrieved from www.epa.gov/hsrb for the HSRB – 23 April 2014 meeting.

USEPA (U.S. Environmental Protection Agency). (2014). Human Studies Review Board; Notification of a public meeting. [EPA-HQ-ORD-2014-0189; FRL-9908-30-ORD]. 79 *Federal Register* 53, 15332-15334.

Wester, R.C., Maibach, H.I., Bucks, D.A.W., & Aufrere, M.B. (1984). *In vivo* percutaneous absorption of paraquat from hand, leg and forearm of humans. *J. Toxicol. Environ. Health,* 14, 759–762.

Wester, R.C., Maibach, H.I. (2005). Regional variation in percutaneous absorption: Principles and applications to human risk assessment. Ch. 5in Bronaugh, R.L. & Maibach, H.I. (eds.) *Percutaneous Absorption: Drugs, Cosmetics, Mechanisms, Methodology, 4th edition,* (pp. 85-93). Boca Raton, FL: Taylor & Francis. 878 p.

APPENDIX A

Work Group on Return of Individual Research Results
Human Studies Review Board
US EPA

Meeting Report and Recommendations

Charge to Work Group

To provide advice, information and recommendations to the US Environmental Protection Agency's (EPA's) Human Studies Review Board (HSRB) on the issue of returning individual research results.

Background

It is generally accepted that, in a clinical context, physicians and other health care providers have an obligation to inform patients about the results of individual diagnostic tests (see, e.g., American College of Physicians [2012]). These tests are being performed solely for the benefit of the patient and the results will have an effect on individualized treatment. As clinicians have an obligation to provide the best care possible and an obligation to respect the right of patients to make voluntary and informed decisions about treatment, disclosure of individual test results is an ethical imperative.

By contrast, there is little consensus as to whether or not investigators have an ethical obligation to inform study participants about the results of tests performed on them as part of a research protocol (see, e.g., testimony from the August 19-20 meeting of the US President's Council for the Study of Bioethical Issues [PCSBI]. PCSBI [2013]). Often, the primary goal of research is not to benefit the individual participant directly but rather to benefit society in general. Research tests and procedures are often done primarily for hypothesis testing or generation, rather than to diagnose disease or to inform physicians and patients about appropriate treatments. These tests also may not be clinically validated or may not be performed in certified laboratories following rigorous quality control standards; it is often illegal to release individual test results that are not performed under these conditions (Clayton et al. 2013). There is a general ethical presumption that study participants should be informed of aggregate and de-identified research findings. However, there is still considerable disagreement about if and when individual subjects should be told about their own individual results from tests performed on them as part of research.

US Federal regulations are largely silent on this topic (see. e.g., Code of Federal Regulations Title 45: Public Welfare. Department of Health and Human Services. Part 46: Protection Of Human Subjects). The only thing that current regulations require is that study participants be told explicitly as part of the consent process about whether or not they will be given research results. They should also be told of new results that may change their decision to participate in the study. There is no statutory requirement to provide individual research results.

Most discussions of researchers' ethical duties to return individual results have focused on reporting incidental findings, usually in the context of genetic or neurological research (Green et al. 2013a; Sandeman et al. 2013; Wolf 2013). If researchers performing genome-wide association studies (GWAS) of genetic factors potentially associated with diabetes, for example, are they obligated to notify a participant if they discover that the subject carries the genetic markers associated with Huntington's disease or hereditary breast cancer? Would a neurobiologist conducting studies of spatial memory using functional magnetic resonance imaging (fMRI) be required to tell a research participant that they have abnormal neural connectivity in the brain?

These debates are usually framed in terms of a duty to warn, with researchers having an obligation to inform research participants of findings that have serious clinical implications (Wolf 2013). The ethical principle of beneficence – the obligation of investigators to maximize potential benefits and minimize potential risks of study participation – would seem to suggest that research participants be told those test results that could directly benefit their health. This would be true in cases where the test results are clear, the clinical implications unequivocal, and treatment or care available.

From this perspective, when there is uncertainty about the test results or their clinical implications the obligation to inform subjects may or may not exist. Some argue that providing individual research results can provide benefit. Research participants in the study of genetic factors potentially associated with diabetes, for example, might use information about potential risks of developing diabetes or other chronic conditions to make lifestyle choices that might reduce the likelihood of developing disease (see, e.g., Affleck 2009). Others make the case that providing individual research results is itself a benefit because it demonstrates respect for participants, honors the participants' right to know, and has the potential to strengthen trust in the investigators and in the research endeavor (Ravitsky and Wilfond 2006).

Others have argued, however, that informing study participants of uncertain or probabilistic test results might actually lead to physical, psychological or social harm (Moynihan et al. 2012). A person who is told that they are likely to develop Huntington's Disease, a progressive neurodegenerative condition for which there is currently no cure, might use this information in a positive way – for example, by making decisions about if and when to have children, each of whom could also carry the trait – or they might react to this disclosure in a negative way – for example, by becoming psychologically depressed or even considering suicide (Lewis 2013).

There is still considerable disagreement about the ethical obligation to return individual results, but some areas of consensus have begun to emerge (Green et al. 2013b). For example, there is some consensus that the duty to disclose individual test results of clinical research increases in proportion to the level of certainty that the information provided will positively affect the diagnosis, prognosis and treatment of the individual. In addition, there is some consensus that researchers should carefully consider the possibility that disclosing research results may harm research subjects. Finally, there is general agreement that researchers should inform research participants about if, when and how individual findings will be communicated.

These considerations are particularly challenging for investigators conducting studies related to the charge of the HSRB, namely intentional exposure studies of compounds under the regulatory authority of the EPA.

Historically, such studies have been conducted using exposure chambers under controlled laboratory conditions, with participants informed of exposure levels as part of the informed consent process (see, e.g., Muttray et al. 2013 and Bartoli et al. 2013 for recent examples of these sorts of studies). A number of recent intentional exposure studies submitted to the HSRB for review, however, have involved observational analysis and measurement of dermal and inhalation exposure to EPA regulated compounds under real-world conditions. Investigators conducting these studies have proposed providing study participants with individual exposure results, despite uncertain benefits. These studies, for instance, are designed only to measure exposure levels, not health effects. In addition, most of the intentional exposure studies that have been reviewed by the HSRB to date were designed to measure levels of exposure that are well below established thresholds for acute toxicity. Finally, these tests are used to measure exposure and are not clinically validated; they are not clinical tests at all.

The prevailing assumption in the current debate about individual research results is that they should be returned only if they are clinically relevant or otherwise actionable. Providing individual results is unlikely to provide any clear or direct health benefit to intentional exposure study participants. Any benefit would likely be informational only, and there is little empirical evidence published to date that suggests that this information would help people reduce their future exposures. However, a growing body of literature from public health ethicists and environmental advocates, among others, suggests that this presumption -- that participants must benefit clinically if individual results are to be returned -- is too narrow and fails to consider issues of subject autonomy and participatory and reciprocal justice (Morello-Frosch et al. 2009; Parkin 2004).

Because of these concerns, study sponsors and the Agency have sought the input of the HSRB on if and when to release individual exposure data to observational study participants, leading to the formation of the Work Group on Return of Individual Research Results.

Work Group Process

The Work Group on Return of Individual Research Results is made up experts in research ethics, community-based participatory research, health risk assessment, toxicology and biostatistics.

The Work Group, which includes both current and former members of the HSRB as well as independent consultants, met for a one-day face-to-face meeting on January 16, 2013 to consider the following questions:

1. In research studies that involve intentional exposure of participants to EPA regulated compounds, do researchers have a moral obligation to offer individual research results to participants? Why or why not?
2. What are the circumstances under which there is a moral obligation to return individual research results to participants of intentional exposure studies?

3. What is ethical basis for any obligation to provide individual research results to participants of intentional exposure studies? Is there an ethical basis for not offering individual research results?

Group discussion of whether or not it is ethically obligatory to return individual research results to study participants was structured around three scenarios adapted from real-world intentional exposure studies submitted to the HSRB for review. These scenarios are summarized below:

Scenario 1: Measurement of dermal and inhalation exposure to a liquid antimicrobial pesticide product applied using a bucket and mop.

Participants include English- and Spanish-speaking janitorial professionals of both genders, recruited using flyers soliciting interest posted at janitorial service companies. Subjects will apply a commercially available (low toxicity) cleaning product to floors using a string mop and bucket for predetermined amounts of time. Activities include mopping and emptying of the mop bucket, but not mixing of the antimicrobial solution. Exposure will be assessed using a whole body dosimeter, hand wash and face wipes, and OHSA Versatile Sampler (OVS) tube sample collection.

Scenario 2: Measurement of dermal and inhalation exposure to a liquid pesticide applied using a backpack or handgun sprayer in utility rights-of way.

Participants include English-speaking utility workers of both genders, recruited using brochures posted in utility company workspaces. Subjects will be engaged in their regular duties as utility workers, applying a commercially available EPA-registered pesticide using a vehicle-mounted handgun or backpack applicator. Exposure will be assessed using a whole body dosimeter, hand wash and face wipes, and OHSA Versatile Sampler (OVS) tube sample collection.

Scenario 3: Dosimetry and effectiveness testing of personal insect repellents under field conditions.

Participants include English-speaking subjects recruited from a database of potential volunteers using a random dialing approach. The database is owned by a contract research organization that recruits potential subjects via advertisements in local newspapers. The study consists of two independent analyses: 1) a laboratory-based dosimetry study to determine the amount of repellent that typical users would apply; and 2) a field-based study of repellent effectiveness. Two formulations of a conditionally registered repellent would be used: a lotion and a spray. Exposure during the laboratory phase would be measured by passive dosimetry using self-adhesive gauze (spray) or by direct measurement (lotion). During the field tests the amount of repellent applied would be standardized, and repellent effectiveness determined by exposure to mosquitoes in a natural environment.

Work group members were asked to address the three charge questions listed above for each scenario, with the group Chair facilitating the discussion in an attempt to reach consensus. If consensus could not be reached on a recommendation and rationale for the HSRB, the majority opinion would be presented to the Board with minority views represented in the associated commentary. For each of the recommendations listed below, consensus was achieved. During subsequent decision of this meeting report, however, one Working Group member raised concerns about Recommendation 3. These concerns are detailed in the attached memo (Appendix 1).

Recommendations

1. For many intentional exposure studies, individual results are unlikely to be clinically relevant. Despite this, study sponsors or investigators have an obligation to offer results to participants.

2. There is an absolute moral obligation to return aggregate results directly to all participants (e.g. via a letter written in lay language), unless the participant declines of notification.

3. There is a presumptive moral obligation to return individual results in a way that is comprehensible, contextualized, relevant and useful if a study participant asks for them.

Rationale

Different ethical frameworks can and have been used to explore the issue of returning research results to participants. However, most of the discussions have been framed around the three principles of *respect for persons*, *beneficence* and *justice*. These three principles are widely recognized and provide a moral foundation for current US regulations and guidance for the ethical conduct of research involving human participants. Support for the Work Group's conclusions can be found in each of these principles.

For example, the principle of *respect for persons* requires that investigators treat research participants as autonomous moral agents capable of making decisions for themselves. In practice, this requires that research participants be allowed to make a voluntary and fully informed choice about whether or not to participate in a study. Included in this is the obligation for investigators to provide to potential volunteers, in a comprehensible and culturally appropriate manner, all information about the study that the participants deem relevant. This includes information about the risks and benefits of participation, and how the results of research will be disseminated to the participant and the community. However, the informed consent process does not end once the participant has agreed to enroll in the study. Rather, it is an ongoing conversation, with participants free to leave the study at any time and for any reason. Moreover, investigators are obligated to communicate to participants, "significant new findings ... which may relate to the subject's willingness to continue participation" (45 CFR 46.116(b)(5)).

The Work Group concluded that respect for persons also extends to informing research participants of results even after the study has ended, as these results may have significant implications for the participants. For example, such data may inform participants of potential workplace risks or provide them with information about reducing workplace exposure to potentially hazardous chemicals like pesticides. It is the individual participant's right to decide if they want to know the results or not, as well as to decide what they will do with this information. Thus, the study sponsors and investigators are morally obligated to offer research results to study participants. It is important to note, however, that this is different from mandatory provision or disclosure of results to participants. As autonomous agents, research subjects also have the right to decline to be given research results.

Similarly, the principle of *beneficence* requires that investigators maximize the potential benefits and minimize the predictable risks of study participation. In the case of intentional exposure studies, the likely benefits to individual research participants are primarily informational. Janitorial or utility workers who routinely handle potentially hazardous chemicals like pesticides may benefit from learning about chemical exposures that are part of their jobs. As exposure is part of these workers' jobs, study participants as a class will likely benefit from disclosure of results.

Some study sponsors and investigators worry that disclosure of research results may pose some risk to participants. Providing research results, for example, might cause psychological distress in those with higher than average exposures or prompt those with lower than average exposures to relax their workplace safety habits in ways that may put them at increased risk of harm. But these risks are individual and unpredictable. Therefore, the moral obligation to minimize risks of study participation does not preclude returning of research results. Potential risks to individual participants do not justify denying likely benefits to all participants. Rather, it requires that investigators return research results in a way that is comprehensible, relevant, contextualized and usable to those who request this information.

Finally, the principle of *justice* requires that research subject selection be equitable and non-exploitative. Individuals and groups that participate in research should benefit, and the study should be responsive to their concerns and needs. There are different concepts of justice: distributive, participatory, rectificatory, and reciprocal. When applied to the research context, the fourth of these – reciprocal justice – suggests that individuals who voluntarily take on the risks of research deserve proportionally more benefit. People who contribute to the research effort deserve something in return, be it access to new treatments, provision of ancillary care or, in the case of non-clinical research like intentional exposure studies, the offer of research results. In the long term, providing these results also demonstrates openness and transparency, building trust between the investigators, the study participants and the larger community.

The Work Group thus found that ethical principles of *respect for persons*, *beneficence* and *justice* place a moral obligation on study sponsors and investigators to offer research results to all study participants. At a minimum, researchers must provide aggregate results to all participants except those who decline notification. Similar moral arguments could be made with respect to returning individualized results to participants, but in its discussions of the three exposure

scenarios the Work Group concluded that there was only a presumptive rather than an absolute obligation to return these results if the subject asks for them.

Depending on the context and goals of the study, sponsors and investigators may be justified in some circumstances in withholding individual results. In particular, the *relevance* and *usability* of individualized results is important in determining if and when these data should be reported. For example, in two of the scenarios discussed – Scenario 1: Measurement of dermal and inhalation exposure to a liquid antimicrobial pesticide product applied using a bucket and mop and Scenario 2: Measurement of dermal and inhalation exposure to a liquid pesticide applied using a backpack or handgun sprayer in utility rights-of way – research participants are professional janitorial and utility workers who use potentially hazardous chemicals routinely. Exposure to these chemicals is not voluntary but is a routine part of their jobs. Thus, there is a strong obligation to return individualized results to participants in these studies as they may be directly relevant to the risks they experience in the workplace and may be of considerable utility (e.g. it may improve safe chemical handling and reduce future exposures, particularly for those with higher than average results). However, these results must be presented in a way that is comprehensible and contextualized, and which minimizes potential psychological and social risks.

By contrast, in Scenario 3 (Dosimetry and effectiveness testing of personal insect repellents under field conditions), the relevance and usability of individualized results was questionable. Participants in this study were healthy volunteers who may or may not be exposed to the test chemical in the future. Even if they are – by using a commercially available formulation of the insect repellent being tested, for example – the individual exposure data obtained during the dosimetry experiments may not be directly comparable to use of a consumer product. Providing individualized results in this case might be morally praiseworthy but not ethically obligatory.

References

Affleck P. 2009. Is it ethical to deny genetic research participants individualised results? *J Med Ethics* 35(4): 209-13.

American College of Physicians. 2012. Ethics Manual, Sixth Edition. Available online at http://www.acponline.org/running_practice/ethics/manual/manual6th.htm. Accessed July 19, 2013.

Bartoli ML, Vagaggini B, Malagrinò L, Bacci E, Cianchetti S, Dente FL, Novelli F, Costa F, Paggiaro P. 2013. Baseline airway inflammation may be a determinant of the response to ozone exposure in asthmatic patients. *Inhal Toxicol* 25(3): 127-33.

Clayton EW, Haga S, Kuszler P, Bane E, Shutske K, Burke W. 2013. Managing incidental genomic findings: legal obligations of clinicians. *Genet Med* 15(8): 624-9.

Department of Health and Human Services. 2009. Code of Federal Regulations Title 45: Public Welfare. Part 46: Protection of Human Subjects. Available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. Accessed July 19, 2013.

Green RC, Lupski JR, Biesecker LG. 2013a. Reporting genomic sequencing results to ordering clinicians: incidental, but not exceptional. *JAMA* 310(4): 365-6.

Green RC, Berg JS, Grody WW, Kalia SS, Korf BR, Martin CL, McGuire AL, Nussbaum RL, O'Daniel JM, Ormond KE, Rehm HL, Watson MS, Williams MS, Biesecker LG. 2013b. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. *Genet Med* 15(7):565-74.

Lewis R. 2013. Incidental findings from genome sequencing – nuances and caveats. *Scientific American.* Available online at http://blogs.scientificamerican.com/guest-blog/2013/03/22/incidental-findings-from-genome-sequencing-nuances-and-caveats. Accessed on July 19. 2013.

Morello-Frosch R, Brody JG, Browne P, Gasoir R, Altman RG, Rudel RA, Pérez C. 2009. Toxic ignorance and right-to-know in biomonitoring results communication: a survey of scientists and study participants. *Environ Health* 8(6): 1-13.

Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. *BMJ* 344:e3502

Muttray A, Gosepath J, Brieger J, Faldum A, Mayer-Popken O, Jung D, Roßbach B, Mann W, Letzel S. 2013. Acute effects of an exposure to 100 ppm 1-methoxypropanol-2 on the upper airways of human subjects. *Toxicol Lett* 220(2): 187-92.

Parkin RT. 2004. Communications with research participants and communities: foundations for best practices. *J Expo Anal Environ Epidemiol* 14: 516-23.

President's Council for the Study of Bioethical Issues. 2013. Transcripts of the August 19-20, 2013 Meeting. Available online at http://bioethics.gov/node/2782. Accessed Septemer 6, 2013.

Ravitsky V, Wilfond BS. 2006. Disclosing individual genetic results to research participants. *Am J Bioeth* 6(6): 8-17.

Sandeman EM, Hernandez Mdel C, Morris Z, Bastin ME, Murray C, Gow AJ, Corley J, Henderson R, Deary IJ, Starr JM, Wardlaw JM. 2013. Incidental findings on brain MR imaging in older community-dwelling subjects are common but serious medical consequences are rare: a cohort study. *PLoS One* 8(8):e71467.

Wolf SM. 2013. Return of individual research results and incidental findings: facing the challenges of translational research. *Annu Rev Genomics Hum Genet* 14: 557-77.

Appendix 1: Memo of Concern

From: Sammy Almashat, MD, MPH
Physician and Staff Researcher, Public Citizen
Member, Work Group on the Return of Individual Research Results

To: EPA Human Studies Review Board

Re: Disagreement with Work Group recommendations to the Human Studies Review Board

I am writing today to express my partial disagreement with the Work Group on the Return of Individual Research Results recommendations on the moral obligations of investigators to offer individual research results to human subjects in intentional exposure studies.

I wholeheartedly support the general intent of the Work Group's recommendations and their rationale for supporting greater transparency in the disclosure of research results.

I also strongly endorse the recommendation that places an absolute moral obligation on investigators to return aggregate research results to subjects, regardless of the relevance or usability of the data, unless the subject declines the offer.

However, I disagree with the recommendation that there is only a presumptive (rather than absolute) obligation to return individual research results, "only if they can and will be presented in a way that is comprehensible, contextualized, relevant and useful." (Working Group on the Return of Individual Research Results, 2013). Rather, the return of individual research results (especially if requested by the subject on an "opt-in" basis) constitutes an absolute moral obligation as a subject's right to know overrides questions of relevance and practical utility.

My objections are for the following reasons:

1. **The moral obligation to return, or not return individual research results should not rely on the investigator's or study sponsor's determination of the relevance or utility of the information.**

   I am concerned that determinations of the relevance and utility of individual research results will be made solely by the investigator or study sponsors. The relevance of a particular set of data is, in part, a subjective determination made by each individual subject (e.g. the simple desire to satisfy one's curiosity is relevant to the subject in a way that cannot be measured objectively). For exposure data in particular, it is often challenging to identify significant clinical consequences from disclosure (or non-disclosure) of the information. It will also be challenging for study investigators to determine the objective relevance (or evaluate the solicited subjective relevance) of research results for *each individual subject*, particularly in large studies involving

heterogeneous groups and highly variable exposure results. For these reasons only the respective subject can determine the relevance and utility of individual research results.

Another concern that arises from the exclusive reliance on study investigators' determination of relevance and utility is a potential tendency among investigators and sponsors, however subtle and unconscious, against providing more information than is absolutely required. Returning individual research results represents a financial and time commitment on the part of the study sponsor that is considerably greater than the return of a single, identical set of aggregate results. The Work Group's recommendation (with which I agree) to make the individual results "comprehensible, contextualized, relevant and useful" adds to the scale of the commitment. Therefore, some sponsors may, in the face of the uncertainty inherent to the abstract notions of "relevance" and "utility," but not necessarily out of any malintent, too often err against returning individual research results.

2. **The potential for unintended harm, not the relevance or utility of individual results, should serve as the sole basis for the determination of the moral obligation to return individual research results in intentional exposure studies.**

The sole consideration relevant to the question of whether or not there is a moral obligation to returning individual results should be the potential for unintended harm to the subject, in the form of psychological, social, or economic difficulty incurred as a result of the disclosure of such information.

Here, I agree with the Work Group's assertion that, "the moral obligation to minimize risks of study participation does not preclude returning of research results" (Working Group on the Return of Individual Research Results, 2013). While the return of aggregate results raises similar concerns of unintended harm, the Working Group did not consider this to be sufficient to exempt investigators from the absolute requirement to return such results in all cases, unless subjects actively decline receipt of the information. In fact, returning aggregate results in the absence of individual results could make the information less relevant to each individual subject. Such a situation of increased uncertainty as to how the aggregate results apply to the individual subject could heighten anxiety or it could mitigate it.

It is also true that the return of individual research results in a way that is not readily comprehensible or interpretable may cause more unintended harm than the return of aggregate results alone. However, here the critical point to consider is that the potential for unintended harm to research subjects as a result of the disclosure of individual research results increases (and decreases) in direct proportion to the relevance or utility of the information to the subject. For example, in scenarios #1 and #2 discussed by the Working Group (Working Group on the Return of Individual Research Results, 2013), potential harms were anticipated only because the exposures studied were relevant to the subjects in some way (e.g. the same potentially dangerous exposures were also present at their worksites). By contrast, in scenario #3, no unintended harms were identified presumably because the exposure was not deemed relevant to subjects' everyday lives. In other words, it is precisely the studies in which

individual results are *least relevant* to subjects' lives that are *least likely* to cause unintended harm to the subject.

In cases in which the potential for harm resulting from disclosure of individual research results is particularly high, investigators should be obligated to inform subjects of this possibility. In light of the Work Group's recommendation for the obligatory return of aggregate results in all circumstances, it is hoped that subjects would be warned of the potential for unintended harm caused by the return of aggregate results. With minor modifications, a similar warning should accompany the return of individual results. Empowering subjects to make informed decisions for themselves enhances autonomy and fosters trust in the research process.

3. "Opt-out" vs. "opt-in" for aggregate and individual research results

While the Work Group's charge was limited to the determination of *whether* a moral obligation should exist to return research results, a consideration of *how* research results should be returned in light of the discrepant moral obligations for aggregate and individual research results is warranted.

I agree with the Work Group that the return of aggregate results should always occur on an "opt-out" basis so as to minimize the number of subjects failing to receive the information for a lack of awareness of their right to do so. I disagree, however, with the proposal for an opt-in system for individual research results. The presumption of lower relevance and utility and a higher likelihood of harm associated with the return of individual versus aggregate results may explain why different standards (i.e., absolute versus presumptive moral obligations) were applied.

As outlined above, I disagree with these assumptions. I believe that an opt-out system should be applied in both cases. Should an opt-in system be adopted for the return of individual research results, however, investigators should be required to disclose this option to subjects during the informed consent process and after study completion.

Work Group on Return of Individual Research Results

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Golden Pacific
LABORATORIES

January 22, 2014

Dr. Saturnino Yanga
California Dept. of Pesticide Regulation
1001 I Street
Sacramento, CA 95812

Dear Dr. Yanga:

I have received and carefully studied the review comments dated December 19, 2013 for the protocol "A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting." The Protocol and Informed Consent form (ICF) have been updated and a "track changes" version submitted electronically with this letter. I have attached a table addressing the review comments from DPR and the responses/edits to each comment.

The protocol has received preliminary approval from an IRB and is now being submitted to the EPA for review by the Human Studies Review Board. Following their review we will incorporate their comments and submit the modified version to the IRB and DPR for final approvals.

Please feel free to contact me with any questions. I can be reached at (949)939-3585 or rtestman@gplabs.com.

Sincerely,

Rob Testman

Robert Testman
Principal Investigator

cc: Don Richmond

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

CA DPR Comments	GPL Response	Protocol Modifications
Section 5, Oversight of Ethical Conduct – page 12. - Note that protocol amendments involving potential health effects of participants must be reviewed and approved by DPR. - Unanticipated problems involving risks to human subjects: report any that occur as soon as possible to DPR.	Section 19, Protocol Changes – page 47. The requirement for notification and/or approval of IRB and DPR is contained in this section of the protocol.	N/A
Section 6E, Balance of Risks and Benefits, Alternative Data Sources – page 15. The protocol states that "biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low." However, within the Reregistration Eligibility Decision for BIT, a dermal penetration value is listed as 40.6%. Even though this is based on a rat study after 72 hours of exposure, it is still relevant.	The statement re low dermal penetration will be deleted.	Modified Section 6.E to remove referenced statement.
Section 7A, Test Substance, Test Substance Identification – page 16. The protocol states that a minimal volume of paint colorant will be added to approximately half of the paint used during the ME. Does the colorant also contain BIT? If so, BIT concentrations should be confirmed after the colorant is added.	BIT concentration will be determined for each batch of paint to be used, including after addition of any colorant. Method development work did not show any contribution to BIT from the colorant.	Modified Section 7.A to clarify that testing will be post-addition of colorant.

CA DPR Comments	GPL Response	Protocol Modifications
Section 7C, Test Substance, Safety Precautions – page 17. One reviewer suggested the researchers review the Material Safety Data Sheet for BIT with the subjects so they are aware of any toxic effects and health risks.	Researchers will review the Informed Consent document with subjects. As part of that review the MSDS will be available and offered to subjects. Researchers will be available to answer any subject questions regarding the MSDS.	N/A
Section 7E, Test Substance, Application Parameters and Amount Applied – page 19. The study design allows for evaluation of exposure of participants while painting. Cleaning of the paint brush, roller, and other painting equipment after the end of the application is not included as part of the exposure study. One reviewer stated this will likely underestimate the exposure since cleaning the painting equipment is a common practice. Consider having the participants clean the equipment as part of the study or conducting a separate monitoring study for cleaning of the equipment.	The inclusion or exclusion of equipment cleaning was reviewed and discussed as part of the Joint Committee review of the study protocol, which included EPA and CDPR. The decision was made that excluding cleanup was the worst case scenario, as residues added from contact or splashing during cleaning activities would likely be outweighed by removal of paint from the hands.	N/A
Section 8B, Monitoring Site – page 20, paragraph 2. The protocol states that analysis of background samples taken in each painting room will be analyzed at the discretion of the Study Director. Since the protocol allows the reuse of the rooms multiple times during the study, it is important to analyze the background samples for the presence of BIT at the beginning each monitoring event.	The background samples are being collected in recognition of the potential issue of cross-contamination. There may be cases where analysis is unnecessary; for example if the subject air tubes do not contain BIT above the LOQ, then background samples would not need to be analyzed. This is why it was left to the Study Director's discretion.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 24, paragraph 2. The protocol states "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR." Revise to "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study." DPR does not require verification of identity, but requires verification of age (at least 18 years of age) for inclusion in the study.	Protocol will be updated.	Section 9.A.ii was updated.
Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 25, last paragraph. The protocol states that final enrollment for potential female subjects will be determined on each study day following a pregnancy test. The protocol should specify that potential female subjects may enroll in the study after the recruitment meeting, but participation in the study will be determined after they take a pregnancy test on the study day.	Current wording of 9Aii states, "For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test." This wording appears to reflect this comment already.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 9B, Subject Recruitment Number – page 27, paragraph 1. The protocol indicates 24 people will be enrolled in the study with the first 18 assigned to ME01 to ME18; the second sequential group of eight will be assigned as primary alternates. The 18 enrolled in the first group and 8 enrolled in the second group equal 26. Revise numbers to equal 24.	Typo corrected.	Corrected.
Section 9B, Subject Sequence Number – page 27; and Section 13A, Field Records – page 44. Clarify storage of records. Section 9B states Golden Pacific Laboratories will retain subject's records indefinitely while Section 13A states the raw data files will be kept in secure files until transferred to a permanent location selected by the Sponsor.	Modified section 13.A to clarify that subject personal information is not included with other raw data files or transferred to Sponsor.	Section 13.A was updated.
Section 9D, Stop Criteria and Medical Management – page 29. The protocol needs to identify who will pay for the medical costs of research-related injuries. This information is appropriately included in the Informed Consent Form.	Added payment information to Section 9.D.	Added the following language from the Informed Consent to section 9.D, "The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered."

CA DPR Comments	GPL Response	Protocol Modifications
Section 10C, Monitoring Event Procedures, ME Activities #3 – page 32. When the subject moves from one room to another room, specify who will move the paint and painting supplies.	Clarified section 10.C.	Added the following language to section 10.C, "Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff."
Section 10D, Monitoring Event Procedures, Sample Collection #1c – page 33. The procedure for rinsing the hands in unclear (e.g., hands submerged in the rinsing solution, solution poured over the hands and the solution collected). Describe how the rinsing will occur.	The description in the protocol was reviewed and found to be clear. Hands are held above bowl, scrubbed with gauze pads wetted with IPA/water and rinsed with IPA/water.	N/A
Section 10D, Monitoring Event Procedures, Sample Collection #4, page 34. The protocol states "The high solubility of BIT in both IPA and water..." Since BIT is soluble in both water and isopropyl alcohol (IPA), provide rationale for using a 50% water/50% IPA mixture versus the use of water alone for removing paint with BIT. Water would be less irritating to the skin than the 50% water/50% IPA mixture.	Removal of test substances from the hands is a more complex system than dissolving neat compounds. Due to the interaction with the skin and skin oils hands are normally washed/rinsed with a surfactant or a mild alcohol along with water. The IPA/water mix is more likely to result in a high percentage removal of BIT from skin than water alone. Surfactants are avoided due to the potential negative influence on sample analysis.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 10D, Monitoring Event Procedures, Sample Collection #6 – Outer and Inner Dosimeter Samples, page 35. The protocol states "The dressing area will be cleaned with cleaning agents appropriate for the study between subjects." Cleaning agents may contain BIT. The protocol should specify the use of BIT-free cleaning agents.	Avoiding the use of cleaning agents containing BIT is important. However, this requirement is the reason for the generic "appropriate for the study" designation. Cleaning agents will be screened for BIT prior to use.	N/A
Protocol section 9b, Subject Sequence Number, page 27, states the subject may obtain copies of their own records from the Principal Investigator on request. This information should also be included in the ICF.	Added language to Informed Consent form (ICF).	Added the following language to ICF, "You may obtain a copy of your own records from the Principal Investigator upon request."
Study Procedure 6 – page 62. Protocol section 10B7 states "The subjects must wear the safety glasses and hat while applying..." The ICF states "You must wear the safety glasses while painting with brush and roller." Revise the ICF to include the requirement that the subjects must wear the hats while applying.	Updated ICF.	Added "and hat" to ICF Study Procedure Item 6.
Study Procedure 10 – page 62. The procedure states "We will turn on your air pumps and ask you to put on your safety glasses" The protocol requires wearing a painter's hat so this procedure should include putting on the hat.	Updated ICF.	Added "hat and" to ICF Procedure Item 10.

CA DPR Comments	GPL Response	Protocol Modifications
In addition to the "once in 5 years" painting requirement, would it be relevant to the study to ask the participants how often they paint?	The purpose of the question is to establish that the subject has at least minimal experience so that training in how to paint will not be needed.	N/A
Section 10C, Monitoring Event Procedures, ME Activities #1, page 31. The protocol states that ceiling ventilation fans will be turned off while the ME is conducted in a room. However, section 8 of the MSDS for the paint covers Exposure Controls and Personal Protection. This section includes the precaution "Use only with adequate ventilation." Under the Ventilation subheading, the MSDS states "Local exhaust preferable. General exhaust acceptable if exposure to materials in Section 2 is maintained below acceptable exposure limits" and refers to an OSHA standard. With the ceiling exhaust fans turned off, add information about how the work environment will be maintained to keep exposure levels below acceptable exposure limits.	The use of the exhaust fan during painting was discussed with the JRC during protocol design. In response to this question EPA has deferred until receiving guidance as part of the HSRB process.	To be determined.
Risks 1 – page 63. In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.	Updated ICF.	Modified ICF - Risks 1 as follows, "...You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher."

CA DPR Comments	GPL Response	Protocol Modifications
The inclusion criteria include the ability to speak and read English or Spanish. The protocol package does not include a Spanish translation of the ICF and Experimental Subjects Bill of Rights. These documents must be submitted before DPR approves the protocol.	The Spanish translation of the ICF/Experimental Subjects Bill of Rights, and recruiting materials will be performed by SAIRB after regulatory reviews of the protocol are completed and the English version is finalized.	To be determined (Spanish translation to be added by IRB after reviews complete).
If the Informed Consent is conducted in Spanish by a Spanish-speaking researcher, the researcher needs to sign the ICF, in addition to the Principal Investigator.	Added to ICF.	Added to ICF Consent and Signature page.
Editorial comments	Reviewed and updated as appropriate.	Updated as appropriate.

Robert Testman

From: Robert Testman
Sent: Friday, January 24, 2014 12:51 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: FW: protocol for the study "A Study for Measurement of Potential ....."
Attachments: CDPR letter 22Jan2014.pdf; AEATF Brush Roller Draft Protocol 22Jan2014 redline.docx

Hi Don,

Attached is a letter with responses to the CDPR comments on the brush and roller study, as well as a redlined version of the revised protocol. The revised protocol incorporates IRB and CDPR comments and is now being submitted to the EPA for HSRB review. Once we receive and incorporate their comments we will route it back to you for approval. I appreciate your help with this process.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Escobar, Olga@CDPR [mailto:Olga.Escobar@cdpr.ca.gov]
Sent: Thursday, December 19, 2013 2:37 PM
To: Robert Testman
Cc: McKenzie, Jenna@CDPR; Nonato, Yvette@CDPR; Richmond, Don@CDPR; Beauvais, Sheryl@CDPR; Ross, Lisa@CDPR; Fan, Anna@OEHHA; Salocks, Charles@OEHHA; Wisniewski, Joy@OEHHA
Subject: protocol for the study "A Study for Measurement of Potential ....."

Mr. Testman:

Attached please find the correspondence to you from Nino Yanga concerning protocol for the study "A Study for Measurement of Potential Dermal and Inhalation Exposure during Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting.

Please contact him directly should you have and questions or concerns.

Note to cc's: A hard copy will not be provided unless requested.

Thank you.

Olga Escobar
Worker Health and Safety Branch
Department of Pesticide Regulation
916-324-8849

December 19, 2013

Robert Testman
Golden Pacific Laboratories, LLC (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, CA 93722

Dear Mr. Testman:

On October 28, 2013, the Department of Pesticide Regulation (DPR) received the protocol for the study **"A Study for Measurement of Potential Dermal and Inhalation Exposure during Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting."** Title 3, California Code of Regulations (3 CCR) Section 6710 requires Department of Pesticide Regulation (DPR) review and approval of pesticide exposure study protocols involving human subjects for studies conducted in California. 3 CCR Section 6710 also requires a concurrent review by the Office of Environmental Health Hazard Assessment (OEHHA).

Below is our review of the study protocol, Informed Consent Form (ICF), and Experimental Subject's Bill of Rights (BOR). Please incorporate the revisions listed in the Human Subject Protection/Ethical Considerations section. Please respond to comments in *General Review* and *Exposure Assessment* sections by either adopting them or providing further explanation to address review comments. Response to Editorial Comments is at your discretion. Once DPR receives your revised study protocol, ICF, and BOR, we will review them and, if acceptable, grant provisional approval of your proposed pesticide exposure study.

Institutional Review Board (IRB) Approval

After making the required revisions to the study protocol and receiving provisional determination of acceptability from DPR, please submit the study protocol, ICF, and BOR to an institutional review board (IRB) for approval. Once you receive the IRB approval, submit the IRB-approved documents to DPR's Worker Health and Safety Branch for approval.

Final DPR Approval

The DPR Director's final decision regarding approval or denial to conduct the proposed study, and the basis for the decision, will be determined once you have secured IRB approval of your revised protocol, ICF, and BOR. Please submit all revised documents to DPR electronically.

Review of Subject Proposal

Our review focused on the following four aspects as summarized below:

I. General Review: The appropriateness of the study design to achieve study objectives,
II. Exposure Assessment: The adequacy of the protocol for exposure assessment purposes,
III. Human Subjects Protection/Ethical Considerations: The adequacy of protective equipment and other measures in preventing over-exposure of study subjects and in conducting a study in accordance with ethical principles, and
IV. Editorial Comments.

I. General Review

The study involves the antimicrobial chemical 1,2-Benzisothiazol-3(2H)-one (BIT)

Protocol

- *Section 5, Oversight of Ethical Conduct – page 12.*
  - Note that protocol amendments involving potential health effects of participants must be reviewed and approved by DPR.
  - Unanticipated problems involving risks to human subjects: report any that occur as soon as possible to DPR.
- *Section 6E, Balance of Risks and Benefits, Alternative Data Sources – page 15.* The protocol states that "biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low." However, within the Reregistration Eligibility Decision for BIT, a dermal penetration value is listed as 40.6%. Even though this is based on a rat study after 72 hours of exposure, it is still relevant.
- *Section 7A, Test Substance, Test Substance Identification – page 16.* The protocol states that a minimal volume of paint colorant will be added to approximately half of the paint used during the ME. Does the colorant also contain BIT? If so, BIT concentrations should be confirmed after the colorant is added.
- *Section 7C, Test Substance, Safety Precautions – page 17.* One reviewer suggested the researchers review the Material Safety Data Sheet for BIT with the subjects so they are aware of any toxic effects and health risks.
- *Section 7E, Test Substance, Application Parameters and Amount Applied – page 19.*The study design allows for evaluation of exposure of participants while painting. Cleaning of the paint brush, roller, and other painting equipment after the end of the application is not included as part of the exposure study. One reviewer stated this will likely underestimate the exposure since cleaning the painting equipment is a common practice. Consider having the participants clean the equipment as part of the study or conducting a separate monitoring study for cleaning of the equipment.
- *Section 8B, Monitoring Site – page 20, paragraph 2.* The protocol states that analysis of background samples taken in each painting room will be analyzed at the discretion of the Study Director. Since the protocol allows the reuse of the rooms multiple times during the study, it is important to analyze the background samples for the presence of BIT at the beginning each monitoring event.

- *Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 24, paragraph 2*. The protocol states "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR." Revise to "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study." DPR does not require verification of identity, but requires verification of age (at least 18 years of age) for inclusion in the study.
- *Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 25, last paragraph*. The protocol states that final enrollment for potential female subjects will be determined on each study day following a pregnancy test. The protocol should specify that potential female subjects may enroll in the study after the recruitment meeting, but participation in the study will be determined after they take a pregnancy test on the study day.
- *Section 9B, Subject Recruitment Number – page 27, paragraph 1*. The protocol indicates 24 people will be enrolled in the study with the first 18 assigned to ME01 to ME18; the second sequential group of eight will be assigned as primary alternates. The 18 enrolled in the first group and 8 enrolled in the second group equal 26. Revise numbers to equal 24.
- *Section 9B, Subject Sequence Number – page 27; and Section 13A, Field Records – page 44*. Clarify storage of records. Section 9B states Golden Pacific Laboratories will retain subject's records indefinitely while Section 13A states the raw data files will be kept in secure files until transferred to a permanent location selected by the Sponsor.
- Section 9D, Stop Criteria and Medical Management – page 29. The protocol needs to identify who will pay for the medical costs of research-related injuries. This information is appropriately included in the Informed Consent Form.
- *Section 10C, Monitoring Event Procedures, ME Activities #3 – page 32*. When the subject moves from one room to another room, specify who will move the paint and painting supplies.
- *Section 10D, Monitoring Event Procedures, Sample Collection #1c – page 33*. The procedure for rinsing the hands in unclear (e.g., hands submerged in the rinsing solution, solution poured over the hands and the solution collected). Describe how the rinsing will occur.
- *Section 10D, Monitoring Event Procedures, Sample Collection #4, page 34*. The protocol states "The high solubility of BIT in both IPA and water..." Since BIT is soluble in both water and isopropyl alcohol (IPA), provide rationale for using a 50% water/50% IPA mixture versus the use of water alone for removing paint with BIT. Water would be less irritating to the skin than the 50% water/50% IPA mixture.
- *Section 10D, Monitoring Event Procedures, Sample Collection #6 – Outer and Inner Dosimeter* Samples, *page 35*. The protocol states "The dressing area will be cleaned with cleaning agents appropriate for the study between subjects." Cleaning agents may contain BIT. The protocol should specify the use of BIT-free cleaning agents.

Informed Consent Form (ICF)

- *Protocol section 9b, Subject Sequence Number, page 27,* states the subject may obtain copies of their own records from the Principal Investigator on request. This information should also be included in the ICF.
- *Study Procedure 6 – page 62*. Protocol section 10B7 states "The subjects must wear the safety glasses and hat while applying..." The ICF states "You must wear the safety glasses while painting with brush and roller." Revise the ICF to include the requirement that the subjects must wear the hats while applying.
- *Study Procedure 10 – page 62*. The procedure states "We will turn on your air pumps and ask you to put on your safety glasses" The protocol requires wearing a painter's hat so this procedure should include putting on the hat.

Qualification Worksheet

- In addition to the "once in 5 years" painting requirement, would it be relevant to the study to ask the participants how often they paint?

II. Exposure Assessment

- None

III. Human Subject Protection/Ethical Considerations

Protocol

- *Section 10C, Monitoring Event Procedures, ME Activities #1, page 31*. The protocol states that ceiling ventilation fans will be turned off while the ME is conducted in a room. However, section 8 of the MSDS for the paint covers Exposure Controls and Personal Protection. This section includes the precaution "Use only with adequate ventilation." Under the Ventilation subheading, the MSDS states "Local exhaust preferable. General exhaust acceptable if exposure to materials in Section 2 is maintained below acceptable exposure limits" and refers to an OSHA standard. With the ceiling exhaust fans turned off, add information about how the work environment will be maintained to keep exposure levels below acceptable exposure limits.
- *Risks 1 – page 63.* In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.

Informed Consent Form (ICF)

- The inclusion criteria include the ability to speak and read English or Spanish. The protocol package does not include a Spanish translation of the ICF and Experimental Subjects Bill of Rights. These documents must be submitted before DPR approves the protocol.
- If the Informed Consent is conducted in Spanish by a Spanish-speaking researcher, the researcher needs to sign the ICF, in addition to the Principal Investigator.

IV. Editorial Comments

- Define acronyms when first used: HVAC (page 20), LOQ (page 16), TBA (page 40), NA (page 41), and MD (AEATF Rationale document, page 5).
- The following references listed on p. 14 of the AEATF II Rationale document are not cited in the text: Jacobs (2006); AHETF (2007); Aklam (2006), and EPA (1998). Likewise, Popendorf (1992) is listed in the references but not cited in the BIT exposure protocol.

<u>*Protocol*</u>

- *Section 6A, Balance of Risks and Benefits – page 13, Line 1:* Add a comma so the sentence reads "... available to EPA from the PHED, the Agency..."
- *Section 9Aii*, Recruitment of Surrogate Workers – page 23, paragraph 4.
  - Revise first mention of Appendix D form title to "Subject Self-Reporting Demographic Form."
  - The second sentence states the investigator will ask the subject the health questions on the Subject Self-Reporting Demographic Form. The next sentence states "The investigator will answer any questions. Revise this sentence to read "The investigator will answer any questions the subject may have."
- *Section 9Aii, Recruitment of Surrogate Workers – page 24, paragraph 4*. Suggested Revising the first sentence to read: The recruitment process will terminate at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited, ...Bill of Rights Form. The revision includes deleting the space before the period at the end of the sentence.
- *Section 9D, Stop Criteria and Medical Management – page 28, paragraph 2, 3rd sentence*. Add a comma after *If instructed* so the sentence will read "If instructed, research staff..."
- *Section 10, Monitoring Event Procedures, page 29*. This sections mentions sampling trains, but does not describe what the sampling trains consist of. The term is described in a parenthetical on page 32 in Section 10C #2. Suggest moving the parenthetical to page 29 where sampling train is first mentioned.
- *Section 10H, Field Recovery Evaluation – page 38 Table*. Units of measure have been included for all fortification levels. Although the units of measure (ng/mL) are the same for the fortification levels for handwipes/washes, suggest adding the unit of measure after 4.0 to ensure clarity.
- *Section 11A, Sample Identification* – page 39. This section lists various codes to help identify samples. The outer and inner dosimeters will be sectioned into upper and lower arms, front and back torso, and upper and lower legs (page 35). The codes identifying samples do not include codes for the upper arms, front and back torso, and upper and lower legs.
- *Section 12B, Analytical Methods – page 41*. The protocol states: "The HPLC/MS/MS methods will be validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits." The subjects' exposures are

not minimized by low detection limits, but by use of PPE and very low levels of BIT in paint, or other exposure parameters.

Informed Consent Form (ICF)

- *Subject Selection – page 60, paragraph 3*. Suggest revising the second sentence by replacing 'anyone' with 'someone' so the sentence will read: We will sign up a few more people than we need, in case someone can't participate on the day of the test.
- *Study Procedure 3 – page 61, paragraph 4:*
  - *Line 2*. Add a comma so the sentence reads "...day of the test, each female volunteer…"
  - *Line 5*. Add a comma so the sentence reads "...give yourself the test, we will ask you…"
- *Study Procedures 12e – page 63*. This item should read "The researcher will help..."
- *Questions about this Study – page 65, paragraph 1.* Suggest revising the sentence to: "If you have any questions, you may ask Robert Testman or any other member of the research team at any time – before, during, or after the study."
- *Questions about the Study – page 65.* : Revise the name of the IRB to Schulman Associates Institutional Review Board.
- *Costs and payments – page 66, paragraph 2*. The second sentence reads like the subjects have more than one consent interview. Suggest revising to "At the end of the informed consent interview..."

Experimental Subject's Bill of Rights

- *Page 66.* Revise the name of the IRB to Schulman Associates Institutional Review Board.

Please submit your revised protocol to DPR electronically so that we can determine provisional acceptability of the study. If you have any questions, please contact Don Richmond of my staff at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov, or myself, at the number listed below.

Sincerely,

(original signed by N. Yanga)

Saturnino "Nino" Yanga, DVM, MPVM, MS
Environmental Program Manager I
Worker Health and Safety Branch
(916) 445-6387

cc: Anna M. Fan, Ph.D., Chief, Pesticide and Environmental Toxicology Branch (PETB), Office of Environmental Health hazard Assessment (OEHHA)
Charles Salocks, Ph.D., Senior Toxicologist, Chief, Pesticide Epidemiology Section, PETB, OEHHA
Joy A. Wisniewski, Ph.D., Staff Toxicologist, PETB, OEHHA
Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Sheryl Beauvais, Ph.D., Senior Toxicologist, WHS, DPR
Jenna McKenzie, Ph.D., Associate Toxicologist, WHS, DPR
Don Richmond, Research Scientist II, WHS, DPR
Dr. Yvette Nonato, Research Scientist I, WHS, DPR

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Monday, February 22, 2016 1:01 PM
To: Robert Testman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Thanks Robert.

I will let you know if we have any questions.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 22, 2016 3:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

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Please advise.

Thank you.

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Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
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Subject: Revised AEA09 Protocol

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Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
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From: Robert Testman
Sent: Monday, February 29, 2016 11:26 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol
Attachments: SAIRB letter 29Feb2016.pdf

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Golden Pacific
LABORATORIES

February 29, 2016

Ms. Denisse Guzman
Board Liaison
Schulman IRB

RE: AEA09 Final Protocol

Dear Ms. Guzman:

As requested please find attached a table of recommendations made by the HSRB/EPA and presented in the written April 8-9, 2014 HSRB meeting report provided to SAIRB previously. The table includes the protocol modifications made as a result of the recommendations, and notes clarifying certain recommendations and responses.

Please feel free to contact me with any questions. I can be reached at (949)939-3585 or rtestman@gplabs.com.

Sincerely,

Robert Testman
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

Recommendation (Agency)	Protocol Modification	Comments
Science Review Recommendations (pages 19-22)		
1a. The middle concentration of BIT in paint should be changed to halfway between low and high concentrations (360 ppm instead of 400 ppm) to improve regression data. **(HSRB)**	The protocol was modified to change the target concentration to be 360 ppm. (Summary section p.8 and Test Substance section p.15).	
1a. Consider including additional factors such as varied types of painting equipment and wall texture to capture more diversity of exposure. **(HSRB)**	The protocol was not expanded to include additional diversity parameters. After discussion with EPA the current design was continued as EPA preferred to keep n=6 subjects per group and vary only concentration.	The HSRB suggested change to the statement that the "protocol captures the range of variation" if additional diversity parameters were not included. The referenced statement was contained in a separate document and not the study protocol.
1b. A number of statistical analyses are recommended to consider for the data analysis. **(HSRB)**	No changes.	The statistical analysis is conducted by EPA using the study data after completion of the study. These comments do not apply to the protocol.
1c. A cutoff point for active ingredient volatility should be considered when using the data from this study. **(HSRB)**	No changes.	The suggestion applies to use by EPA of the study data rather than to protocol design.
1c. A painter's sock/hood should be considered in place of a painter's hat. **(HSRB)**	Addition of a dosimeter cloth sample under the painter's hat was added (Subject Preparation section p.31, Sample Collection section p.33, Appendix I p.108-119).	After discussion with EPA a painter's hat will continue to be used as it provides better protection and comfort for the subjects, and is expected to capture at least as much paint splatter as a sock/hood. EPA also requested an additional dosimeter cloth be placed under the hat to monitor any possible penetration of paint through the hat.
1c. Subjects should be offered protective booties for their shoes. **(HSRB)**	No changes.	Subjects were already offered the option of protective shoe covers if they want them (Informed Consent Study Procedure, Item 5).

Recommendation (Agency)	Protocol Modification	Comments
1d. The test room should be ventilated with an exhaust fan to provide fresh air throughout the monitoring event. **(HSRB)**	The ceiling exhaust fan use was updated to remain on during the entire ME (Monitoring Site section p.20, ME Activities section p.31, Field Study Personnel section p.37).	EPA initially requested the fan be turned off. CDPR and HSRB agreed it should be continuously on. Room airflow will be measured and reported (Monitoring Site section p.20).
1e. The collection of wall wipes to determine background levels was questioned. **(HSRB)**	No changes.	The protocol specifies that the wall wipes will be analyzed at the Principal Investigator's discretion. They were included to aid in interpretation of results related to subject contact with previously painted surfaces.
1e. Industry standard drying times should be considered. **(HSRB)**	No changes.	The paint label and industry were already consulted in developing the drying/re-entry time specified in the protocol.
1e. The paint should be used as manufactured without further dilution. **(HSRB)**	No changes.	The protocol specifies that for mid and high concentrations of BIT in paint a minimal volume of dipropylene glycol will be used as a vehicle for the BIT. No other dilution of the paint is specified or will be performed.
1e. The paint sheen should be specified. **(HSRB)**	No changes.	The paint specified in the protocol is a "Interior Latex Flat" per label included in Appendix A.
1f. A member suggested the EPA require measurements which will characterize exposure variation. A member suggested EPA clearly enumerate conservative and non-conservative factors embedded in the study design. **(HSRB)**	No changes.	These items are directed at EPA and no guidance to implement change was received from EPA.
1f. Recommend that the companion washing protocol should be implemented first and results evaluated prior to implementing this protocol. **(HSRB)**	No changes.	The washing protocol study (AEA08) results were summarized and sent to EPA for review. Clearance was given to move forward with the brush/roller study (AEA09).
Ethics Review Recommendations (pages 26-27)		

Recommendation (Agency)	Protocol Modification	Comments
1a. Study exclusions should be expanded to include allergies and sensitivities to BIT or chemical products. **(EPA)**	Exclusion criteria were updated (p. 26).	
1b. The board disagreed with stating there is "little" incremental risk from participation in the study. **(HSRB)**	The protocol was updated to state there is "limited" incremental risk from participation in the study. (Rationale for Use of Human Subjects section p. 11)	
1c. The board recommended that researchers consider offering subjects their choice of researcher sex to help them changes clothes. **(HSRB)**	No changes.	Subjects are informed that a same sex researcher will assist them and have the option to withdraw without penalty if they are uncomfortable. Potential legal liability and research staff comfort also need to be considered.
1d. The board recommended that the use of "applicators" in reference to subjects be changed to "appliers." **(HSRB)**	The word "applicators" was changed to "appliers" globally.	
1e. Clear definition of "good" health should be added. **(HSRB)**	No changes.	Subject questionnaire asks "Do you consider your general health good enough to participate in this study as described?" This question seems appropriate and clear.
1e. Exclusion criteria for health related issues should be evaluated. Informed consent should be updated as needed. **(HSRB)**	Updated exclusion criteria to remove diabetes and immunological suppression exclusions. Added an exclusion for "Other health conditions that make participation difficult or unsafe (e.g. broken bone)." The Informed Consent was updated to reflect the revised exclusion (Subject Selection section).	Health related exclusions are necessary to reduce risk to subjects from physical exertion required during the study activities.
1e. The board recommended that section 10 of the Informed Consent Study Procedure be updated to clarify any identifying features will not be shown in photos/videos. **(HSRB)**	The Informed Consent was updated to say "faces, tattoos, or other identifying features" will not be shown.	

Recommendation (Agency)	Protocol Modification	Comments
1e. The board recommended the words "from you" be added to section 12.a of the Informed Consent Study Procedure. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the word "some" be replaced with "any" in section 1 of the Informed Consent Risks. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the use of "tested" be updated to "take part" in the Informed Consent Costs and Payments section. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the Confidentiality section of the Informed Consent be updated to clarify any identifying features will not be shown in photos/videos. **(HSRB)**	The Informed Consent was updated to say "will not show your face or other identifying features (such as tattoos)."	
1f. The board recommended that researchers complete a course of human subjects protection within 3 years of study participation. **(HSRB)**	No changes.	Our standard operating procedures require completion of the NIH human subject protection course within 3 years of any work with subjects.
Other Items		
Researchers should offer a paint edger and paint cup to subjects and allow them to decide if they want to use these items. **(EPA)**	The protocol was modified to offer these items to subjects.	

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Tuesday, March 01, 2016 7:29 AM
To: Robert Testman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Thank you Rob.

I will certainly get back to you if there are any questions.

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Subject: RE: Revised AEA09 Protocol - Study Status Notification III
Attachments: SSN III.PDF

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

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Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

SchulmanIRB

Offices: Cincinnati, Ohio | Research Triangle Park, NC
www.sairb.com

Study Status Notification III

DATE: 3/3/2016

TO: Robert J. Testman, M.B.A.

FROM: Denisse Guzman, Board Liaison
Schulman IRB

RE: **Protocol#:** AEA09
IRB#: 201307317
Sponsor: Antimicrobial Exposure Assessment Task Force II
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The above-referenced item was *Conditionally Approved* at the 11/14/2013 Board meeting. On 3/3/2016, the Board reviewed the Revised Protocol dated 01/05/2016, accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) and site letter dated 02/29/2016 submitted in response to the Study Status Notification dated 12/04/2013

The purpose of this memo is to inform you that the response satisfies the condition of approval.

Board comments regarding the informed consent template are currently being consolidated. Upon completion, you will receive a draft of the informed consent template for your review and revision. **As a reminder, client-preference edits to the informed consent, including formatting, client version dates and other special requirements, should be applied prior to finalizing the document.**

Thank you for your assistance with the above-referenced study. You may contact me at 919-287-4900 if you have concerns or questions.

Please note: This is not an approval letter. The Schulman approval letter will be sent under separate cover.

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Thursday, March 03, 2016 10:47 AM
To: Robert Testman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review
Attachments: Draft IC 1 to Client.docx

Rob,

Please confirm receipt of this message.

Attached please find the DRAFT of the informed consent (IC), with the board's comments and tracked revisions incorporated. Should the sponsor/CRO have any feedback or revisions to the IC(s), please make the changes directly within the document or convey the feedback by inserting comments. The board's comments include requests for additional feedback or revision(s) to the IC by the sponsor/CRO. The track changes feature of Word is activated; please enter changes directly into the document(s) and return the revised document(s) to me for review. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please call or e-mail me with any questions about these documents.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Denisse Guzman
Sent: Thursday, March 3, 2016 12:59 PM
To: 'Robert Testman'
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Study Status Notification III

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

Denisse Guzman, CIM | Board Liaison

Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 1, 2016 2:26 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Please find attached a signed letter with a HSRB/EPA recommendations and response table as requested. Please let me now if you need any modifications or additional information.

Also, please note that the receipt of final approval from CDPR after IRB approval is consistent with the prior studies conducted for IIRB/SAIRB including the most recent AEA08 study. I would be happy to discuss this with you.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, February 26, 2016 2:16 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Robert,

After reviewing all the documentation submitted in response to the Study Status Notification II dated 12/04/2013, the following has been noted:

The SSN indicated that the Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval. The Board Reviewer acknowledges the Final Version of the protocol however as it appears this final version of the protocol is not being re-submitted to the HSRB for review and approval, we require a signed Administrative Letter listing the HSRB recommendations bearing directly on this protocol for this study (1.a-f- pages 19-21) and the EPA Recommendations (1.a- f- pages 26-29) as outlined in the letter to the EPA from the HSRB dated June 25, 2014 for the AEAO9 study. (similar to the table submitted to the CDPR with the DPR review comments and the responses/edits to each comment).

In addition, please note that this condition may need to go back to the full Board for review and further discussion given that an approval letter from CDPR will not be available.

Please feel free to contact me should you have any questions.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
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dguzman@sairb.com |Visit us at http://www.sairb.com
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 22, 2016 3:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM

To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

~~November 7, 2013~~

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Draft 1 to the Client 03/03/2016 DG

INFORMED CONSENT FORM

Study Title: (Protocol ~~120463~~AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

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We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman ~~Associates~~ Institutional Review Board~~, Inc.~~ (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency ~~(or~~ EPA~~)~~. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II ~~(AEATF)~~. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label.

We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical-based products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

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If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

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Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air

sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

~~9~~8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

~~10~~9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

~~11~~10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

~~12~~11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks
If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

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You do not waive (give up) any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. ~~This may indirectly benefit you and others when you do painting.~~ You may ~~also~~ benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying

for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman ~~Associates Institutional Review Board, Inc.~~IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Draft 1 to the Client 03/03/2016 DG

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

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~~November 7, 2013~~

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Draft 1 to the Client 03/03/2016 DG

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman ~~Associates Institutional Review Board, Inc.~~ IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time.~~,~~

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or ~~(~~(949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____ **Formatted:** Font: 12 pt
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

BOARD COPY

Megan Boatwright

From: Robert Testman
Sent: Thursday, March 03, 2016 10:57 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

I have received the message and will review the IC shortly.

Thanks!
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, March 3, 2016 10:47 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Rob,

Please confirm receipt of this message.

Attached please find the DRAFT of the informed consent (IC), with the board's comments and tracked revisions incorporated. Should the sponsor/CRO have any feedback or revisions to the IC(s), please make the changes directly within the document or convey the feedback by inserting comments. The board's comments include requests for additional feedback or revision(s) to the IC by the sponsor/CRO. The track changes feature of Word is activated; please enter changes directly into the document(s) and return the revised document(s) to me for review. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please call or e-mail me with any questions about these documents.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Denisse Guzman
Sent: Thursday, March 3, 2016 12:59 PM
To: 'Robert Testman'
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Study Status Notification III

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 1, 2016 2:26 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Please find attached a signed letter with a HSRB/EPA recommendations and response table as requested. Please let me now if you need any modifications or additional information.

Also, please note that the receipt of final approval from CDPR after IRB approval is consistent with the prior studies conducted for IIRB/SAIRB including the most recent AEA08 study. I would be happy to discuss this with you.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, February 26, 2016 2:16 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Robert,

After reviewing all the documentation submitted in response to the Study Status Notification II dated 12/04/2013, the following has been noted:

The SSN indicated that the Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval. The Board Reviewer acknowledges the Final Version of the protocol however as it

appears this final version of the protocol is not being re-submitted to the HSRB for review and approval, we require a signed Administrative Letter listing the HSRB recommendations bearing directly on this protocol for this study (1.a-f-pages 19-21) and the EPA Recommendations (1.a- f- pages 26-29) as outlined in the letter to the EPA from the HSRB dated June 25, 2014 for the AEAO9 study. (similar to the table submitted to the CDPR with the DPR review comments and the responses/edits to each comment).

In addition, please note that this condition may need to go back to the full Board for review and further discussion given that an approval letter from CDPR will not be available.

Please feel free to contact me should you have any questions.

Regards,

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Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

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Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
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Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Robert Testman
Sent: Thursday, March 03, 2016 3:57 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review
Attachments: Draft IC 1 to Client reviewed.docx

Hi Denisse,

Please find attached the reviewed ICF. The board suggested changes are fine. I also made a suggested change to p3 from "chemical-based products" to "chemical products". This change was suggested by HSRB in the protocol and should have been made here as well. I also changed "SAIRB" to "Schulman IRB" in two places on p.9 to be consistent with the other changes. Thanks for getting this out to me quickly.

Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, March 3, 2016 10:47 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

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Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

~~November 7, 2013~~

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Draft 1 to the Client 03/03/2016 DG

INFORMED CONSENT FORM

Study Title: (Protocol ~~120463~~AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

BOARD COPY

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman ~~Associates~~ Institutional Review Board~~, Inc.~~ (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency ~~(~~or EPA~~)~~. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II ~~(AEATF)~~. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label.

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We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection
To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical ~~-based~~ products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

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If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

BOARD COPY

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air

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sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

~~9~~8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

~~10~~9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

~~11~~10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

~~12~~11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

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6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

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You do not waive (give up) any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. ~~This may indirectly benefit you and others when you do painting.~~ You may ~~also~~ benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying

for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman ~~Associates Institutional Review Board, Inc.~~IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. ~~SAIRB~~Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the ~~SAIRB, Inc.~~Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

BOARD COPY

~~November 7, 2013~~

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman ~~Associates Institutional Review Board, Inc.~~ IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time.~~,~~

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or ~~-~~(949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____ **Formatted:** Font: 12 pt
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

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Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Friday, March 04, 2016 9:02 AM
To: Robert Testman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review
Attachments: Draft IC 1.docx

RE: Informed Consent (IC) Approval
NUMBER OF ICs: 1[] **DRAFT #1**
Protocol #: AEA09
Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).
IRB#: 201307317
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Hello Rob,

Attached you will find a clean copy of the latest draft of the informed consent for this study. If you agree that the draft informed consent is complete and accurate as written, please indicate this by typing your name and date in the space below. If not, please forward your requested changes to me for review.

Please ensure Sponsor/CRO edits to the informed consent, including your versioning (if applicable), formatting, and other special requirements are completed prior to submitting your acceptance.

Schulman will add the Schulman version date at the bottom left margin of each page to reflect the date on which Schulman accepted the final revisions to the template IC.

FOR SPONSOR/CRO USE:

Sponsor/CRO (or authorized designee) reviewed the draft informed consent(s) and agrees they are complete and accurate as written.

Click here to enter text. Click here to enter text.
Typed Name of Sponsor/CRO Representative or Designee **Date**

FOR SCHULMAN INTERNAL PURPOSES ONLY:

Final Version Date/ Staff Member Initials: Click here to enter text.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
0 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com

Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, March 3, 2016 6:57 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

Please find attached the reviewed ICF. The board suggested changes are fine. I also made a suggested change to p3 from "chemical-based products" to "chemical products". This change was suggested by HSRB in the protocol and should have been made here as well. I also changed "SAIRB" to "Schulman IRB" in two places on p.9 to be consistent with the other changes. Thanks for getting this out to me quickly.

Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, March 3, 2016 10:47 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Rob,

Please confirm receipt of this message.

Attached please find the DRAFT of the informed consent (IC), with the board's comments and tracked revisions incorporated. Should the sponsor/CRO have any feedback or revisions to the IC(s), please make the changes directly within the document or convey the feedback by inserting comments. The board's comments include requests for additional feedback or revision(s) to the IC by the sponsor/CRO. The track changes feature of Word is activated; please enter changes directly into the document(s) and return the revised document(s) to me for review. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please call or e-mail me with any questions about these documents.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
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From: Denisse Guzman
Sent: Thursday, March 3, 2016 12:59 PM
To: 'Robert Testman'
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Study Status Notification III

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 1, 2016 2:26 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Please find attached a signed letter with a HSRB/EPA recommendations and response table as requested. Please let me now if you need any modifications or additional information.

Also, please note that the receipt of final approval from CDPR after IRB approval is consistent with the prior studies conducted for IIRB/SAIRB including the most recent AEA08 study. I would be happy to discuss this with you.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, February 26, 2016 2:16 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Robert,

After reviewing all the documentation submitted in response to the Study Status Notification II dated 12/04/2013, the following has been noted:

The SSN indicated that the Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB)

indicating review and approval. The Board Reviewer acknowledges the Final Version of the protocol however as it appears this final version of the protocol is not being re-submitted to the HSRB for review and approval, we require a signed Administrative Letter listing the HSRB recommendations bearing directly on this protocol for this study (1.a-f- pages 19-21) and the EPA Recommendations (1.a- f- pages 26-29) as outlined in the letter to the EPA from the HSRB dated June 25, 2014 for the AEAO9 study. (similar to the table submitted to the CDPR with the DPR review comments and the responses/edits to each comment).

In addition, please note that this condition may need to go back to the full Board for review and further discussion given that an approval letter from CDPR will not be available.

Please feel free to contact me should you have any questions.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 22, 2016 3:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

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INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

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We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label.

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We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection
To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

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If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

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Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air

BOARD COPY

sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

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d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

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6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study

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If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

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Megan Boatwright

From: Robert Testman
Sent: Friday, March 04, 2016 11:19 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

This version looks good to me.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, March 4, 2016 9:02 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

RE: Informed Consent (IC) Approval
NUMBER OF ICs: 1[] **DRAFT #1**
Protocol #: AEA09
Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).
IRB#: 201307317
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Hello Rob,

Attached you will find a clean copy of the latest draft of the informed consent for this study. If you agree that the draft informed consent is complete and accurate as written, please indicate this by typing your name and date in the space below. If not, please forward your requested changes to me for review.

Please ensure Sponsor/CRO edits to the informed consent, including your versioning (if applicable), formatting, and other special requirements are completed prior to submitting your acceptance.

Schulman will add the Schulman version date at the bottom left margin of each page to reflect the date on which Schulman accepted the final revisions to the template IC.

FOR SPONSOR/CRO USE:

Sponsor/CRO (or authorized designee) reviewed the draft informed consent(s) and agrees they are complete and accurate as written.

Robert Testman — March 4, 2016
Typed Name of Sponsor/CRO Representative or Designee — **Date**

FOR SCHULMAN INTERNAL PURPOSES ONLY:

Final Version Date/ Staff Member Initials: Click here to enter text.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, March 3, 2016 6:57 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

Please find attached the reviewed ICF. The board suggested changes are fine. I also made a suggested change to p3 from "chemical-based products" to "chemical products". This change was suggested by HSRB in the protocol and should have been made here as well. I also changed "SAIRB" to "Schulman IRB" in two places on p.9 to be consistent with the other changes. Thanks for getting this out to me quickly.

Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, March 3, 2016 10:47 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Rob,

Please confirm receipt of this message.

Attached please find the DRAFT of the informed consent (IC), with the board's comments and tracked revisions incorporated. Should the sponsor/CRO have any feedback or revisions to the IC(s), please make the changes directly within the document or convey the feedback by inserting comments. The board's comments include requests for additional feedback or revision(s) to the IC by the sponsor/CRO. The track changes feature of Word is activated; please enter changes directly into the document(s) and return the revised document(s) to me for review. Please provide rationale or protocol reference in support of any significant IC revisions to facilitate the review of your request.

Please call or e-mail me with any questions about these documents.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Denisse Guzman
Sent: Thursday, March 3, 2016 12:59 PM
To: 'Robert Testman'
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Study Status Notification III

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
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dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 1, 2016 2:26 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Please find attached a signed letter with a HSRB/EPA recommendations and response table as requested. Please let me now if you need any modifications or additional information.

Also, please note that the receipt of final approval from CDPR after IRB approval is consistent with the prior studies conducted for IIRB/SAIRB including the most recent AEA08 study. I would be happy to discuss this with you.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, February 26, 2016 2:16 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Robert,

After reviewing all the documentation submitted in response to the Study Status Notification II dated 12/04/2013, the following has been noted:

The SSN indicated that the Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval. The Board Reviewer acknowledges the Final Version of the protocol however as it appears this final version of the protocol is not being re-submitted to the HSRB for review and approval, we require a signed Administrative Letter listing the HSRB recommendations bearing directly on this protocol for this study (1.a-f- pages 19-21) and the EPA Recommendations (1.a- f- pages 26-29) as outlined in the letter to the EPA from the HSRB dated June 25, 2014 for the AEAO9 study. (similar to the table submitted to the CDPR with the DPR review comments and the responses/edits to each comment).

In addition, please note that this condition may need to go back to the full Board for review and further discussion given that an approval letter from CDPR will not be available.

Please feel free to contact me should you have any questions.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 22, 2016 3:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
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Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Friday, March 04, 2016 12:20 PM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Thank you Rob.

I am confirming receipt of your completed IC review documentation; thank you. We will now begin preparing your approval documents.

After your approval documents have been prepared, management of this study within Schulman will be transitioned from me to Jeff Atlas, Operation Coordinator who will serve as your primary Schulman contact for this study. Jeff is copied on this e-mail. For any questions or assistance during the conduct of this study, please feel free to contact Jeff at JAtlas@sairb.com.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
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From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, March 4, 2016 2:19 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

This version looks good to me.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, March 4, 2016 9:02 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

RE: Informed Consent (IC) Approval
NUMBER OF ICs: 1[] **DRAFT #1**

Protocol #: AEA09
Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).
IRB#: 201307317
Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Hello Rob,

Attached you will find a clean copy of the latest draft of the informed consent for this study. If you agree that the draft informed consent is complete and accurate as written, please indicate this by typing your name and date in the space below. If not, please forward your requested changes to me for review.

Please ensure Sponsor/CRO edits to the informed consent, including your versioning (if applicable), formatting, and other special requirements are completed prior to submitting your acceptance.

Schulman will add the Schulman version date at the bottom left margin of each page to reflect the date on which Schulman accepted the final revisions to the template IC.

FOR SPONSOR/CRO USE:

Sponsor/CRO (or authorized designee) reviewed the draft informed consent(s) and agrees they are complete and accurate as written.

Robert Testman — March 4, 2016
Typed Name of Sponsor/CRO Representative or Designee — **Date**

FOR SCHULMAN INTERNAL PURPOSES ONLY:

Final Version Date/ Staff Member Initials: 03/04/2016 DG

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, March 3, 2016 6:57 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Hi Denisse,

Please find attached the reviewed ICF. The board suggested changes are fine. I also made a suggested change to p3 from "chemical-based products" to "chemical products". This change was suggested by HSRB in the protocol and should

have been made here as well. I also changed "SAIRB" to "Schulman IRB" in two places on p.9 to be consistent with the other changes. Thanks for getting this out to me quickly.

Rob

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Sent: Thursday, March 3, 2016 10:47 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol - Draft IC Review

Rob,

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Please call or e-mail me with any questions about these documents.

Regards,

Denisse Guzman, CIM | Board Liaison
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dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Denisse Guzman
Sent: Thursday, March 3, 2016 12:59 PM
To: 'Robert Testman'
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol - Study Status Notification III

Dear Robert,

Attached please find Study Status Notification III, which communicates to you the outcome of the Board review of your responses to the condition of approval as outlined in Study Status Notification II (dated 12/04/2013). We will now begin preparation of your IRB documents.

Board comments regarding the Informed Consent are currently being consolidated and will be forwarded to you for review upon completion.

Have a great day.

Denisse Guzman, CIM | Board Liaison
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dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 1, 2016 2:26 AM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Please find attached a signed letter with a HSRB/EPA recommendations and response table as requested. Please let me now if you need any modifications or additional information.

Also, please note that the receipt of final approval from CDPR after IRB approval is consistent with the prior studies conducted for IIRB/SAIRB including the most recent AEA08 study. I would be happy to discuss this with you.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Friday, February 26, 2016 2:16 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Robert,

After reviewing all the documentation submitted in response to the Study Status Notification II dated 12/04/2013, the following has been noted:

The SSN indicated that the Board requires submission of the final version of the protocol as well as accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval. The Board Reviewer acknowledges the Final Version of the protocol however as it appears this final version of the protocol is not being re-submitted to the HSRB for review and approval, we require a signed Administrative Letter listing the HSRB recommendations bearing directly on this protocol for this study (1.a-f- pages 19-21) and the EPA Recommendations (1.a- f- pages 26-29) as outlined in the letter to the EPA from the HSRB dated June 25, 2014 for the AEAO9 study. (similar to the table submitted to the CDPR with the DPR review comments and the responses/edits to each comment).

In addition, please note that this condition may need to go back to the full Board for review and further discussion given that an approval letter from CDPR will not be available.

Please feel free to contact me should you have any questions.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 22, 2016 3:39 PM
To: Denisse Guzman
Cc: Jeffrey Atlas; Danni Melita; Megan Boatwright
Subject: RE: Revised AEA09 Protocol

Hi Denisse,

Attached please find documentation of the HSRB Meeting report, and the initial CDPR review with our response. Please note that final CDPR approval will not be given until we have an IRB approval letter.

Please let me know if you would like any of the redlined documents or any other info to help in your review.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 22, 2016 8:33 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>; Danni Melita <DMelita@sairb.com>; Megan Boatwright <mboatwright@gplabs.com>
Subject: RE: Revised AEA09 Protocol

Hello Rob,

Thank you for the revised protocol and IC. However, the Board had also requested accompanying documentation from the California Department of Pesticide Regulation (CDPR) and Human Studies Review Board (HSRB) indicating review and approval.

Please advise.

Thank you.

Denisse Guzman, CIM | Board Liaison
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 | **Direct Line:** 919-287-4934 | **FAX:** 866-377-3359
dguzman@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 19, 2016 1:52 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: Revised AEA09 Protocol

Hi Jeff,

Please find attached the final version of the AEA09 protocol. We do need SAIRB to prepare Spanish translation of the ICF, subject self-reporting form, script, and newspaper ad. I am attaching a separate word document with the ICF for your convenience, however it is identical to that in the protocol appendices. If you would like a redlined version of the protocol showing changes I can provide that. Please let me know if you have any questions.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Monday, March 7, 2016 11:48 AM
To: Robert Testman <rtestman@gplabs.com>
Subject: INITIAL APPROVAL documents posted for Protocol AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**INITIAL APPROVAL**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Initial Approval Letter	Mar 07, 2016
	Initial Informed Consent	
	Initial Approval Comparison IC	

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.com

APPROVED: 11/14/2013
EXPIRATION DATE: 11/09/2016

March 04, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Initial Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:		
• **Protocol dated 11/04/2013:**	**Full Board:**	**11/14/2013**
• **Protocol dated 01/05/2016:**	**Full Board:**	**03/03/2016**
• **Site Letter dated 02/29/2016**	**Full Board:**	**03/03/2016**
• **Informed Consent:**	**Full Board:**	**03/03/2016**
The following information is specific to the investigator referenced above:		
• **Your site(s) was approved to conduct this study:**	**Full Board:**	**11/14/2013**
• **Site specific Informed Consent(s) finalized by Schulman on:**		**03/04/2016**

The Board approved the items listed above. You must use only the "Schulman Approved" informed consent(s).

NOTE: It is the responsibility of the Principal Investigator to ensure that required subsequent reviews by EPA, by the Human Studies Review Board (HSRB,) and if the research is to be conducted in California, by the California Department of Pesticide Regulation (CDPR) have been completed before initiation of the study. Changes have also been made to the informed consent to reflect the above noted revisions.

NOTE: The Board initially conditionally approved this research study on 11/14/2013 and has since conditionally re-approved it on 11/13/2014 and 11/10/2015 pending receipt of the responses to satisfy the condition(s) of approval. Therefore, the "Expiration Date" identified in the box above is consistent with the last conditional re-approval granted by the Board on 11/10/2015.

In order to participate in this research study, an adult study subject must provide his/her own written consent for participation. An adult subject is an individual who has attained the legal age for consent to treatments or the procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. The Board **has not approved** consent of subjects via a legally authorized representative for this study. Accordingly, a subject must not be enrolled in this research study via the consent of a legally authorized representative.

This approval will last twelve (12) months.

If the study is expected to last beyond the approval period, re-approval must be requested at least eight (8) weeks prior to the expiration date noted above. The first report to the Board on the status of this study is due ten (10) months from the approval date or at the time the study closes, whichever is earlier. The appropriate form is available at www.sairb.com.

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

As a California site, you are required by California's Health & Safety Code §24173 to provide the subject or subject's conservator or guardian, or other representative, as specified in §24175, with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment. The copy must be signed and dated by the subject or the subject's conservator or guardian, or other representative. Please visit our IRB Forms page to download a copy of the California Bill of Rights.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

The current Board Membership List is available to download at the link on SiteAccess at www.sairb.com. Please maintain the appropriate Board Membership List with your study binder.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

MEMO

FROM: Schulman IRB ("Schulman" or the "Board")
SUBJECT: Word versions of consent(s)

Within this zipped folder please find the Word version(s) of the currently approved site-specific IC document.

Schulman is providing the Word version(s) of the IC document for the purpose of obtaining translation and/or facilitating future IC edits deemed necessary secondary to an Amendment, updated Investigator's Brochure (IB), etc.

Thank you.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

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IRB#201307318
DATE: March 4, 2016

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

SCHULMAN APPROVED
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Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

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5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

    When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks
If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

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3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

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Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

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Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

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5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

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11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks
If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

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Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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DATE: March 4, 2016

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

INFORMED CONSENT FORM

~~Study Title:~~ ~~Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wash~~
Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:

Robert J. Testman, M.B.A.~~Megan T. Boatwright~~
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue~~,~~ Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field ~~Research Associates~~Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue~~,~~ Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue~~, Suite 105~~
~~Fresno, CA 93722~~
~~Phone: 559-275-9091~~

~~**Field Location:**~~ ~~Golden Pacific Laboratories, LLC~~
~~4720 W. Jennifer Avenue,~~ Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

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24-Hour Phone Number: ~~559-917-1736 (Megan Boatwright~~949-939-3585 (Robert Testman)

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IRB#201307318
DATE: March 4, 2016

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

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Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical ~~is removed from the surface of~~may reach your ~~palm~~skin when ~~a small amount of~~ you paint with interior latex paint ~~or rubbing (isopropyl) alcohol containing the chemical is applied to each of your hands and allowed to sit for 45 minutes.~~using a brush and roller. We will measure how much chemical ~~can be removed from your hands by rinsing and scrubbing your hand with a gauze wipe soaked with a solution of isopropyl alcohol (IPA)~~gets on the clothing you wear and ~~water~~on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate ~~how much chemical people are exposed to when painting~~the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

~~The paint in this study will be Sherwin-Williams Interior Latex Paint. This is a paint product that is sold in many stores. The product is used to paint walls, ceilings, doors, and trim inside of homes and businesses. It contains a small amount of a chemical called BIT, which helps keep bacteria from growing in the paint can.~~

A group of companies that make products to reduce ~~mold and bacteria~~microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright~~, Thomas Moate~~ and Natan Chavez are with Golden Pacific Laboratories. ~~Megan Boatwright~~Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. ~~-~~This is a commonly used paint product. This product is used to paint walls~~, ceilings, doors,~~ and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We ~~will also test a solution of~~have added some extra BIT ~~in rubbing alcohol.~~to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label ~~for the paint.~~. We

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will also give you the Material Safety Data Sheet or "MSDS" for ~~the paint and the BIT chemical~~this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a ~~government~~Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer. ~~You cannot participate;~~ if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, ~~or~~ paint products~~;~~, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have ~~severe diabetes; if you have a suppressed immune system such as with an organ transplant or active chemotherapy; or if you have~~ heart or breathing problems; or if you have other health problems that would make participation difficult.

~~Twenty~~Eighteen to twenty-four people will be in this study~~, and eight~~. We will sign up a few more people ~~will be selected as alternates~~than we need, in case anyone can't participate on the day of the test.

We will do the study ~~at Golden Pacific Laboratories at~~ in an unoccupied building here~~,4720 W. Jennifer Ave., Suite 105,~~ in Fresno County. You can ~~be~~participate in the study only once. If you are ~~an~~the alternate on one day and are not selected, you may be able to be in the study on another day.

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Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright~~,~~ or ~~the laboratory General Manager,~~ Thomas Moate~~,~~; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we

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IRB#201307318
DATE: March 4, 2016

will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

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DATE: March 4, 2016

Study Procedure

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~~1. If you are selected as one of the subjects, you will go to this location in Fresno: Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, at the time you have been told and meet the research team.~~

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

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2. ~~Megan Boatwright~~Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the ~~study~~test each female volunteer will go to a private area and will be given a ~~urine~~ pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

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4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

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DATE: March 4, 2016

5. ~~We~~Someone of your own gender will ~~ask~~show you to ~~be seated in a chair~~a clean, private changing area, and ~~make sure~~help you ~~are comfortable~~get ready for the study. We will ask you to ~~place your hands upright on the table in front of you. We will place a small amount of paint or rubbing alcohol on the palm of each of~~take off your ~~hands~~street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and ~~then ask you to keep your hands upright on~~ long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the ~~table for 45 minutes. After 45 minutes we will~~ long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If

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you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

b. The researcher will scrub your hands with ~~gauze pads~~cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same ~~mixture~~solution, and save the rinse ~~water.~~solution;

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~~6.~~

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected ~~the hand wipe sample~~all these samples, you will ~~wash your hands~~dress again ~~with soap and water~~in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

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Risks

If you are in this study you would be exposed to ~~few~~several kinds of risks:

1. Risk of a reaction to the latex paint~~,~~ or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary ~~itching~~eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. ~~A very small amount, less than a teaspoon, is being used therefore these risk are minimal.~~You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before~~,~~ be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any ~~other discomfort,~~of the paint in your eye, stop painting right away and tell a researcher.

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2. Risk of ~~skin irritation~~discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

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3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from ~~the rubbing~~ alcohol ~~and water mixture,~~wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands ~~that were~~ or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too ~~small to see before~~hot. We will monitor the temperature and humidity during the test, and will stop the study ~~started~~if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

~~2.~~6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

~~3.~~7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

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Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. -The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, ~~Megan Boatwright~~Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

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Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits

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You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. ~~This may indirectly benefit you and others when you do painting.~~ You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-~~microbial~~bacterial products for paint on the market.

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Questions about this Study

If you have questions, you can ask them at any time; before, during, or after the study. Just ask ~~Megan Boatwright~~Robert Testman or any other member of the research team.

~~This study was reviewed by Schulman Associates Independent Review Board, Inc. (SAIRB).~~ If you have any questions about your rights as a ~~volunteer,~~ research subject, and/or concerns or complaints regarding this research study, you should write to ~~report a problem in the study, please~~Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call ~~SAIRB~~ toll-free ~~at~~ 1-~~(~~888~~)~~-557-2472~~. You can reach them during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST~~ or from 5 am to 3 pm Pacific Time~~, Monday through Friday. SAIRB~~. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the ~~SAIRB, Inc.~~Schulman IRB website - www.sairb.com.

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Costs and Payment

It will cost you nothing to participate in this study. At the end of ~~each~~the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually ~~tested~~take part.

Confidentiality

We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

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We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

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Right to Withdraw

You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study

~~Megan Boatwright~~Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. ~~She~~He might remove you if, for example:

- ~~She~~He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

~~1.~~ 1. To be told the purpose of the study;
~~2.~~ 2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
~~3.~~ 3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
~~4.~~ 4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
~~5.~~ 5. To be told the alternatives to participating in the study;
~~6.~~ 6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
~~7.~~ 7. To be told what sort of medical treatment is available if any complications arise;
~~8.~~ 8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
~~9.~~ 9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

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~~You may contact the~~ If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman ~~*Associates Independent Review Board (SAIRB),*~~ IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll ~~-~~free ~~*at (*~~1-888~~*)* -557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time, ~~if you have a question about your rights as a research subject.~~

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If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: ~~Megan Boatwright~~Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

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Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

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Date/Time: _____ _____
~~Megan Boatwright~~
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

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Megan Boatwright

From: Robert Testman
Sent: Tuesday, March 08, 2016 3:30 PM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: spanish translation for AEA09

Hi Jeff,

Now that the AEA09 protocol is approved we need to get a Spanish translation of the informed consent, subject self-reporting form, newspaper ad, and subject invite to participate script. These should be similar to the AEA08 versions, but there are changes to all. Can you arrange for the translation?

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Wednesday, March 09, 2016 5:40 AM
To: Robert Testman
Cc: Megan Boatwright
Subject: RE: Spanish translation for AEA09

Hi Rob,

The IC was sent for translation on Monday. I will request the additional documents be translated as well.

Best Regards,

Jeff Atlas

Jeff Atlas, BS, CIP | Operations Coordinator I
Schulman IRB
10 Laboratory Drive | Suite 200 | Research Triangle Park, NC 27709
Office: 919-287-4900 |Direct: 919-287-4938 | FAX: 866-377-3359
jatlas@sairb.com |Visit us at http://www.sairb.com
Please consider the environment before printing this e-mail.

Follow Schulman on Twitter: **@SchulmanIRB**
Connect with Schulman on LinkedIn: https://www.linkedin.com/company/schulman-irb

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, March 8, 2016 6:30 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Megan Boatwright <mboatwright@gplabs.com>
Subject: spanish translation for AEA09

Hi Jeff,

Now that the AEA09 protocol is approved we need to get a Spanish translation of the informed consent, subject self-reporting form, newspaper ad, and subject invite to participate script. These should be similar to the AEA08 versions, but there are changes to all. Can you arrange for the translation?

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Thursday, March 10, 2016 12:09 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: TRANSLATION documents posted for AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**TRANSLATION**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**
Posted Date:	**03/10/2016**

PI Name	**Document Type**	**Language**
Testman, Robert J.	Initial ICD Packet Translation	Spanish

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.com

March 10, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Translated Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

- Spanish Informed Consent Form, approved on March 4, 2016

The Board is in receipt of the enclosed certified Spanish translation(s) of the Informed Consent(s) for the above protocol. The enclosed translated item(s) listed above, reflect(s) the approval date of the latest "Schulman-Approved" English version(s).

cvh

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yyyy format

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA09) Estudio para medir la potencial exposición dérmica y por inhalación durante la aplicación con brocha y rodillo de una pintura de látex que contiene un producto pesticida antimicrobiano en superficies interiores

Investigador principal:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Coordinadores de campo:

Megan T. Boatwright (inglés)
Coordinadora de campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Natan R. Chavez (inglés y español)
Asociado de investigaciones en el campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate, M.S. (inglés)
Asociado de investigaciones en el campo
Gerente general
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Instalaciones en el campo: (Lugar de la entrevista para el consentimiento informado del sujeto)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Lugar de los procedimientos del estudio)
Un edificio comercial vacante en Fresno County, CA

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono las 24 horas: 949-939-3585 (Robert Testman)

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

Le estamos pidiendo que considere participar en un estudio de investigación porque tiene experiencia pintando con brocha y rodillo. Su participación es voluntaria. Este formulario de consentimiento informado explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar y comentarlo con sus amigos o familia antes de decidir si desea participar en el estudio. Si tiene alguna pregunta o si no entiende algo de este formulario, pida a uno de nosotros que se lo expliquemos. Si prefiere hablar en español, por favor indíquelo así. Le podemos explicar el estudio en inglés o en español.

Schulman Institutional Review Board, Inc. (Schulman), un comité institucional de revisión, ha aprobado la información que contiene este documento de consentimiento y ha autorizado al médico del estudio para que efectúe el estudio. Un comité institucional de revisión (Institutional Review Board o IRB, por sus siglas en inglés) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado que usted participe en el estudio. Es a usted a quien corresponde examinar la información de este documento de consentimiento y, seguidamente, decidir si desea participar en el estudio.

Finalidad de este estudio

Golden Pacific Laboratories está llevando a cabo esta investigación. Nos gustaría saber cuánta sustancia química puede caer en su piel cuando aplica una pintura de látex para interiores con una brocha y un rodillo. Mediremos la cantidad de la sustancia química que le cae en la ropa que usa y en sus manos, cara y cuello. Le pediremos que pinte superficies interiores como paredes, cielorraso y molduras. También nos gustaría saber la cantidad de la sustancia química que se encuentra en el aire que usted respira durante el estudio. Esta información se proporcionará a la Agencia de Protección Ambiental de EE. UU. o EPA por sus siglas en inglés. La EPA usará esta información para evaluar los niveles de exposición a las sustancias químicas de la pintura de este estudio y de otras pinturas similares a ella.

Un grupo de compañías que fabrica productos para reducir la cantidad de microorganismos paga este estudio. Este grupo de compañías se llama Grupo Operativo de Evaluación de la Exposición a Agentes Antimicrobianos II (Antimicrobial Exposure Assessment Task Force II). La EPA ha registrado estos productos como pesticidas.

Robert Testman, Thomas Moate, Megan Boatwright y Natan Chavez trabajan en Golden Pacific Laboratories. Robert Testman está a cargo del estudio. Thomas Moate, Megan Boatwright y Natan Chavez también están capacitados para explicar el estudio y contestar cualquier pregunta que pudiera tener. Natan Chavez habla español. Él será el principal investigador de habla hispana.

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Producto de prueba
El producto de prueba es una pintura de látex para interiores de Sherwin-Williams. Esta es una pintura de uso común. Este producto se usa para pintar paredes y molduras en casas y empresas. El producto de prueba contiene una sustancia química conocida como BIT que ayuda a evitar el crecimiento bacteriano. Hemos añadido una cantidad adicional de BIT a la pintura para este estudio, pero no más que la necesaria para evaluar su exposición a este producto. Se le entregará una copia de la etiqueta del producto. También le daremos la hoja de datos de seguridad del material, o "MSDS" por sus siglas en inglés, de este producto, si lo desea.

Selección de sujetos
Para participar en el estudio debe estar sano y tener 18 años de edad o más. Debe poder leer y hablar inglés o español. Necesitará comprobar su edad con un documento de identidad con fotografía expedido por el gobierno, como una licencia para conducir o un pasaporte. Debe tener experiencia pintando con brocha y rodillo, pero no ser pintor profesional. Debe querer participar en este estudio. Debe estar dispuesto a firmar este consentimiento, el formulario Declaración de derechos de los sujetos participantes en experimentos y una ficha de calificación. Le pediremos que proporcione cierta información personal adicional y que siga las instrucciones de los investigadores.

No podrá participar en esta investigación si es empleado o cónyuge de un empleado de Golden Pacific Laboratories, de cualquiera de las compañías que pagan esta investigación, del Consejo Americano de Química (American Chemistry Council) o de un fabricante de pinturas; si está embarazada o lactando; si ha tenido reacciones alérgicas al jabón, alcohol isopropílico, productos de pintura o productos químicos (incluido el BIT); si tiene psoriasis, eccema, llagas o cortaduras abiertas en la piel; si tiene problemas cardiacos o respiratorios; o si tiene otros problemas médicos que dificultaran su participación.

En este estudio participarán entre dieciocho y veinticuatro personas. Inscribiremos a unas pocas personas más que las que necesitamos en caso de que alguien no pueda participar el día de la prueba.

Haremos el estudio en un edificio vacante aquí en Fresno County. Puede participar en el estudio solamente una vez. Si en un día usted es el suplente y no se lo selecciona, es posible que pueda participar en el estudio otro día.

Inscripción en el estudio
Hoy se va a reunir con el investigador principal, Robert Testman, con los coordinadores de campo, Megan Boatwright o Thomas Moate; o si lo prefiere, con un investigador que habla español. Ellos le darán más información sobre lo que debe esperar durante el estudio y lo que se espera de usted. También contestarán cualquier pregunta que tenga sobre el estudio. Usted puede decidir hoy si desea participar en el estudio o puede llevarse a casa este formulario para conversarlo con su familia y amigos antes de tomar su decisión.

Le preguntaremos sobre su experiencia como pintor y sobre su salud general. Le preguntaremos su nombre y edad, y si tiene alguna afección en la piel de sus manos. Si decidimos que es apto, y si usted decide que quiere participar en el estudio, le pediremos que firme este consentimiento informado y el formulario Declaración de derechos de los sujetos participantes en experimentos. Luego le preguntaremos su estatura y peso y la talla de su ropa.

Si lo inscribimos en el estudio, le pediremos que venga al sitio del estudio cierto día y a cierta hora. Lo llamaremos un día antes para recordarle y asegurarnos de que aún desea participar en el estudio. También le pediremos que se asegure de tomar una ducha o darse un baño antes de ir al sitio del estudio.

Procedimiento del estudio
Si se lo selecciona, hará la prueba en cuartos pequeños construidos dentro de un edificio vacante ubicado en Fresno County. La prueba durará 3 o 4 horas en un día. Después de que llegue se pondrá ropa especial para la prueba y se le colocarán dos bombas pequeñas para tomar muestras del aire que respira. Luego le pediremos que pinte las paredes, los cielorrasos, los zócalos, la moldura de la ventana y la moldura de la puerta con una brocha y un rodillo de pintura. Le proporcionaremos todo el equipo que usará, como una brocha, un rodillo, una bandeja para el rodillo, trapos para pintura, etc. Usted pintará como lo hace normalmente cuando pinta una habitación en su propia casa. Se le pedirá que use aproximadamente dos galones de pintura en varios cuartos. Puede descansar entre cuartos si lo necesita. El tiempo real que pasará pintando puede ser de varias horas. Después recogeremos la ropa especial que usó, usted se pondrá su propia ropa, recibirá su pago y se irá.

Esto es exactamente lo que sucederá.

1. El día del estudio usted irá al sitio del estudio a la hora que se le dijo, y se reunirá con el equipo de estudio.

2. Robert Testman y el equipo de investigación revisarán con usted y con los otros participantes lo que sucederá, y usted tendrá otra oportunidad de hacer preguntas. Le recordaremos que en cualquier momento, antes o después de que comience el estudio, puede cambiar de parecer con respecto a su participación en el estudio. Todo lo que necesita hacer es decirnos que cambió de parecer. No sufrirá sanciones de ningún tipo si decide abandonar el estudio.

3. Dado que es importante que usted NO participe en este estudio si está embarazada, el día de la prueba cada voluntaria pasará a un área privada y recibirá un kit de prueba de embarazo como los que puede comprar en la farmacia. Una investigadora le explicará cómo usarlo y contestará sus preguntas. Después de hacerse la prueba le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no se le preguntará la razón y no se registrarán los resultados de la prueba. Se le pagarán $100 por venir al sitio de la prueba y entonces podrá irse. Si desea permanecer en el estudio, una investigadora capacitada verificará los resultados con usted. Nadie aparte de usted verá los resultados pero nosotros haremos una nota indicando que la prueba se hizo.

4. Antes de que comience la prueba se lavará las manos y la cara con jabón Ivory y agua, y se las secará con toallas de papel. Revisaremos sus manos para asegurarnos de que no tiene cortaduras, raspaduras ni ninguna afección que pudiera aumentar el riesgo de que sufra problemas en la piel durante la prueba.

5. Una persona de su mismo sexo lo llevará a un área limpia y privada para que se cambie y se prepare para el estudio. Le pediremos que se quite su ropa excepto la ropa interior. Luego se pondrá calzoncillos largos de algodón (*long johns*), una camiseta de algodón de mangas largas y pantalones largos de algodón. Nosotros le proporcionaremos toda esta ropa. Es posible que tengamos que recortar el reborde de las mangas o de las piernas de los calzoncillos largos para que no sobresalgan. Colocará su propia ropa y sus objetos de valor en un área de almacenamiento bajo llave, y usted conservará la llave. Usará su propio calzado, pero si quiere le daremos cubiertas para evitar que le caiga pintura en los zapatos.

6. Le daremos una gorra de pintor y gafas de seguridad para que las use mientras pinta. Debe usar estos artículos mientras pinta con la brocha o el rodillo.

7. Le instalaremos en el cinturón, alrededor de su cintura, dos pequeñas bombas para muestreo de aire. Si no lleva cinturón le proporcionaremos uno para que lo use. Le colocaremos un pequeño tubo en el cuello de la camisa y lo conectaremos en una de las bombas. Instalaremos un pequeño tomador de muestras de aire en la otra bomba y lo colocaremos frente a usted con una pequeña correa alrededor de su pecho. Ambas bombas tomarán muestras del aire que respira mientras pinta. Cada bomba es del tamaño aproximado de un radio portátil. El tubo es del tamaño de un lápiz, y el tomador de muestras de aire es aproximadamente del tamaño de una bola de tenis.

8. Le mostraremos el equipo que usará para pintar, incluido el pequeño cubo que contiene la pintura, la brocha, el rodillo, la bandeja para el rodillo, el mango de extensión y los trapos para pintura. También contaremos con ribeteadores de pintura y pequeños vasos de pintura por si desea usarlos. Le preguntaremos si tiene alguna pregunta.

9. Lo llevaremos a uno de los cuartos pequeños en donde comenzará a trabajar. Encenderemos las bombas de aire que le colocamos y le pediremos que se ponga la gorra y las gafas de seguridad. Le entregaremos una lata de pintura cerrada que contiene pintura. Quitará la tapa de la lata de pintura con un abridor. Usará una brocha con la lata de pintura para pintar las molduras de una o más paredes. Verterá algo de pintura de la lata en la bandeja para el rodillo y pintará con el rodillo el cielorraso y las paredes. Cuando se termine la pintura de la lata, le daremos una lata nueva hasta que haya usado la cantidad asignada. Uno de nosotros lo observará mientras trabaja, anotando el tiempo que trabaja y la cantidad de superficie que pinta. También podemos tomar fotografías o grabar videos para mostrar lo que sucedió en el estudio, pero en el informe final, tales fotografías no mostrarán rostros, tatuajes ni otras características identificadoras. **Si no desea que se le tomen fotografías, no debe participar en este estudio.**

10. Le pediremos que aplique aproximadamente dos galones de pintura. Trabajará en tantos cuartos como sea necesario para usar la cantidad asignada de pintura. Puede tomar un breve descanso en cualquier momento que desee, tal como lo haría en el trabajo. No podrá fumar ni comer durante la prueba, pero puede consumir una bebida fría durante su descanso. Si necesita usar el baño, uno de los investigadores le limpiará sus manos antes de que vaya, para recoger cualquier pintura que pueda tener en ellas.

11. Cuando termine de pintar, un investigador de su mismo sexo lo llevará al área donde se cambia la ropa y le tomará muestras:

    a. El investigador le quitará la gorra de pintor, las bombas tomadoras de muestras de aire y el equipo.

    b. El investigador frotará sus manos con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua, se las enjuagará con la misma solución y guardará la solución del enjuague.

    c. El investigador le limpiará la cara y el cuello con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua para recoger cualquier pintura que pudiera tener en la piel.

    d. El investigador lo ayudará a quitarse los zapatos (y los calcetines si lo desea).

    e. El investigador lo ayudará a quitarse la camiseta y los pantalones y los guardará para analizarlos.

    f. El investigador lo ayudará a quitarse los calzoncillos largos y los guardará para analizarlos.

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Cuando hayamos tomado todas estas muestras, se vestirá otra vez con su propia ropa. Revisaremos sus manos antes de que se vaya para ver si las tiene enrojecidas o muestra otros signos de irritación. Le pagaremos $100 en efectivo y podrá irse.

Riesgos
Si participa el este estudio estaría expuesto a varias clases de riesgos:

1. El riesgo de una reacción a la pintura de látex o al ingrediente de pesticida (BIT) de la pintura. El contacto directo con la pintura puede causar enrojecimiento de los ojos, dolor e inflamación o irritación de la piel, de manera temporal, y la respiración del vapor puede causar tos e irritar su garganta. Usará gafas de seguridad para evitar que le caiga pintura en los ojos, y camiseta de manga larga y pantalones para evitar que le caiga pintura en la piel. También podría tener una reacción alérgica a la pintura. Pudiera sentirse mareado o tener dolor de cabeza. Si anteriormente ha tenido una reacción a un producto de pintura, asegúrese de decírnoslo. Si nota enrojecimiento o comezón, se siente mareado o piensa que le cayó pintura en los ojos, deje de pintar inmediatamente y dígaselo al investigador.

2. Riesgo de molestia Las bombas de aire instaladas en su cinturón y las mangueras de aire usadas para muestrear el aire que respira pueden causarle incomodidad. También pudiera resultarle incómodo usar dos capas de ropa.

3. Riesgo de lesiones Se le pedirá que use equipo para pintura y unas escaleras para pintar los cuartos. Si perdiera el equilibrio y cayera pudiera resultar herido. Si piensa que necesita ayuda para evitar lesionarse, o pudiera haberse lesionado, dígaselo a un miembro del equipo de investigación.

4. Riesgo de escozor causado por el lavado con alcohol y las toallitas El alcohol isopropílico diluido usado para frotar y enjuagar sus manos y limpiar su cara y cuello puede causarle escozor si tiene alguna cortadura o abrasiones en las manos o en la cara.

5. Riesgo de calor Como usará una capa adicional de ropa, pudiera tener demasiado calor. Supervisaremos la temperatura y la humedad durante la prueba, y detendremos el estudio si aumenta demasiado la temperatura para su seguridad. Si siente desvanecerse o demasiado calor, o está sudando mucho, deje de pintar inmediatamente y notifíquelo a un miembro del equipo de investigación.

6. Riesgo de sentir vergüenza Es posible que sienta vergüenza que un investigador esté presente mientras se cambia de ropa. Esto es necesario para asegurarnos de que la ropa le queda adecuadamente y que no se ensucie cuando termine la prueba. El investigador que lo ayudará será de su mismo sexo y será la única persona presente con usted. Usted usará su propia ropa interior en todo momento.

7. Si es mujer, le podría sorprender enterarse el día de la investigación que está embarazada. Solamente usted sabrá si los resultados de la prueba muestran que está embarazada, y no se registrarán estos resultados.

Riesgos desconocidos o imprevisibles
La participación en este estudio pudiera conllevar otros riesgos que desconocemos o que no podemos predecir. Si nos enteramos de algo nuevo que pudiera influenciar su decisión de participar, se lo notificaremos inmediatamente.

Lesiones relacionadas con la investigación
Si se lesiona o enferma mientras participa en el estudio, se le proporcionará atención en una instalación médica cercana. Si es necesario lo llevaremos ahí. AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no pague su propio seguro o el seguro de un tercero en el cual tenga cobertura. El investigador principal, en consulta con el profesional médico del sitio, decidirán si usted sufre una lesión o enfermedad que se debe a su participación en el estudio. Si dentro del período de 24 horas de su participación en el estudio experimenta una reacción en la piel u otro efecto adverso que usted cree que se relaciona con su participación en el estudio, debe buscar tratamiento médico y llamar al investigador principal, Robert Testman, a Golden Pacific Laboratories (559 275-9091) tan pronto como sea posible. Ningún expediente médico formará parte del estudio.

Al firmar este formulario no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio será porque usted quiere hacerlo. No recibirá un beneficio directo si decide participar y no sufrirá daños si decide no participar. Es su decisión.

Beneficios
Su participación en este estudio no le producirá beneficios directos. Lo que aprendamos de este estudio nos ayudará a asegurarnos de que los productos de pintura como la pintura de látex de Sherwin-Williams se puede usar con seguridad. Usted se pudiera beneficiar si pide sus resultados de este estudio, pues se puede enterar de cuánta pintura le cayó en el cuerpo en comparación con otros trabajadores que hicieron la misma tarea. Las personas que pagan el estudio también se beneficiarán del mismo, ya que ellos necesitan hacer este estudio para mantener en el mercado sus productos antibacterianos para pintura.

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Preguntas sobre este estudio
Si tiene preguntas, puede formularlas en cualquier momento, antes durante o después del estudio. Simplemente hágalas a Robert Testman o a cualquier otro miembro del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico. Schulman IRB está a cargo de proteger sus derechos. Puede encontrar más información sobre sus derechos y el papel de los investigadores en el sitio web de Schulman IRB, www.sairb.com.

Costos y pagos
No le costará nada participar en este estudio. Al final de la entrevista para el consentimiento informado se le pagarán $20 en efectivo por su tiempo y las inconveniencias de venir a nuestra oficina. Si se lo selecciona para el estudio y va al sitio del estudio asignado, se le pagarán $100 en efectivo cuando termine el día, independientemente de si participa o no.

Confidencialidad
Le daremos un número de ID especial para este estudio y registraremos e informaremos todos los datos usando este número. Solo conservaremos un registro que relacione su nombre con este número de ID, y lo guardaremos separado de otros datos, en un gabinete bajo llave. No lo identificaremos por su nombre ni de ninguna otra manera en los informes del estudio. Ninguna fotografía suya que se use en un informe de este estudio mostrará su cara ni ninguna otra característica que lo identifique (como tatuajes).

Restringiremos el acceso a los expedientes de este estudio a solo unas pocas personas. Pero las personas que pagan el estudio, las agencias gubernamentales que revisarán los informes, y SAIRB, Inc., que vigila su seguridad, pueden revisar los expedientes del estudio. Debido a esto no podemos garantizar completamente la confidencialidad. Puede obtener una copia de sus propios expedientes con el investigador principal si la solicita.

Derecho a retirarse del estudio
Puede retirarse de este estudio en cualquier momento, por cualquier motivo. Simplemente notifíquelo a cualquier miembro del equipo de investigación. Si decide no participar en este estudio o retirarse del mismo, no se lo penalizará de ninguna manera ni perderá ningún beneficio.

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Retiro del estudio
Robert Testman, el investigador principal a cargo de este estudio, puede retirarlo del estudio aunque usted desee permanecer en él. Lo pudiera retirar si, por ejemplo:

- Piensa que si usted permanece en el estudio correría riesgos.
- Usted no sigue las indicaciones de los investigadores.
- El estudio se detiene porque aumenta mucho la temperatura para continuar de forma segura, o por otra razón.

Si se lo retira del estudio o si se detiene todo el estudio, se le pagará de todas maneras por su tiempo e inconveniencias.

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FORMULARIO DECLARACIÓN DE DERECHOS DE LOS SUJETOS PARTICIPANTES EN EXPERIMENTOS

Los siguientes son los derechos de cualquier persona a la que se pide que participe en un estudio de investigación. Como sujeto de un experimento, tengo los siguientes derechos:

1. Que se me diga el propósito del estudio.
2. Que se me diga lo que me sucederá y si cualquiera de los procedimientos, pesticidas o dispositivos es diferente del que se utilizaría en la práctica normal.
3. Que se me informe acerca de los riesgos, efectos secundarios o malestares frecuentes e/o importantes, o de las cosas que me sucederán durante el estudio.
4. Que se me informe si puedo esperar algún beneficio de mi participación y, de ser así, cuál podría ser el beneficio.
5. Que se me digan las alternativas a participar en el estudio.
6. Que se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el curso del estudio.
7. Que se me diga qué tipo de tratamiento médico está disponible en caso de que surjan complicaciones.
8. Rehusarme absolutamente a participar o cambiar de parecer acerca de mi participación después de que el estudio haya comenzado. Esta decisión no afectará mi estado con mi empleador.
9. Recibir una copia del formulario de consentimiento firmado y fechado; y
10. No ser presionado cuando esté considerando si deseo participar en el estudio;

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico.

Si tiene otras preguntas, debe formularlas al investigador principal o a los investigadores del estudio.

Contactos telefónicos:

Investigador principal: Robert Testman (559) 275-9091 o (949) 939-3585

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

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Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de Derechos de los Sujetos, y todas mis preguntas han sido contestadas en un idioma que entiendo bien. Acepto voluntariamente participar en este estudio como sujeto de investigación. Al firmar este formulario no renuncio a ninguno de mis derechos legales. Recibiré mi propia copia de este formulario con todas las firmas.

Fecha y hora: _____ _____
Firma del sujeto

_____
Nombre del sujeto (en letra de imprenta)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

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CERTIFICATION OF TRANSLATION

Protocol Number: AEA09
IRB Number: 201307318
PI: Robert J. Testman, M.B.A.
Material Type (if applicable): Informed Consent
Description (if applicable):
This is to certify that this Spanish translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Diane Barrett

Translated from English source document approved 03/04/2016

Diane Barrett 03/10/2016

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Sent: Monday, March 14, 2016 2:08 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: TRANSLATION documents posted for AEA09 [Country:US]
Importance: High

Robert,

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PI Name	Document Type	Language
Testman, Robert J.	Recruitment / Study-Related Material Translation	Spanish

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Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.c

March 14, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Translated Recruitment/Study Related Materials
IRB NO.:	201307318
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA09
CONTACT:	Robert Testman - Golden Pacific Laboratories, LLC

Material Type: Subject Information Sheet	**Material Item No.:** MA1601860-0
Description: Subject Self-Reporting Demographic Form, approved as pg. 83 of protocol	**Review Date:** 03/07/16

The Board acknowledges receipt of the enclosed certified Spanish translation of the Recruitment/Study Related Material(s) for the above protocol. **The review date above reflects the date the English version was approved or acknowledged.**

Acknowledged English material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

Any variation of approved or acknowledged materials (other than contact information) must be resubmitted for review.

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1601860-0** ON ALL CORRESPONDENCE
WebPortal/Paperless

All dates are in mm/dd/yyyy format

APÉNDICE D: FORMULARIO DEMOGRÁFICO DEL SUJETO PARA LLENAR POR SÍ MISMO

Hoja de trabajo para calificación

Estudio sobre la exposición en trabajadores AEA09 de la AEATF (*Antimicrobial Exposure Assessment Task Force*, Grupo de trabajo de evaluación de la exposición antimicrobiana): Situación de aplicación de pintura de látex para interiores con brocha y rodillo

Parte I: *Preguntas de la entrevista*	***C/NC***
1. ¿Tiene algún problema de la piel en las manos (por ejemplo, psoriasis, eczema, etc.)? ☐ Sí ☐ No	
2.¿Tiene dificultad para respirar? ¿Enfisema o asma moderada o grave? ☐ Sí ☐ No	
3. ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio, derrame cerebral o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta no controlada? ☐ Sí ☐ No	
4. ¿Tiene algún otro problema de salud que pueda dificultar su participación en este estudio tal como se describió? ☐ Sí ☐ No	
5. ¿Es empleado o está casado con un empleado de una compañía de AEATF, GPL, un fabricante de pinturas o el ACC? (el entrevistador explicará las iniciales de las distintas entidades) ☐ Sí ☐ No	

Parte II: *Para que la llene el candidato*			
6. Nombre		9. Peso: libras	
7. Dirección		10. Estatura: pies pulgadas	
		11. Talla de camisa: ☐ **P** ☐ **M** ☐ **G** ☐ **XG** ☐ **XXG** ☐ **XXXG**	
8. Ciudad, estado, código postal		12. Cintura: ☐ 24-28 pulgadas ☐ 28-32 pulgadas ☐ 32-36 pulgadas ☐ 36-40 pulgadas ☐ 40-44 pulgadas ☐ 44-50 pulgadas	
13. Teléfono(s)			
14. Edad en años =	15. Fecha de nacimiento:	16. Sexo ☐ M ☐ F	
17. ¿Es residente del condado de Fresno? ☐ Sí ☐ No		18. ¿Pintó con brocha y rodillo los últimos 5 años? ☐ Sí ☐ No	
		19. ¿Trabajó como pintor profesional los últimos 10 años? ☐ Sí ☐ No	
20. Idioma de preferencia: ☐ Inglés ☐ Español		21. Lee: ☐ Inglés ☐ Español	
22. ¿Está embarazada? ☐ NC ☐ Sí ☐ No		23. ¿Está amamantando? ☐ NC ☐ Sí ☐ No	
24. ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio tal como se describió? ☐ Sí ☐ No			
25. ¿El olor de la pintura para interiores o la sensación en la piel de la pintura para interiores le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
26. ¿Frotarse la piel con alcohol o jabón le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
Verificación de la edad mediante documento de identificación realizada por el entrevistador: ☐ Sí ☐ No _____ _____ Firma del sujeto Fecha			

Idioma de la entrevista: ☐ Inglés ☐ Español	Nombre del entrevistador:
Fecha de la entrevista:	Firma del entrevistador:

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Subject Information Sheet – MA1601860-0
Description (if applicable): Subject Self-Reporting Demographic Form

MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APÉNDICE D: FORMULARIO DEMOGRÁFICO DEL SUJETO PARA LLENAR POR SÍ MISMO

Hoja de trabajo para calificación

Estudio sobre la exposición en trabajadores AEA09 de la AEATF (*Antimicrobial Exposure Assessment Task Force*, Grupo de trabajo de evaluación de la exposición antimicrobiana): Situación de aplicación de pintura de látex para interiores con brocha y rodillo

Parte I: *Preguntas de la entrevista*	***C/NC***
1. ¿Tiene algún problema de la piel en las manos (por ejemplo, psoriasis, eczema, etc.)? ☐ Sí ☐ No	
2.¿Tiene dificultad para respirar? ¿Enfisema o asma moderada o grave? ☐ Sí ☐ No	
3. ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio, derrame cerebral o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta no controlada? ☐ Sí ☐ No	
4. ¿Tiene algún otro problema de salud que pueda dificultar su participación en este estudio tal como se describió? ☐ Sí ☐ No	
5. ¿Es empleado o está casado con un empleado de una compañía de AEATF, GPL, un fabricante de pinturas o el ACC? (el entrevistador explicará las iniciales de las distintas entidades) ☐ Sí ☐ No	

Parte II: *Para que la llene el candidato*			
6. Nombre		9. Peso: libras	
7. Dirección		10. Estatura: pies pulgadas	
		11. Talla de camisa: ☐ **P** ☐ **M** ☐ **G** ☐ **XG** ☐ **XXG** ☐ **XXXG**	
8. Ciudad, estado, código postal		12. Cintura: ☐ 24-28 pulgadas ☐ 28-32 pulgadas ☐ 32-36 pulgadas ☐ 36-40 pulgadas ☐ 40-44 pulgadas ☐ 44-50 pulgadas	
13. Teléfono(s)			
14. Edad en años =	15. Fecha de nacimiento:	16. Sexo ☐ M ☐ F	
17. ¿Es residente del condado de Fresno? ☐ Sí ☐ No		18. ¿Pintó con brocha y rodillo los últimos 5 años? ☐ Sí ☐ No	
		19. ¿Trabajó como pintor profesional los últimos 10 años? ☐ Sí ☐ No	
20. Idioma de preferencia: ☐ Inglés ☐ Español		21. Lee: ☐ Inglés ☐ Español	
22. ¿Está embarazada? ☐ NC ☐ Sí ☐ No		23. ¿Está amamantando? ☐ NC ☐ Sí ☐ No	
24. ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio tal como se describió? ☐ Sí ☐ No			
25. ¿El olor de la pintura para interiores o la sensación en la piel de la pintura para interiores le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
26. ¿Frotarse la piel con alcohol o jabón le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
Verificación de la edad mediante documento de identificación realizada por el entrevistador: ☐ Sí ☐ No _____ _____ Firma del sujeto Fecha			

Idioma de la entrevista: ☐ Inglés ☐ Español	Nombre del entrevistador:
Fecha de la entrevista:	Firma del entrevistador:

March 14, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Translated Recruitment/Study Related Materials
IRB NO.:	201307318
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA09
CONTACT:	Robert Testman - Golden Pacific Laboratories, LLC

Material Type: Ad-Print	**Material Item No.:** MA1601862-0
Description: Approved as pg. 95 of protocol.	**Review Date:** 03/07/16

The Board acknowledges receipt of the enclosed certified Spanish translation of the Recruitment/Study Related Material(s) for the above protocol. **The review date above reflects the date the English version was approved or acknowledged.**

Acknowledged English material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

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PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1601862-0** ON ALL CORRESPONDENCE
WebPortal/Paperless

All dates are in mm/dd/yyyy format

APÉNDICE F: ANUNCIOS EN PERIÓDICOS PARA LA BÚSQUEDA DE SUJETOS DE INVESTIGACIÓN

SE BUSCAN PINTORES AFICIONADOS

Se buscan voluntarios que deseen participar en un estudio de investigación que evalúa la exposición a componentes de la pintura al pintar en el interior con una brocha y un rodillo. Los voluntarios recibirán una compensación de hasta $120 por las molestias de participar. No se aceptan pintores profesionales.

Comuníquese con Robert Testman (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091 para obtener más información.

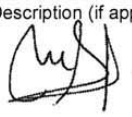
Estudio patrocinado por *Antimicrobial Exposure Assessment Task Force* (AEATF, Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos); administrado por *American Chemistry Council* (ACC, Consejo Estadounidense de Química) y dirigido por Golden Pacific Laboratories (GPL) de Fresno, CA. 559-275-9091

Versión: 04/11/2013

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Ad-Print - MA1601862-0
Description (if applicable): N/A



MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

MMB

3/14/2016 8:00 AM (PST)

APÉNDICE F: ANUNCIOS EN PERIÓDICOS PARA LA BÚSQUEDA DE SUJETOS DE INVESTIGACIÓN

SE BUSCAN PINTORES AFICIONADOS

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Comuníquese con Robert Testman (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091 para obtener más información.

Estudio patrocinado por *Antimicrobial Exposure Assessment Task Force* (AEATF, Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos); administrado por *American Chemistry Council* (ACC, Consejo Estadounidense de Química) y dirigido por Golden Pacific Laboratories (GPL) de Fresno, CA. 559-275-9091

Versión: 04/11/2013

March 14, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Translated Recruitment/Study Related Materials
IRB NO.:	201307318
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA09
CONTACT:	Robert Testman - Golden Pacific Laboratories, LLC

Material Type: Phone Screen	**Material Item No.:** MA1601861-0
Description: Subject Invitation to Participate Script. Approved as pg. 98-99 of protocol	**Review Date:** 03/07/16

The Board acknowledges receipt of the enclosed certified Spanish translation of the Recruitment/Study Related Material(s) for the above protocol. **The review date above reflects the date the English version was approved or acknowledged.**

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PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1601861-0** ON ALL CORRESPONDENCE
WebPortal/Paperless

All dates are in mm/dd/yyyy format

APÉNDICE G: GUIÓN DE INVITACIÓN A PARTICIPAR PARA EL SUJETO

Guión de invitación a participar para el sujeto

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

Queremos determinar la cantidad de productos químicos que se encuentra en el aire que respira o que puede entrar en contacto con la piel cuando aplica productos de pintura con una brocha y un rodillo. Mediremos la cantidad de compuestos de pintura que quede en la ropa que vista y en las manos, cara y cuello. Además, mediremos la cantidad presente en el aire que respira en el momento que pinte habitaciones.

El producto de prueba será la PINTURA DE LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

Debe haber pintado con una brocha y un rodillo en los últimos cinco años, pero no haber trabajado como pintor profesional en los últimos diez años.

Su participación en el estudio durará alrededor de medio día. Le proporcionaremos una ropa especial que deberá usar durante la prueba. Le colocaremos una pequeña bomba de aire para tomar muestras del aire que respira. Luego, se le pedirá que pinte paredes, molduras y zócalos con los productos de prueba. Deberá usar una brocha y un rodillo para aplicar dos galones de pintura. Cuando termine, deberá cambiarse para volver a ponerse su ropa y devolver la ropa especial al equipo de investigación.

¿Le gustaría saber más sobre este proyecto?

(If no, thank them for their time.)

(If yes, instruct them as follows)

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del día del estudio. Para reunir los requisitos para participar, debe mostrar una identificación con foto para comprobar su edad. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni amamantando.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está ubicada en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con el investigador principal, Robert Testman. Si prefiere, podemos realizar la entrevista en español. La entrevista se programará para la fecha y hora que le resulte más conveniente, incluso durante un fin de semana. Le explicaremos el estudio en detalle, entre otras cosas, qué puede esperar y qué se espera de usted. Responderemos todas sus preguntas. La primera visita durará alrededor de una hora. Deberá traer un documento de identificación con foto emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

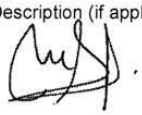
(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Phone Screen - MA1601861-0
Description (if applicable): Subject Invitation to Participate Script



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APÉNDICE G: GUIÓN DE INVITACIÓN A PARTICIPAR PARA EL SUJETO

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El producto de prueba será la PINTURA DE LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

Debe haber pintado con una brocha y un rodillo en los últimos cinco años, pero no haber trabajado como pintor profesional en los últimos diez años.

Su participación en el estudio durará alrededor de medio día. Le proporcionaremos una ropa especial que deberá usar durante la prueba. Le colocaremos una pequeña bomba de aire para tomar muestras del aire que respira. Luego, se le pedirá que pinte paredes, molduras y zócalos con los productos de prueba. Deberá usar una brocha y un rodillo para aplicar dos galones de pintura. Cuando termine, deberá cambiarse para volver a ponerse su ropa y devolver la ropa especial al equipo de investigación.

¿Le gustaría saber más sobre este proyecto?

(If no, thank them for their time.)

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(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

Megan Boatwright

From: Robert Testman
Sent: Tuesday, May 03, 2016 4:44 PM
To: Jeffrey Atlas
Cc: Megan Boatwright
Subject: Protocol amendment for AEA09
Attachments: 120463 - Protocol Amendment No 1.pdf

Hi Jeff,

Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

PROTOCOL AMENDMENT NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: April 26, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section B. Analytical Method (Protocol page 41), the fourth paragraph reads:

   "GPL Analytical Method GPL-MTH-079…"

   will now read:

   "GPL Analytical Method GPL-MTH-081…"

2. In Section B. Analytical Method (Protocol page 41), the sixth paragraph reads:

   "All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile/ 50% water, to quantitate."

   will now read:

   "All subject samples, except hand wipes/washes and air sampling tubes, will be extracted using methanol/water/formic acid (70:30:0.016, v/v/v) [MWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Air sampling tubes will be extracted using acetonitrile/water/formic acid (70:30:0.016, v/v/v) [AWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using MWF, to quantitate."

3. In Section 10. Monitoring Event Procedures (Protocol page 29), the additional information is added for pre-washing of outer dosimeters (due to potential background BIT residues in the matrix):

   "All outer dosimeter pants and shirts will be pre-washed to remove potential background BIT residues before use. Outer dosimeters will be washed in a commercial or residential washing machine on a cold wash cycle with no detergent

RJT 05/02/16

added. Pants and shirts are hung to dry, folded into new large plastic bags labeled with the date of the pre-washing, then considered ready for use."

Justification:

The above changes:

1. Correct a typo
2. Clarifies the analytical method summary.
3. Adds information on how to pre-wash cotton outer dosimeters.

Effect on the Study:

No adverse impact on the study.

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR: 05/02/16

Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE: 4/29/16

Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Robert Testman
Sent: Wednesday, May 04, 2016 9:58 AM
To: Amanda Helmes
Cc: Peggy Kellerman; Christina Chevrier; Megan Boatwright
Subject: RE: Protocol amendment for AEA09
Attachments: SAIRB Change Form - Amendment 1.pdf

Hi Amanda,

Thanks for your reply. Please see attached the completed protocol change form. I was not sure if you would prefer me to email this to the "submission" email, or if sending directly to you was acceptable. Let me know if I should submit in a different manner. I assumed since the amendment itself was very short and summarized the changes that it was acceptable as the summary of changes, but I can put something different together if needed.

Thanks,
Rob

From: Amanda Helmes [mailto:AHelmes@sairb.com]
Sent: Wednesday, May 4, 2016 7:06 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Peggy Kellerman <PKellerman@sairb.com>; Christina Chevrier <CChevrier@sairb.com>
Subject: RE: Protocol amendment for AEA09

Hello Rob,

I was forwarded your email by my colleague Jeff. Thank you for your submission! The following information is needed before the submission can be sent for preliminary review.

- Please complete the attached submission form.

Kind Regards,
Amanda

Amanda Helmes | Board Liaison
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100, ext. 236 |Fax: 866-596-1535| ahelmes@sairb.com
Visit us at http://www.sairb.com

Please check our website for updated forms.
Use our SmartForms to save time and minimize errors – login to eSubmission 2.0 to submit your new site or study.

From: Jeffrey Atlas
Sent: Tuesday, May 3, 2016 8:23 PM
To: Amanda Helmes; Peggy Kellerman; Christina Chevrier
Subject: Fwd: Protocol amendment for AEA09

Hey ladies,

Please see the attached. I've not confirmed receipt nor requested the submission form.

Thanks.

---------- Forwarded message ----------
From: "**Robert Testman**" <rtestman@gplabs.com>
Date: Tue, May 3, 2016 at 4:44 PM -0700
Subject: Protocol amendment for AEA09
To: "Jeffrey Atlas" <JAtlas@sairb.com>
Cc: "Megan Boatwright" <mboatwright@gplabs.com>

Hi Jeff,
Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.
Thanks,
Rob
Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

SCHULMAN
ASSOCIATES IRB

Protocol/Informed Consent Change Form

1. Submission information: Use this form to submit changes to the protocol (e.g. amendment, administrative change) or informed consent document (IC) for Board review.

2. Submission instructions: Submit via Secure eSubmission or email to Submissions@sairb.com.

SECTION 1.0: Study & Contact Information

1. Date: 05/04/2016

2. IRB No.: 201307317

3. Sponsor: AEATF II

4. Protocol No.: AEA09

5. The item(s) submitted for review on this form are for use at (choose one):

☒ A single site >>> Complete **a.** and **b.**:

a. Principal/Qualified Investigator's name: Robert Testman

b. ☒ **If required, Sponsor/CRO approval is attached.**

☐ A subset of sites >>> List all participating site(s) by PI/QI name or IRB#: _____

☐ All sites (sponsor/CRO only) >>> Complete **c.**:

c. Specify the site locations: ☐ USA ☐ Canada >>> Complete **d.**:

d. Has the item(s) been submitted to Health Canada?

☐ No >>> Provide an explanation: _____

☐ Yes >>> ☐ No Objection Letter (NOL)/Acknowledgement attached -OR- ☐ Submitted to Health Canada on: _____

Note: Schulman will process submitted item(s) for all open sites unless otherwise directed. Any institutional requirements for local IRBs must be communicated to Schulman at the time of submission.

6. Contact information for this submission:

Name: Robert Testman
Company: Golden Pacific Laboratories
Phone: 559-275-9091
Email: rtestman@gplabs.com

SECTION 2.0: Protocol/IC Change Information

1. What type of item are you submitting? Check all that apply and provide the additional information as applicable:

☒ Protocol Amendment/Revised Protocol >>> Provide the amendment/revision date: 4/26/2016 and number (if applicable): 1
☒ Required summary of changes are attached.

☐ Dear Subject/Dear Investigator Letter >>> Provide the letter date: _____ -OR- ☐ Not dated

☐ Administrative Letter/Change/ Protocol Clarification Letter >>> Provide the letter/change date: _____

☐ Revised IC >>> List all ICs for the study that will be revised by this request: _____
☐ Required rationale and sponsor/CRO approval, if required, is attached.

☐ New IC/Addendum >>> Provide the rationale for all requested revisions and documentation of sponsor/CRO approval.
☐ Required rationale and sponsor/CRO approval, if required, is attached.

☐ Other: _____ >>> Provide the item date: _____

2. What is the status of study enrollment?

☐ Enrollment open ☐ Enrollment closed ☒ Site(s) not yet initiated

3. What is the status of study subjects? Check all that apply:

☐ Subjects active ☒ No subjects active ☐ Subjects in follow-up only (not receiving active intervention [e.g. IP, device])
☐ Other: _____

4. Does this submission include any product safety updates (e.g., revised IB, package inserts, etc.)?

☒ No
☐ Yes >>> ☐ Item previously submitted to Schulman -OR- ☐ Submitting item via Product Safety Submission Form

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Protocol/Informed Consent Change Form

5. Does this submission result in the need for change(s) to the current Schulman approved IC template for the study?

☒ No ☐ Yes **>>>** Complete **a.** through **c.**:

a. ☐ **Requested changes attached via tracked changes to the MS Word version of the current Schulman approved IC.**

b. The revised IC is intended to be presented to: Check all that apply.

☐ New enrollees ☐ Only subjects receiving active intervention (e.g. IP, device)

☐ All current subjects ☐ Other: _____

Provide rationale if requesting not to reconsent all actively enrolled subjects: _____

Note: The final determination will be made by the Board upon review of the item.

c. Specify one of the following regarding IC translation:

☐ No IC translation is needed.

☐ I will obtain my own translation through a certified translator and provide for Schulman review prior to use.

☐ I authorize Schulman to translate the IC and associated cost for: ☐ All previously translated sites and languages

☐ Only specified sites and languages: _____

Note: Confirm authorization for translations with the sponsor/CRO prior to submission, if necessary.

6. Does this submission create a sub-study to the protocol?

☒ No ☐ Yes **>>>** Submit the Sub-Study/Additional Research Submission Form and complete **a.** and **b.**:

a. Will all Schulman approved sites be participating in the sub-study?

☐ Yes ☐ No **>>>** List the participating site(s) by PI name or IRB#: _____

b. Submit the Revised Compensation Form **for all site(s) participating in the sub-study.**

7. Does this submission create an extension to the protocol?

☒ No ☐ Yes **>>>** Complete **a.** and **b.**:

a. Will all Schulman approved sites be participating in the extension?

☐ Yes ☐ No **>>>** List the participating site(s) by PI name or IRB#: _____

b. Submit the Revised Compensation Form **for all site(s) participating in the extension.**

8. Does this submission modify the study subject compensation/reimbursement?

☒ No ☐ Yes **>>>** Complete **a.**:

a. Who will be responsible for submitting Revised Compensation Forms for sites?

☐ Sponsor/CRO ☐ Sites

Note: Site approval documents cannot be released until a Revised Compensation Form is received for each site.

9. Does this submission result in the need to submit recruitment or study-related materials for Board review?

☒ No ☐ Yes **>>>** Submit all materials for review using the Recruitment/Study-Related Material Submission Form.

Note: Board review of recruitment and study-related materials will be sent under separate cover.

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Megan Boatwright

From: Amanda Helmes <AHelmes@sairb.com>
Sent: Wednesday, May 04, 2016 10:40 AM
To: Robert Testman
Cc: Peggy Kellerman; Christina Chevrier; Megan Boatwright
Subject: RE: Protocol amendment for AEA09

Hello Rob,

Thank you for your quick response! You do not have to submit this is a different manner; sending directly to me was great. Also you are correct, a summary of changes is not needed for the amendment. Your submission is complete and has been sent for preliminary review, which may take 1 to 2 business days. The determination of the type of review will be made during that time. If the review qualifies for expedited review, the pre-review serves as the board review. You may view the WebPortal for an update regarding if the submission will be expedited or full Board Review. If it's determined to be reviewed by the full Board, a meeting date will be listed.

I hope you have a great rest of the day!

Kind Regards,
Amanda

Amanda Helmes | Board Liaison
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100, ext. 236 |Fax: 866-596-1535| ahelmes@sairb.com
Visit us at http://www.sairb.com

Please check our website for updated forms.
Use our SmartForms to save time and minimize errors – login to eSubmission 2.0 to submit your new site or study.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Wednesday, May 4, 2016 12:58 PM
To: Amanda Helmes
Cc: Peggy Kellerman; Christina Chevrier; Megan Boatwright
Subject: RE: Protocol amendment for AEA09

Hi Amanda,

Thanks for your reply. Please see attached the completed protocol change form. I was not sure if you would prefer me to email this to the "submission" email, or if sending directly to you was acceptable. Let me know if I should submit in a different manner. I assumed since the amendment itself was very short and summarized the changes that it was acceptable as the summary of changes, but I can put something different together if needed.

Thanks,
Rob

From: Amanda Helmes [mailto:AHelmes@sairb.com]
Sent: Wednesday, May 4, 2016 7:06 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: Peggy Kellerman <PKellerman@sairb.com>; Christina Chevrier <CChevrier@sairb.com>
Subject: RE: Protocol amendment for AEA09

Hello Rob,

I was forwarded your email by my colleague Jeff. Thank you for your submission! The following information is needed before the submission can be sent for preliminary review.

- Please complete the attached submission form.

Kind Regards,
Amanda

Amanda Helmes | Board Liaison
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100, ext. 236 |Fax: 866-596-1535| ahelmes@sairb.com
Visit us at http://www.sairb.com

Please check our website for updated forms.
Use our SmartForms to save time and minimize errors – login to eSubmission 2.0 to submit your new site or study.

From: Jeffrey Atlas
Sent: Tuesday, May 3, 2016 8:23 PM
To: Amanda Helmes; Peggy Kellerman; Christina Chevrier
Subject: Fwd: Protocol amendment for AEA09

Hey ladies,

Please see the attached. I've not confirmed receipt nor requested the submission form.

Thanks.

---------- Forwarded message ----------
From: "**Robert Testman**" <rtestman@gplabs.com>
Date: Tue, May 3, 2016 at 4:44 PM -0700
Subject: Protocol amendment for AEA09
To: "Jeffrey Atlas" <JAtlas@sairb.com>
Cc: "Megan Boatwright" <mboatwright@gplabs.com>

Hi Jeff,
Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.
Thanks,
Rob
Rob Testman

rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Monday, May 9, 2016 7:31 AM
To: Robert Testman <rtestman@gplabs.com>
Subject: AMENDMENT/REVISED IC documents posted for Protocol AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**AMENDMENT/REVISED IC**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Amended Approval Letter	May 09, 2016

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.com

May 06, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Updated Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:	Review Type	Approval Date
• Protocol Amendment No. 1 dated 04/26/2016	Expedited	05/04/2016

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

Megan Boatwright

From: Robert Testman
Sent: Monday, June 13, 2016 1:20 PM
To: Amanda Helmes
Cc: Peggy Kellerman; Christina Chevrier; Megan Boatwright
Subject: Protocol amendment 2 for AEA09
Attachments: 120463 - Protocol Amendment No 2.pdf; SAIRB Change Form - Amendment 2.pdf

Hi Amanda,

Please see attached amendment 2 for AEA09 along with the completed protocol change form. Let me know if you need any further information.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

SCHULMAN
ASSOCIATES IRB

Protocol/Informed Consent Change Form

1. Submission information: Use this form to submit changes to the protocol (e.g. amendment, administrative change) or informed consent document (IC) for Board review.

2. Submission instructions: Submit via Secure eSubmission or email to Submissions@sairb.com.

SECTION 1.0: Study & Contact Information

1. Date: 05/04/2016

2. IRB No.: 201307317

3. Sponsor: AEATF II

4. Protocol No.: AEA09

5. The item(s) submitted for review on this form are for use at (choose one):

☒ A single site >>> Complete **a.** and **b.**:

a. Principal/Qualified Investigator's name: Robert Testman

b. ☒ **If required, Sponsor/CRO approval is attached.**

☐ A subset of sites >>> List all participating site(s) by PI/QI name or IRB#: _____

☐ All sites (sponsor/CRO only) >>> Complete **c.**:

c. Specify the site locations: ☐ USA ☐ Canada >>> Complete **d.**:

d. Has the item(s) been submitted to Health Canada?

☐ No >>> Provide an explanation: _____

☐ Yes >>> ☐ No Objection Letter (NOL)/Acknowledgement attached -OR- ☐ Submitted to Health Canada on: _____

Note: Schulman will process submitted item(s) for all open sites unless otherwise directed. Any institutional requirements for local IRBs must be communicated to Schulman at the time of submission.

6. Contact information for this submission:

Name: Robert Testman Company: Golden Pacific Laboratories

Phone: 559-275-9091 Email: rtestman@gplabs.com

SECTION 2.0: Protocol/IC Change Information

1. What type of item are you submitting? Check all that apply and provide the additional information as applicable:

☒ Protocol Amendment/Revised Protocol >>> Provide the amendment/revision date: 6/10/2016 and number (if applicable): 2

☒ Required summary of changes are attached.

☐ Dear Subject/Dear Investigator Letter >>> Provide the letter date: _____ -OR- ☐ Not dated

☐ Administrative Letter/Change/ Protocol Clarification Letter >>> Provide the letter/change date: _____

☐ Revised IC >>> List all ICs for the study that will be revised by this request: _____

☐ Required rationale and sponsor/CRO approval, if required, is attached.

☐ New IC/Addendum >>> Provide the rationale for all requested revisions and documentation of sponsor/CRO approval.

☐ Required rationale and sponsor/CRO approval, if required, is attached.

☐ Other: _____ >>> Provide the item date: _____

2. What is the status of study enrollment?

☒ Enrollment open ☐ Enrollment closed ☐ Site(s) not yet initiated

3. What is the status of study subjects? Check all that apply:

☒ Subjects active ☐ No subjects active ☐ Subjects in follow-up only (not receiving active intervention [e.g. IP, device])

☐ Other: _____

4. Does this submission include any product safety updates (e.g., revised IB, package inserts, etc.)?

☒ No

☐ Yes >>> ☐ Item previously submitted to Schulman -OR- ☐ Submitting item via Product Safety Submission Form

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SCHULMAN
ASSOCIATES IRB

Protocol/Informed Consent Change Form

5. Does this submission result in the need for change(s) to the current Schulman approved IC template for the study?

☒ No ☐ Yes **>>>** Complete **a.** through **c.**:

a. ☐ **Requested changes attached via tracked changes to the MS Word version of the current Schulman approved IC.**

b. The revised IC is intended to be presented to: Check all that apply.

☐ New enrollees ☐ Only subjects receiving active intervention (e.g. IP, device)

☐ All current subjects ☐ Other: _____

Provide rationale if requesting not to reconsent all actively enrolled subjects: _____

Note: The final determination will be made by the Board upon review of the item.

c. Specify one of the following regarding IC translation:

☐ No IC translation is needed.

☐ I will obtain my own translation through a certified translator and provide for Schulman review prior to use.

☐ I authorize Schulman to translate the IC and associated cost for: ☐ All previously translated sites and languages

☐ Only specified sites and languages: _____

Note: Confirm authorization for translations with the sponsor/CRO prior to submission, if necessary.

6. Does this submission create a sub-study to the protocol?

☒ No ☐ Yes **>>>** Submit the Sub-Study/Additional Research Submission Form and complete **a.** and **b.**:

a. Will all Schulman approved sites be participating in the sub-study?

☐ Yes ☐ No **>>>** List the participating site(s) by PI name or IRB#: _____

b. Submit the Revised Compensation Form **for all site(s) participating in the sub-study.**

7. Does this submission create an extension to the protocol?

☒ No ☐ Yes **>>>** Complete **a.** and **b.**:

a. Will all Schulman approved sites be participating in the extension?

☐ Yes ☐ No **>>>** List the participating site(s) by PI name or IRB#: _____

b. Submit the Revised Compensation Form **for all site(s) participating in the extension.**

8. Does this submission modify the study subject compensation/reimbursement?

☒ No ☐ Yes **>>>** Complete **a.**:

a. Who will be responsible for submitting Revised Compensation Forms for sites?

☐ Sponsor/CRO ☐ Sites

Note: Site approval documents cannot be released until a Revised Compensation Form is received for each site.

9. Does this submission result in the need to submit recruitment or study-related materials for Board review?

☒ No ☐ Yes **>>>** Submit all materials for review using the Recruitment/Study-Related Material Submission Form.

Note: Board review of recruitment and study-related materials will be sent under separate cover.

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PROTOCOL AMENDMENT NO.: 2
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: June 10, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section 11.B. Transportation (Protocol page 39), the paragraph reads:

   "Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain of-custody record will be available for each sample." will now read:

   "Samples will be transported from the exposure site to the analytical laboratory by study personnel shortly after collection. A chain of-custody record will be available for each sample."

Justification:

Since the exposure site is in very close proximity to the analytical laboratory the samples can be placed directly into the analytical laboratory freezer and dry ice transport is not necessary.

Effect on the Study:

No adverse impact on the study.

PREPARED BY:

FIELD COORDINATOR: 06/10/16
Megan T. Boatwright, B.S. Date
Golden Pacific Laboratories, LLC

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR: 06/10/16
Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE: 06/10/16
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Amanda Helmes <AHelmes@sairb.com>
Sent: Monday, June 13, 2016 1:35 PM
To: Robert Testman
Cc: Peggy Kellerman; Christina Driskell; Megan Boatwright
Subject: RE: Protocol amendment 2 for AEA09

Hello Rob,

Thank you for your email! I have forwarded this to the correct team for processing. You will be contacted if any additional information is needed.

Kind Regards,
Amanda

Amanda Helmes | Board Liaison
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office: 513-761-4100, ext. 236 |Fax: 866-596-1535| ahelmes@sairb.com
Visit us at http://www.sairb.com

Please check our website for updated forms.
Use our SmartForms to save time and minimize errors – login to eSubmission 2.0 to submit your new site or study.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, June 13, 2016 4:20 PM
To: Amanda Helmes
Cc: Peggy Kellerman; Christina Driskell; Megan Boatwright
Subject: Protocol amendment 2 for AEA09

Hi Amanda,

Please see attached amendment 2 for AEA09 along with the completed protocol change form. Let me know if you need any further information.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Thursday, June 16, 2016 6:07 AM
To: Robert Testman <rtestman@gplabs.com>
Subject: AMENDMENT/REVISED IC documents posted for Protocol AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**AMENDMENT/REVISED IC**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Amended Approval Letter	Jun 16, 2016

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Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN IRB
www.sairb.com

June 15, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Updated Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:	Review Type	Approval Date
• Protocol Amendment No. 2 dated 06/10/2016	Expedited	06/15/2016

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

Single Site Study Periodic and Continuing Review Report

Schulman IRB | sairb.com | 513.761.4100

Contact Information	
Name of User:	Robert Testman
Title:	President
Phone:	559-275-9091
E-mail:	rtestman@gplabs.com
Country:	US

Study Information	
IRB Number:	201307318
Protocol Number:	AEA09
Sponsor:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PI/QI Name:	Testman, Robert J.
[X] This document will be submitted by the Principal Investigator (PI)/Qualified Investigator (QI) or Designee authorized by the PI/QI to submit on behalf of the PI/QI.	

Report Information			
Represent:	Sponsor/CRO	**Documentation For:**	Single Site and Protocol Review
Report Type:	Periodic/Continuing Review		
Have any subjects been consented since the beginning of this study?			Yes

Report Information Uploads	
Site/Study Reopen Uploads:	
IRB Transfer Uploads:	

Study Status Information		
What is the current site enrollment status?		
Enrollment is closed at this site		
What was the date the first subject was consented at your site?		05/11/2016
What was the date of the most recent study visit?		07/01/2016
Please provide the date of the final contact with the last study subject:		
Since your last report, have any subjects transferred?		No
	# transferred to your site (include these subjects in Number of consented subjects in the following question)	
	# transferred from your site (include these subjects in Number of Withdrawals in the following question)	
Please complete the following information for all subjects consented for this study at your site:		
	Number of consented subjects	37
	Number of Screen Failures	5
	Number of Subjects Withdrawn	4
	Number of Subjects who Completed the Study	28
	Number of Subjects still Active in the Study	0
Have any subjects been withdrawn since your last report to Schulman?		Yes

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Initials:	LY	Number:	12
Reason:	unable to contact		
Initials:	CB	Number:	1
Reason:	subject request		
Initials:	TJ	Number:	2
Reason:	subject request		
Initials:	AP	Number:	34
Reason:	unable to contact		

Since your last report, have you consented subjects from any of the following groups?		
	Anyone who cannot read (blind or illiterate)	No
	Employees/immediate family members of employees	No
	If "Yes", was a Non-Coercion Statement Request Form submitted to Schulman?	
	Children (anyone under the age of majority in your state/province)	No
	Non-English speaking persons	No
	Consented via legally authorized representative (LAR)	No
IC Attachment selection:	Attached below	
Please provide any additional information about the Informed Consent documents if necessary:		
Please indicate whether any of the following have occurred at your site since your last report.		
	Change of Site Location:	No
	If "Yes", was change in site location reported to Schulman?	
	Change of PI/QI:	No
	If "Yes", was change of PI/QI reported to Schulman?	
	Change or addition of Sub-Investigator(s):	No
	If "Yes", was change or addition of Sub-Investigator(s) reported to Schulman?	
	Change in Subject Compensation:	No
	If "Yes", was change in subject compensation reported to Schulman?	

Study Status Information Uploads	
Site Enrollment:	
Informed Consents:	120463 icf.pdf
Site Occurrences:	

Subject Safety Information	
Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?	No
If "Yes", were the items of noncompliance reported to Schulman?	
Since your last report, have there been any Unanticipated Adverse Device Effects (UADEs)?	N/A - not a device study
If "Yes", were the UADEs reported to Schulman?	
Since your last report, have there been any Unanticipated Problems Involving Risk to Human Subjects or Others?	No
If "Yes", were the Unanticipated Problems Involving Risk to Human Subjects or Others reported to Schulman?	
Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?	No
If "Yes", was this previously reported to Schulman?	
If not previously reported, please explain:	
Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?	No
Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk of the subjects?	No

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If "Yes", was the alteration of the risk/benefit analysis previously submitted to Schulman?	
If the risk/benefit analysis of the study was altered, please explain:	

Subject Safety Uploads	
Subject Willingness:	
Compensation / Complaints:	
Risk / Benefit Analysis:	

Regulatory History Information			
Has this site and/or investigator associated with this study been audited by the FDA, OHRP, EPA, HPFB, or any other government agency during this study?			Yes
If "Yes", please list all audits below:			
Agency:	CA Dept. of Pesticide Review		
Physician/Investigator:	Robert Testman	Audit End Date:	06/15/2016
Was a form FDA 483, Inspection Exit Notice or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?			No
Please attach all related correspondence for all of the audits listed, including the site response with corrective actions:			Attached below
Are there any state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?			No
If "Yes", was a written explanation and all relevant documents submitted to Schulman?			
If not done previously, please explain:			
Since your last report to Schulman, has any investigator involved with this study:			
Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on any protocol, or refuse to review any protocol?			No
Had the FDA, OHRP, or EPA (US sites) or HPFB (Canadian sites) terminate a study?			No
Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g., suspension, revocation, or restriction?			No
Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?			No
Been convicted or charged with a crime (misdemeanor or felony)?			No
Had a state/provincial medical board take a disciplinary action against his/her license, or is currently under investigation?			No
If "Yes" to any of the above issues, please explain:			

Regulatory History Uploads	
Audit Info:	dr06-23.pdf
Pending Charges / Complaints:	
PI Issues:	

Financial Interest Information	
During the last 12 months, has any investigator involved in this study:	
Been an officer, director or employee of the sponsor of this research study?	No
Held ownership interest (equity or stock options) related to the research in excess of $5,000 when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?	No
Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more of any one single entity?	No
Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?	No
Held any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.)	No

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Received, or made any arrangement to receive, any significant payment of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: payments by the sponsor to support activities of the investigator that have a monetary value of more than $5,000 exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.)	No
Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?	No
Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: (i) compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; (ii) compensation in the form of an equity interest in the sponsor of the study; or (iii) compensation tied to sales of the product, such as royalty interest.)	No
Has the noted Conflict of Interest (COI) been previously reported?	
If "No", when did the COI begin?	
If "No", have subjects been enrolled since the COI began?	
If "Yes", does the COI still exist?	
If COI still exists, has there been any change to the previously reported COI?	
Since your last report, have there been any changes to the clinical trial budget?	

Financial Interest Uploads	
Conflict of Interest:	
Changes to Budget:	

Protocol Information		
Enrollment Status:		
Estimated Closure / Completed Dates	Enrollment Closure:	
	Active Participation Ends:	07/01/2016
	Study Closure:	01/31/2017
Consented Subjects	Enrolled:	
	Active:	
	Withdrawn:	
Please provide a reason for the withdrawals (if applicable):		
Enrolled Subjects	Males:	17
	Females:	15
	Hispanic:	0
	Non-Hispanic:	0
	Caucasian:	0
	Native American / Aboriginal:	0
	African:	0
	Asian:	0
	Other:	0

Is there a data safety monitoring board/committee for this study?	No
If "Yes", has the Committee met since the last report?	
Anticipated meeting date of the Committee:	
Have there been any interim findings, published findings and/or multicenter trial reports pertinent to the conduct of this study since the Board's initial review or last continuing review of the protocol?	No
Have there been any significant findings that may affect subjects' willingness to stay in the study?	
Have these findings occurred since the Board's initial review or last continuing review of the protocol?	
If "Yes", please explain:	
Have there been any Unanticipated Problems Involving Risk to Human Subjects or Others since the Board's initial review or last continuing review of the protocol?	
If "Yes", have you already submitted the Unanticipated Problem Report Form to Schulman for each event?	
Since your last report, have there been any Unanticipated Adverse Device Effects (UADEs)?	

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If "Yes", were the UADEs reported to Schulman?	
Have there been any changes in the risk to benefit ratio associated with participation in this study since the Board's initial review or last continuing review of the protocol?	
If "Yes", has this been previously reported to Schulman?	
If not reported, please explain:	

Protocol Information Uploads	
Enrollment Status:	
DSMB/Committee Forms:	
Findings/Reports:	
Subject Willingness:	
Risk/Benefit Ratio:	

Submission Comments

Electronic Receipt Acknowledgement	
Date/Time Sent:	10/27/2016 12:03:38 PM ET
Acknowledgement Number:	201307318_10272016120338

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From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Thursday, October 27, 2016 9:02 AM
To: Robert Testman <rtestman@gplabs.com>
Subject: eSubmission 2.0 System - Document Submission Confirmation
Importance: High

Robert

The following documents have been successfully submitted via Schulman Associates IRB **eSubmission™ 2.0** system:

Submission Type:	Single Site Study Periodic and Continuing Review Report
Submission Form:	Single Site Study Periodic and Continuing Review Report Form.pdf (Schulman Submission Format)
Submission Comments:	

List of Uploaded Files:

File Type	File Name	Description
Informed Consent	120463 icf.pdf	
Audit Documentation	dr06-23.pdf	CDPR audit

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone:	559-275-9091
Email:	rtestman@gplabs.com

Acknowledgement #:	201307318_10272016120338
Form ID:	OR1623832
IRB Number:	201307318
Investigator:	Testman, Robert J.
Sponsor:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
Protocol Number:	AEA09
Submitted Date/Time:	Oct 27 2016 12:02PM

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[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Monday, November 7, 2016 4:01 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol AEA09 [Country:US]
Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category:	**CONTINUING/PERIODIC REVIEW**
Document Delivery:	**PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol:	**AEA09 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Re-Approval Letter	Nov 07, 2016

★New★Need to Access These Documents? Login to **Study Documents Direct™** to immediately access the only documents related to this alert.
Need to Access All Documents? Login to **SiteAccess** from **www.sairb.com** and use **Study Documents** feature.
Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

Do not reply. This email address is not monitored.

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REAPPROVED: 11/07/2016
EXPIRATION DATE: 11/06/2017

November 07, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Reapproval
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board received your Study Status Report form on the referenced protocol.

This letter is to inform you that the Board approved your site(s) to conduct this study for another 12 months. If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval. You can find the Study Status Report Form at www.sairb.com. Continue to use the latest Schulman approved informed consent(s).

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

WebPortal/Paperless

Robert Testman

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Monday, September 11, 2017 7:30 PM
To: Robert Testman
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman (1st Reminder)

Importance: High

1st REMINDER

Date: Sep 11, 2017
Investigator: Robert J. Testman
Sponsor: AMERICAN CHEMISTRY COUNCIL - ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA09
IRB#: 201307318

PERIODIC REVIEW DUE

IRB approval expires in approximately 8 weeks

Click Here to Complete Form

A completed SmartForm must be submitted for review at least 4 weeks prior to the approval expiration date on your approval or reapproval letter.

Federal regulations require that all studies be reviewed at least annually by an IRB. Please take necessary measures to comply with this federal regulation. If there are circumstances that prevent you from submitting the SmartForm, please contact Schulman's Ongoing Review team immediately.

NOTE:

Reports received within 2 weeks of expiration are subject to a **Late Renewal Review Fee**.

Thank you

Ongoing Review
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If received in error, please reply to this communication. The information contained in this communication is confidential, for the exclusive use of the recipient listed above. Any reading, disclosure, use or reproduction of this communication other than by the intended recipient, is prohibited.

Robert Testman

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Monday, October 16, 2017 7:32 PM
To: Robert Testman
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman (Final Notice)

Importance: High

FINAL NOTICE-IMMEDIATE RESPONSE REQUESTED

Date: Oct 16, 2017
Investigator: Robert J. Testman
Sponsor: AMERICAN CHEMISTRY COUNCIL - ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA09
IRB#: 201307318

PERIODIC REVIEW DUE

IRB approval is at risk of expiration

Click Here to Complete Form

A completed SmartForm must be submitted for review at least 4 weeks prior to the approval expiration date on your approval or reapproval letter.

Federal regulations require that all studies be reviewed at least annually by an IRB. Please take necessary measures to comply with this federal regulation.If there are circumstances that prevent you from submitting the SmartForm, please contact Schulman's Ongoing Review team immediately.

NOTE:

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Thank you

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Robert Testman

From: MaryJo Carter <MaryJo.Carter@sairb.com>
Sent: Tuesday, October 17, 2017 11:10 AM
To: Robert Testman
Cc: has_shah@americanchemistry.com
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman

Importance: High

Robert,

IRB approval to conduct American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II) protocol AEA09 expires 11/03/2017 and we have not received a Study Status Report. In order to avoid a lapse in approval, please follow the link below to complete the form. You can also access the form via the Schulman website at www.sairb.com.

Please let me know if you have any questions or need assistance in completing the form.

Reports received within 2 weeks of expiration are subject to a Late Renewal Review Fee.

Thank you for your prompt attention to this.

Regards,
MaryJo Carter

MaryJo Carter | Specialist, Ongoing Review
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office 513.761.4100 ext. 5211 | **Fax** 866.657.7917 | MaryJo.Carter@sairb.com

---

From: Site Reminder [mailto:SiteReminderReplies@sairb.com]
Sent: Monday, October 16, 2017 10:32 PM
To: rtestman@gplabs.com
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman (Final Notice)
Importance: High

FINAL NOTICE-IMMEDIATE RESPONSE REQUESTED

Date: Oct 16, 2017
Investigator: Robert J. Testman
Sponsor: AMERICAN CHEMISTRY COUNCIL - ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA09
IRB#: 201307318

PERIODIC REVIEW DUE

1

IRB approval is at risk of expiration

Click Here to Complete Form

A completed SmartForm must be submitted for review at least 4 weeks prior to the approval expiration date on your approval or reapproval letter.

Federal regulations require that all studies be reviewed at least annually by an IRB. Please take necessary measures to comply with this federal regulation.If there are circumstances that prevent you from submitting the SmartForm, please contact Schulman's Ongoing Review team immediately.

NOTE:

Reports received within 2 weeks of expiration are subject to a **Late Renewal Review Fee**.

Thank you

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Robert Testman | rtestman@gplabs.com

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Subject Safety

- Form Requirements
- Study & Site Information
- Subject Information
- Issue Information
- Submission Summary

Noncompliance Submission ▸ Submission Summary

Noncompliance Issue/Deviation Submission Summary

Review completed form information including all attachments prior to submission. This is a preview only. To make changes, click on the "Back" button. To submit the form, click on the "Submit" button.

Print Preview Only

User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/25/2017
Date the Noncompliance occurred	06/07/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
Please see Protocol Deviation 1 Document for details	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
Items 3 and 6 the chemist responsible was re-trained. Items 4 and 7 were due to missing protocol information and future protocols will need to address. Item 1 has been discussed with sponsor and EPA to avoid in future protocols. Item 2 was due to a vendor non-performance issue and that vendor will not be used again. Item 5 was due to a device failure and sufficient backup was present to ensure integrity.	

Please enter any additional submission comments:

Print Preview Only

< Back Submit

Friday
October 27, 2017
5:22 PM EST

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Cincinnati, OH | 513.761.4100
Research Triangle Park, NC | 919.287.4900

Megan Boatwright

From: Robert Testman
Sent: Friday, October 27, 2017 2:27 PM
To: Megan Boatwright
Subject: FW: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

From: Schulman Technical Support [mailto:alertreply@sairb.com]
Sent: Friday, October 27, 2017 2:24 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: eSubmission 2.0 System - Document Submission Confirmation
Importance: High

Robert

The following documents have been successfully submitted via Schulman Associates IRB eSubmission™ 2.0 system:

Submission Type:	Noncompliance Issue/Deviation Submission Acknowledgement
Submission Form:	Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:	Please see Protocol Deviation #1 document.

List of Uploaded Files:

Submitting User Information

Company:	Golden Pacific Labs
Name:	Robert Testman
Phone:	559-275-9091
Email:	rtestman@gplabs.com

Acknowledgement #:	201307318_10272017172354
Form ID:	SN1724653
IRB Number:	201307318
Investigator:	Robert Testman
Sponsor:	American Chemistry Council

Protocol Number: AEA09
Submitted Date/Time: Oct 27 2017 5:23PM

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[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From: Robert Testman
Sent: Friday, October 27, 2017 2:27 PM
To: Megan Boatwright
Subject: FW: Periodic Report Due Now for AEA09 PI: Robert J. Testman
Attachments: 120463 - Protocol Deviation No 1.pdf

From: Robert Testman
Sent: Friday, October 27, 2017 2:26 PM
To: 'MaryJo Carter' <MaryJo.Carter@sairb.com>
Subject: RE: Periodic Report Due Now for AEA09 PI: Robert J. Testman

Hi MaryJo,

Please find attached a protocol deviation for study AEA09. I submitted the form electronically, but did not find a way to attach the file for your records. We intend to close out the study as soon as the deviation is processed.

Thanks,
Rob

From: MaryJo Carter [mailto:MaryJo.Carter@sairb.com]
Sent: Tuesday, October 17, 2017 11:10 AM
To: Robert Testman <rtestman@gplabs.com>
Cc: has_shah@americanchemistry.com
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman
Importance: High

Robert,

IRB approval to conduct American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II) protocol AEA09 expires 11/03/2017 and we have not received a Study Status Report. In order to avoid a lapse in approval, please follow the link below to complete the form. You can also access the form via the Schulman website at www.sairb.com.

Please let me know if you have any questions or need assistance in completing the form.

Reports received within 2 weeks of expiration are subject to a Late Renewal Review Fee.

Thank you for your prompt attention to this.

Regards,
MaryJo Carter

MaryJo Carter | Specialist, Ongoing Review
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office 513.761.4100 ext. 5211 | **Fax** 866.657.7917 | MaryJo.Carter@sairb.com

From: Site Reminder [mailto:SiteReminderReplies@sairb.com]
Sent: Monday, October 16, 2017 10:32 PM
To: rtestman@gplabs.com
Subject: Periodic Report Due Now for AEA09 PI: Robert J. Testman (Final Notice)
Importance: High

FINAL NOTICE-IMMEDIATE RESPONSE REQUESTED

Date: Oct 16, 2017

Investigator: Robert J. Testman

Sponsor: AMERICAN CHEMISTRY COUNCIL - ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)

Protocol: AEA09

IRB#: 201307318

PERIODIC REVIEW DUE

IRB approval is at risk of expiration

Click Here to Complete Form

A completed SmartForm must be submitted for review at least 4 weeks prior to the approval expiration date on your approval or reapproval letter.

Federal regulations require that all studies be reviewed at least annually by an IRB. Please take necessary measures to comply with this federal regulation.If there are circumstances that prevent you from submitting the SmartForm, please contact Schulman's Ongoing Review team immediately.

NOTE:

Reports received within 2 weeks of expiration are subject to a **Late Renewal Review Fee**.

Thank you

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If received in error, please reply to this communication. The information contained in this communication is confidential, for the exclusive use of the recipient listed above. Any reading, disclosure, use or reproduction of this communication other than by the intended recipient, is prohibited.

PROTOCOL DEVIATION NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

List of Deviations, Dates, Reasons for Deviation, and Effect on Study

1. **Date of Deviation: N/A**

   Description of Deviation: For the inner dosimeter (ID) garments worn by the subjects painting in ME01, ME02, ME04, ME06, ME07, ME10, ME12, ME13, ME16 and ME17, BIT background contamination was observed at higher levels than total residues found in outer dosimeters. Summary ID residues will be reported using an EPA reviewed penetration factor applied to outer dosimeter samples for these subjects (Section 12B).

   Reason for Deviation: The analytically determined residues in ID samples for these subjects were higher than OD samples. A subsequent investigation demonstrated that some inner dosimeter lots were received contaminated with BIT from the manufacturer.

   Effect on the Study: The eight subject inner dosimeters from non-contaminated lots will be used to calculate a penetration factor which will be applied to calculate summary statistics for the study. Estimates based on using a penetration factor will allow for representative data on dermal exposure.

2. **Date of Deviation: May 5, 2016**

   Description of Deviation: The Protocol states: IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle (Section 9.A.ii). The advertisement was unable to be placed in the California Advocate.

   Reason for Deviation: Staff at the California Advocate indicated that the advertisement would be placed in the next available issue, May 20, 2016. However, no copies of the paper could be found and phone calls to confirm placement were not returned.

   Effect on the Study: No adverse impact on the study. Recruitment proceeded through the Fresno Bee and Vide en Valle newspapers which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled in the study.

3. **Date of Deviation: June 8, 2016 – June 10, 2016**

Description of Deviation: The additional BIT added to the test substance was dissolved in diethylene glycol instead of dipropylene glycol (Section 7A).

Reason for Deviation: Analytical coordinator oversight.

Effect on the Study: No adverse impact on the study. The solvent used is very similar chemically to that called for in the protocol. All paints were assayed in triplicate prior to use to ensure acceptable BIT concentration.

4. **Date of Deviation: June 7, 2016 – April 27, 2017**

Description of Deviation: The BIT internal standard was used after its September 21, 2015 retest date (Section 12Aii).

Reason for Deviation: The BIT internal standard was custom synthesized and was not retested prior to use.

Effect on the Study: No adverse impact on the study. The BIT internal standard is used consistently in both calibration standards and samples to normalize the peak area ratio of the reference substance. A currently retested internal standard substance is not required as exact purity has no effect on analytical results.

5. **Date of Deviation: May 3, 2016 – June 14, 2016**

Description of Deviation: The test substance containers were temporarily stored at ambient temperature at GPL with a data logger to monitor storage conditions until transfer to field contractor personnel. Upon downloading the data logger data, it was discovered that the device did not record any temperature data (Section 7A).

Reason for Deviation: Device malfunction.

Effect on the Study: No adverse impact on the study. Temperature min/max is recorded weekly at a nearby GPL room temperature location and the temperature range was 21 °C – 25 °C.

6. **Date of Deviation: December 12, 2016 – April 26, 2017**

Description of Deviation: Select inner dosimeter (8 sets), outer dosimeters (7 sets), painter's hats (6 sets), air sampling tube (1 set), and background wall wipe (1 set) samples were analyzed after being stored frozen for 6 months, later than the experimentally confirmed stability interval (Section 12C).

Reason for Deviation: Personnel oversight.

Effect on the Study: No adverse impact on the study. All samples, including those analyzed after the storage interval, were analyzed with field fortified samples which did not show low analyte recovery. This demonstrates that samples were stable after being stored frozen beyond 6-months.

7. **Date of Deviation: June 13, 2016 – July 1, 2016**

Description of Deviation: Study samples were generated in this study using ID suffixes not listed in Section 11A or Appendix I. These samples were generally background air sampling tubes, background wall wipes, and sweat wipes. (Section 11A).

Reason for Deviation: Example sample ID information for these matrices was inadvertently not included in the protocol when it was written.

Effect on the Study: No adverse impact on the study. The background wall wipes, air sampling tubes, and sweat wipes are all referenced in the protocol, however the ID suffixes designating sample identification was not listed in page 39 of the protocol or the study sample list.

PREPARED BY: _____ DATE: 10/27/17

STUDY DIRECTOR: _____ 10/27/17
Robert J. Testman, M.B.A Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESNTATIVE: _____ 10/27/17
Has Shah, Ph.D. Date
Sponsor Representative

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Robert Testman | rtestman@gplabs.com

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Study Status Report

- Form Requirements
- Report Information
- Study Contact
- Study Status
- Subject Safety
- Regulatory History
- Financial Interest
- Submission Summary

Study Status Report Submission › Submission Summary

Single Site Study Final Report

Review completed form information including all attachments prior to submission. This is a preview only. To make changes, click on the "Back" button. To submit the form, click on the "Submit" button.

Print Preview Only

Study And Contact Information			
Name of User:	Robert Testman		
Title:	President		
Phone:	559-275-9091	**Fax:**	
E-mail:	rtestman@gplabs.com		
Country:	US		
IRB Number:	201307318		
Protocol Number:	AEA09		
Sponsor:	American Chemistry Council		
PI/QI Name:	Robert Testman		
[✓] This document will be submitted by the Principal Investigator (PI)/Qualified Investigator (QI) Or Designee authorized by the PI/QI to submit on behalf of the PI/QI.			

Report Information			
Represent:	Site/Investigator	**Documentation For:**	Single Site and Protocol Review
Report Type:	Closure		
Have any subjects been consented at your site since the beginning of this study?			Yes
Are any subjects still participating in this study, including follow-up or subjects being followed until death for survival analysis?			No

Study Status Information		
What is the current site enrollment status?		
Enrollment is closed at this site		
What was the date the first subject was consented at your site?		05/11/2016
What was the date of the most recent study visit?		07/01/2016
Please provide the date of the final contact with the last study subject:		07/01/2016
Since your last report, have any subjects transferred?		No
	# transferred to your site (include these subjects in Number of consented subjects in the following question)	
	# transferred from your site (include these subjects in Number of Withdrawals in the following question)	
Please complete the following information for all subjects consented for this study at your site:		
	Number of consented subjects	37
	Number of Screen Failures	5
	Number of Subjects Withdrawn	4
	Number of Subjects who Completed the Study	28
	Number of Subjects still Active in the Study	0
Have any subjects been withdrawn since your last report to Schulman?		No
Since your last report, have you consented subjects from any of the following groups?		
	Anyone who cannot read (blind or illiterate)	No
	Children (anyone under the age of majority in your state/province)	No
	Non-English speaking persons	No
	Consented via legally authorized representative (LAR)	No

IC Attachment selection:	Attached below
Please provide any additional information about the Informed Consent documents if necessary:	

Please indicate whether any of the following have occurred at your site since your last report.

	Change of Site Location:	No
	If "Yes", was change in site location reported to Schulman?	
	Change of PI/QI:	No
	If "Yes", was change of PI/QI reported to Schulman?	
	Change or addition of Sub-Investigator(s):	No
	If "Yes", was change or addition of Sub-Investigator(s) reported to Schulman?	
	Change in Subject Compensation:	No
	If "Yes", was change in subject compensation reported to Schulman?	

Subject Safety Information

Since your last report, have there been any reportable items of noncompliance with the protocol, Board requirements or regulations?	Yes
If "Yes", were the items of noncompliance reported to Schulman?	Yes
Since your last report, have there been any Unanticipated Adverse Device Effects (UADEs)?	N/A - not a device study
If "Yes", were the UADEs reported to Schulman?	
Since your last report, have there been any Unanticipated Problems Involving Risk to Human Subjects or Others?	No
If "Yes", were the Unanticipated Problems Involving Risk to Human Subjects or Others reported to Schulman?	
Since your last report, have you provided subjects with any additional information not contained in a Board approved document that may affect their willingness to stay in the study?	No
If "Yes", was this previously reported to Schulman?	
If not previously reported, please explain:	
Since your last report, have any subjects sought compensation for injury or made complaints regarding the conduct of the study?	No
Since your last report, has anything occurred in this study which, in your opinion, would alter the initial risk/benefit analysis of the study (such as new information or changes that may adversely affect the safety of the subjects or conduct of the clinical trial or increase the risk of the subjects?	No
If "Yes", was the alteration of the risk/benefit analysis previously submitted to Schulman?	
If the risk/benefit analysis of the study was altered, please explain:	

Regulatory History Information

Has this site and/or investigator associated with this study been audited by the FDA, OHRP, EPA, HPFB, or any other government agency during this study?			Yes
If "Yes", please list all audits below:			
Agency:	California Dept of Pesticide Review		
Physician/Investigator:	Robert Testman	**Audit End Date:**	06/15/2016
Was a form FDA 483, Inspection Exit Notice or Health Canada Notification of Deficiencies Letter, or other agency's equivalent received for the audit?			No
Please attach all related correspondence for all of the audits listed, including the site response with corrective actions:			Previously Submitted
Are there any state/provincial medical board complaints and/or charges currently pending against any investigator or staff member associated with this study?			No
If "Yes", was a written explanation and all relevant documents submitted to Schulman?			
If not done previously, please explain:			
Since your last report to Schulman, has any investigator involved with this study:			
Had a sponsor, CRO, or an IRB/REB terminate, suspend, impose restrictions or sanctions on any protocol, or refuse to review any protocol?			No
Had the FDA, OHRP, or EPA (US sites) or HPFB (Canadian sites) terminate a study?			No
Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g., suspension, revocation, or restriction?			No
Resigned his/her medical staff membership or surrendered clinical privileges while under investigation by the medical staff or its designee?			No
Been convicted or charged with a crime (misdemeanor or felony)?			No
Had a state/provincial medical board take a disciplinary action against his/her license, or is currently			No

under investigation?	
If "Yes" to any of the above issues, please explain:	

Financial Interest Information	
Since your last report, has any investigator involved in this study:	
Held a position as an officer or member of the Board of Directors of the sponsor or CRO of this study?;	No
Held ownership interest (equity or stock options) related to the research in excess of $5,000 when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family?	No
Held ownership interest (equity or stock options) related to the research whose value when aggregated for the immediate family represents 5% or more of any one single entity?	No
Held ownership interest (equity or stock options) related to the research of any value held in a non-publicly traded company?	No
Held any proprietary interest related to the research? (A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.)	No
Received, or made any arrangement to receive, any significant payment of other sorts related to the research to support activities of the investigator? (A significant payment of other sorts is defined as: payments by the sponsor to support activities of the investigator that have a monetary value of more than $5,000 exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family.)	No
Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study?	No
Entered into any financial arrangement related to the research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: (i) compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; (ii) compensation in the form of an equity interest in the sponsor of the study; or (iii) compensation tied to sales of the product, such as royalty interest.)	No
Has the noted Conflict of Interest (COI) been previously reported?	
If "No", when did the COI begin?	
If "No", have subjects been enrolled since the COI began?	
If "Yes", does the COI still exist?	
If COI still exists, has there been any change to the previously reported COI?	
Since your last report, have there been any changes to the clinical trial budget?	

Please enter any additional submission comments:

Attached Documents:

File Name	File Description	File Type
120463 icf.pdf		Informed Consent

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 30, 2017 8:15 AM
To: Robert Testman
Subject: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

Robert

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Submission Type: Single Site Study Final Report
Submission Form: Single Site Study Final Report Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

File Type	File Name	Description
Informed Consent	120463 icf.pdf	

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
Phone: 559-275-9091
Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017111456
Form ID: OR1721416
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 11:14AM

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Robert Testman

From: MaryJo Carter <MaryJo.Carter@sairb.com>
Sent: Monday, October 30, 2017 11:21 AM
To: Robert Testman
Subject: RE: Additional Noncompliance/Deviation Information Needed for 201307318_10272017172354

Hi Rob,

I followed up with the Subject Safety team, and they said that each deviation has to be its own report. We categorize each deviation, so they have to be submitted individually for categorization.

Regards,
MaryJo Carter

MaryJo Carter | Specialist, Ongoing Review
Schulman IRB | 4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
Office 513.761.4100 ext. 5211 | **Fax** 866.657.7917 | MaryJo.Carter@sairb.com

---

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, October 30, 2017 1:58 PM
To: MaryJo Carter <MaryJo.Carter@sairb.com>
Subject: FW: Additional Noncompliance/Deviation Information Needed for 201307318_10272017172354

Hi MaryJo,

I got the following email asking for more information, however it does not specify what information is wanted. Can you assist? Does this mean that each deviation item should be a separate report?

Thanks,
Rob

From: Subject Safety Follow Up [mailto:subjectsafetyfollowup@sairb.com]
Sent: Monday, October 30, 2017 10:48 AM
To: Robert Testman <rtestman@gplabs.com>
Subject: Additional Noncompliance/Deviation Information Needed for 201307318_10272017172354

Workflow Notification

Hello,

Schulman IRB has received your Noncompliance/Deviation Report Form(s).
The Report **CANNOT** be processed without the below requested information.

Please submit these using separate reports.

Please do not resubmit a new report, unless otherwise requested. Instead, please reply directly to this email with your response WITHIN FIVE (5) BUSINESS DAYS.
Thank you for your assistance.

Regards,

Subject Safety
Schulman IRB

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- Issue Information
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Noncompliance Submission ▸ Submission Summary

Noncompliance Issue/Deviation Submission Summary

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	05/03/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
The test substance containers were temporarily stored at ambient temperature at GPL with a data logger to monitor storage conditions until transfer to field contractor personnel. Upon downloading the data logger data, it was discovered that the device did not record any temperature data (Section 7A). No adverse impact on the study. Temperature min/max is recorded weekly at a nearby GPL room temperature location and the temperature range was 21 °C – 25 °C.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
Data loggers are already on a routine maintenance program and have been very reliable. This data logger unit malfunctioned. The temperature logger in a nearby room gives good assurance of compliance.	

Please enter any additional submission comments:

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Noncompliance Issue/Deviation Submission Summary

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	07/01/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
For the inner dosimeter (ID) garments worn by the subjects painting in ME01, ME02, ME04, ME06, ME07, ME10, ME12, ME13, ME16 and ME17, BIT background contamination was observed at higher levels than total residues found in outer dosimeters. A subsequent investigation demonstrated that some inner dosimeter lots were received contaminated with BIT from the manufacturer.Summary ID residues will be reported using an EPA reviewed penetration factor applied to outer dosimeter samples for these subjects (Section 12B). The eight subject inner dosimeters from non-contaminated lots will be used to calculate a penetration factor which will be applied to calculate summary statistics for the study. Estimates based on using a penetration factor will allow for representative data on dermal exposure.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
This issue was determined to be caused by a manufacturing process change by the garment supplier. Future studies with BIT will include additional screening of new material lots.	

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	06/07/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
The BIT internal standard was used after its September 21, 2015 retest date (Section 12Aii). No adverse impact on the study is expected. The BIT internal standard is used consistently in both calibration standards and samples to normalize the peak area ratio of the reference substance. A currently retested internal standard substance is not required as exact purity has no effect on analytical results.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
The protocol should have stated that re-certification was not required for the internal standard. This will be added to future protocols.	

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	05/05/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
The Protocol states: IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle (Section 9.A.ii). The advertisement placement was unable to be confirmed in the California Advocate. Staff at the California Advocate indicated that the advertisement would be placed in the next available issue, May 20, 2016. However, no copies of the paper could be found and phone calls to confirm placement were not returned. Recruitment proceeded through the Fresno Bee and Vide en Valle newspapers which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled in the study.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
Future protocols will not include advertisements in the California Advocate.	

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- Issue Information
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Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	06/08/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
The additional BIT added to the test substance was dissolved in diethylene glycol instead of dipropylene glycol (Section 7A). This was due to analytical coordinator oversight. No adverse impact on the study is expected. The solvent used is very similar chemically to that called for in the protocol. All paints were assayed in triplicate prior to use to ensure acceptable BIT concentration.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
The analytical coordinator was re-trained. The QA unit was tasked with conducting a phase audit of any test article preparation for IRB studies.	

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Subject Safety

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Noncompliance Submission ▸ Submission Summary

Noncompliance Issue/Deviation Submission Summary

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	06/13/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
Study samples were generated using ID suffixes not listed in Section 11A or Appendix I. These samples included background air sampling tubes, background wall wipes, and sweat wipes. The protocol describes the collection of these matrices, however codes for these matrices were inadvertently not included in the protocol when it was written. No impact is expected as appropriate codes were assigned during the study.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
Future protocols will require additional review of matrix codes.	

Please enter any additional submission comments:

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Subject Safety

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Noncompliance Submission ▸ Submission Summary

Noncompliance Issue/Deviation Submission Summary

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User Information			
Name of User:	Robert Testman		
Title:	President		
Company:	Golden Pacific Labs	**Representing:**	Site/Investigator
Phone:	559-275-9091		
E-mail:	rtestman@gplabs.com		
Country:	US		

Study and Site Information	
IRB Number	201307318
Protocol Number	AEA09
Sponsor	American Chemistry Council
Name of PI [US]/QI [CAN]	Robert Testman

Noncompliance Issue Information	
Subject Initials	
Subject Number	
Is the Subject still Enrolled?	Not Applicable
If the Subject is no longer enrolled, please provide an explanation below.	
Date Site became aware of the Noncompliance Issue	10/27/2017
Date the Noncompliance occurred	12/12/2016
Is the sponsor aware of the Noncompliance issue?	Yes
If "No", when will the sponsor be notified?	
Describe the Noncompliance issue in detail, including how it has been resolved.	
Select inner dosimeter (8 sets), outer dosimeters (7 sets), painter's hats (6 sets), air sampling tube (1 set), and background wall wipe (1 set) samples were analyzed after being stored frozen for 6 months, later than the experimentally confirmed stability interval (Section 12C). No adverse impact on the study is expected. All samples, including those analyzed after the storage interval, were analyzed with field fortified samples which did not show low analyte recovery. This demonstrates that samples were stable after being stored frozen beyond 6 months.	
Did the Noncompliance issue adversely affect the safety or welfare of the study subjects or others?	No
If the answer was "Yes" please explain.	
Did the Noncompliance issue adversely affect the integrity of the study data?	No
If the answer was "Yes" please explain.	
Please describe the corrective measures that have been put in place to prevent similar Noncompliance issues from occurring at your site in the future.	
Future protocols which include field fortified samples to demonstrate storage stability will not include an analysis date reqirement.	

Please enter any additional submission comments:

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 30, 2017 1:05 PM
To: Robert Testman
Subject: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

Robert

The following documents have been successfully submitted via Schulman Associates IRB **eSubmission™ 2.0** system:

Submission Type: Noncompliance Issue/Deviation Submission Acknowledgement
Submission Form: Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
Phone: 559-275-9091
Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017160519
Form ID: SN1724747
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 4:05PM

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 30, 2017 1:10 PM
To: Robert Testman
Subject: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

Robert

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Submission Form: Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
Phone: 559-275-9091
Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017161009
Form ID: SN1724748
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 4:10PM

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Company: Golden Pacific Labs
Name: Robert Testman
Phone: 559-275-9091
Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017162549
Form ID: SN1724749
IRB Number: 201307318
Investigator: Robert Testman
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Company: Golden Pacific Labs
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Acknowledgement #: 201307318_10302017163114
Form ID: SN1724753
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
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Company: Golden Pacific Labs
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Acknowledgement #: 201307318_10302017163641
Form ID: SN1724755
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 4:36PM

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Importance: High

Robert

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Submission Form: Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
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Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017164157
Form ID: SN1724757
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 4:41PM

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 30, 2017 1:48 PM
To: Robert Testman
Subject: eSubmission 2.0 System - Document Submission Confirmation

Importance: High

Robert

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Submission Form: Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

Submitting User Information

Company: Golden Pacific Labs
Name: Robert Testman
Phone: 559-275-9091
Email: rtestman@gplabs.com

Acknowledgement #: 201307318_10302017164807
Form ID: SN1724760
IRB Number: 201307318
Investigator: Robert Testman
Sponsor: American Chemistry Council
Protocol Number: AEA09
Submitted Date/Time: Oct 30 2017 4:48PM

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Robert Testman

From: Schulman Technical Support <alertreply@sairb.com>
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To: Robert Testman
Subject: CLOSURE documents posted for Protocol AEA09 [Country:US]

Importance: High

Robert,

IRB documents have been posted and are available via Schulman IRB **SiteAccess**.

Document Category: **CLOSURE**
Document Delivery: **PAPERLESS DELIVERY** - IRB documents are only available electronically. No follow up hard copies will be sent to the Site.
Protocol: **AEA09 [COUNTRY:US]**
Indication: **Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Testman, Robert J.	Closure Letter	Oct 30, 2017

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STUDY CLOSURE: 10/30/2017

October 30, 2017

FROM:	Schulman IRB
TO:	Robert J. Testman
SUBJECT:	Study Closure
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board received your Final Report on the referenced protocol.

This letter is to confirm that the Board closed the files on the referenced protocol.

WebPortal/Paperless

APPENDIX O.

CORRESPONDENCE WITH CDPR

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Date	Page Range	Document(s)
28 Oct 13	1334	RTestman→DRichmond transmittal of Brush and Roller Paint Protocol 120463 dated 25 October 2013 and Scenario Design
	1335-1422	Protocol 120463 dated 25 October 2013
	1423-1436	Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design dated 25 October 2013
30 Oct 13	1437	DRichmond→RTestman acknowledging receipt of protocol
10 Dec 16	1438	RTestman→DRichmond requesting status update of CDPR review of protocol
19-20 Dec 16	1439	OEscobar→RTestman→MBoatwright transmittal of letter from CDPR review of Protocol 120463 submitted 28 October 2013, including summary of revisions needed to protocol, Informed Consent (ICF), and Experimental Subject's Bill of Rights (BOR)
	1440-1446	CDPR Review Letter dated December 19, 2013
24 Jan 14	1447	RTestman→DRichmond transmittal of letter response to CDPR review (19 Dec 13)
	1448	Cover Letter dated January 22, 2014
	1449-1456	Summary Table of CDPR Comments, GPL Responses, and Protocol Modifications
	1457-1587	Protocol 120463 dated 22 January 2014 in tracked changes
15 Mar 16	1588	RTestman→DRichmond transmittal of IRB Approved Final Protocol, SAIRB Approval Letter and signed letter to SAIRB summarizing HSRB and EPA recommendations and how GPL addressed each in the final version of the protocol
	1589-1738	Protocol 120463 dated 05 January 2016
	1739-1740	SAIRB Approval Letter dated March 4, 2016
	1741-1745	Signed Summary Letter
17 Mar 16	1746	OEscobar→RTestman notification that a letter from CDPR with final approval was available
	1747-1748	Approval Letter dated March 17, 2016
3 May 16	1749	RTestman→DRichmond transmittal of Protocol Amendment 1
	1750-1751	Protocol Amendment 1
4 May 16	1752	DRichmond→RTestman acknowledging receipt of Protocol Amendment 1 and requesting IRB Approval of Amendment 1
6 May 16	1753	TLouie→RTestman transmittal of letter from CDPR acknowledging receipt of Amendment 1, stating there was no actions that required CDPR Approval, and requesting SAIRB Approval Letter
	1754-1755	CDPR Letter dated May 5, 2016
9 May 16	1756	RTestman→DRichmond transmittal of SAIRB Protocol Amendment 1 Approval Letter

Date	Page Range	Document(s)
	1757	Letter dated May 6, 2016 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 1
20 Jun 16	1758	RTestman→DRichmond transmittal of Protocol Amendment 2 and SAIRB Approval Letter
	1759	Letter dated June 15, 2016 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 2
	1760-1761	Protocol Amendment 2
23 June 16	1762	TLouie→RTestman notification that a letter from CDPR summarizing observations of study monitoring was available
	1763	CDPR Letter dated June 23, 2016
	1764-1766	Observations of Studies Involving Human Subjects Form for 120463
24 June 16	1767	TLouie→RTestman transmittal of letter from CDPR acknowledging receipt of Amendment 2 and stating there was no actions that required CDPR Approval
	1768	CDPR Letter dated June 23, 2016
31 Oct 17	1769	RTestman→DRichmond transmittal of SAIRB Study Closure Letter and Protocol Deviation 1 for completeness of records although not required by protocol
	1770	SAIIR Study Closure Letter dated October 30, 2017
	1771-1773	Protocol Deviation 1

Megan Boatwright

From: Robert Testman
Sent: Monday, October 28, 2013 3:05 PM
To: Don Richmond
Cc: Megan Boatwright
Subject: New protocol for review
Attachments: AEATF Brush Roller Draft Protocol 25Oct2013.docx; AEATF Brush Roller Scenario Design Document 25Oct2013.doc

Hi Don,

Please see attached a new protocol involving human subjects that will be conducted in California, and the associated scenario design document. The protocol was submitted to EPA for preliminary technical comments from EPA and CDPR, and incorporates those comments. We will also be submitting the protocol for IRB review. Please let me know if you have any questions, etc.

Thanks,
Rob

P.S. – as a heads up Megan will have an additional protocol later this week for a removal efficiency study that supports this study (waiting for EPA comments).

Rob Testman
estman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

***DRAFT* PROTOCOL**

25 October 2013

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

May 2014

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEAXX

GPL Study Number

120463

Total Number of Pages: XXX

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No:	AEAXX
GPL Study No:	120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date:	May 2014
Proposed Experimental Termination Date:	August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
7B.1	Test, Control, and Reference Substances Labeling	12.0
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Sponsor / Sponsor Representative:

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II
c/o Has Shah, Ph.D.
700 2nd Street NE
Washington, DC 20002
Phone: (202) 249-6724
E-Mail: has_shah@americanchemistry.com

Study Director and Principal Investigator:	Robert J. Testman (English) Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: 559-275-9091 E-Mail: rtestman@gplabs.com
Field Coordinators:	Megan T. Boatwright (English) Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mboatwright@gplabs.com Natan R. Chavez (English and Spanish) Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: nchavez@gplabs.com Thomas F. Moate (English) Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave. Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: tmoate@gplabs.com
Analytical Coordinator:	Kimon P. Acedo Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: kacedo@gplabs.com
Field Location:	Fresno County, CA
Reviewing IRB:	Schulman Associates IRB, Inc. 1550 Sawgrass Corporate Parkway Suite 120 Sunrise, FL 33323 Phone: (954) 327-0778 Website: www.sairb.com

2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 400 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 400 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all PPE (i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable,

thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as

outlined in section 4 of the scenario design document. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is little incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: *(954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California DPR and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and

California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California Department of Pesticide Regulation [DPR]) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations, and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data

available to EPA from the PHED the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or IPA will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own sex. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low (Bartels, 2013), and the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 400 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 400 ppm and 600 ppm. GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study.

A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantification of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint types. The table below lists the proposed LOQ for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample

Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an

unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue. Subjects will be provided dry cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount

of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design

document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).
Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 8 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 10 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The amount of active ingredient handled (AiAH) will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Applicators to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates. At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24

initially selected are required, randomized subject 25 will be contacted followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate applicators (or 'workers') for the MEs. This includes the planned 18 surrogate workers needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire about the health of the subject. The investigator will answer any questions. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well

as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate when at the end of the 4 week recruitment time period a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form . If fewer than 24 subjects have been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in

7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and Subject Self-Reporting Demographic Form

- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies to latex paint, soaps or isopropyl alcohol
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential applicators of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study

sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of eight will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the

Principal Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink.

The on-site health professional will immediately be contacted for further medical management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an

approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same sex. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer

dosimeter shirt will be tucked into the pants. A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections. Ceiling ventilation fans will be turned off while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be provided

additional test substance until they have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same sex. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

    a. The researcher will help subjects take off the painter's hat and save it for analysis.

b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse with the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

f. The researcher will help subjects take off the long underwear, and save it for analysis.

g. When all samples have been collected, subjects will dress again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat will be removed with the assistance of a researcher (study team member) of the same sex, placed in a pre-labeled glass jar and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing, sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™ filters samples will be placed in temporary frozen storage as soon

after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of

clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same sex and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in "gross violation" or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time

actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.
5. Prepare field fortification samples.

6. Monitor temperature and humidity, ensure room vent fans are off during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site (e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of inner dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA??-BRS-01-ID-LA:

AEA?? = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	TBA
Purity:	TBA
Date Received:	TBA
Expiration Date:	TBA

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS methods will be validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits. The limit of quantification (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the matrix spikes. A solvent blank will be injected prior to injecting the analytical standards for each run.

Each analytical set will include two laboratory fortified samples, a solvent blank and a control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be

transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

Evaluation of benchmark adequacy. A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);

11. Sample information (including inventory, chain of custody);
12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be kept in a separate location and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts

(Appendix H), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the QAU. The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Principal Investigator and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.

6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.
9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.
13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

Robert J. Testman
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, California 93722
Telephone: 559-275-9091
Fax: 559-275-1810
E-mail: rtestman@gplabs.com

B. Quality Assurance Unit

Anantdeep K. Kang, M.S.
ASK GLP Consulting
1577 Dartmouth Ave.
Clovis, California 93619
Telephone: 559-960-6164

*A.K. Kang will report directly to the GPL Board of Directors, i.e., independent of any involvement of the Study Director or other investigators.

C. Field Coordinators

Megan T. Boatwright
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Fresno, CA 93722
Phone: (559) 275-9091
E-mail: mboatwright@gplabs.com

Natan R. Chavez (English and Spanish)
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Thomas F. Moate (English)
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D. Analytical Coordinator

Kimon P. Acedo
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4720 W. Jennifer Avenue, Suite 105
Fresno, California 93722
Telephone: 559-275-9091
E-mail: kacedo@gplabs.com

19. PROTOCOL APPROVALS

Has Shah, Ph.D.
Sponsor's Representative
Date

Robert J. Testman
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC
Date

Megan T Boatwright
Field Coordinator (English)
Golden Pacific Laboratories, LLC
Date

Kimon P. Acedo
Analytical Coordinator
Golden Pacific Laboratories, LLC
Date

Anantdeep K. Kang, M.S.
Quality Assurance
ASK GLP Consulting
Date

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

Bartels, 2013. Personal Communication. Abstract of Determination of The In-Vitro Dermal Absorption of 1,2-Benzisothiazolin-3-one.

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol.* Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012, Complies with:			
OTC	Yes	LEED®09 CI	Yes
SCAQMD	Yes	LEED®09 NC	Yes
CARB	Yes	LEED®09 CS	Yes
CARB SCM 2007	Yes	LEED®09 H	Yes
MPI #	53	NGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer

Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry

Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent

Flash Point: N/A

Finish: 0-5 units @ 85°

Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic

A86W00151

VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12

Volume Solids: 43 ± 2%

Weight Solids: 61 ± 2%

Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

continued on back

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE. Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
HOTW 03/25/2013 A86W00151 09 47

The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet.

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or, absorbed through skin. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles or face shield) long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaiminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

FIRST AID	
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latices, Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Car Care Products Including Car Washes, Car Waxes, And Silicone Emulsions, Home Care Cleaning Products Including Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	**5383-121**
EPA Establishment Number	**5383-NJ-1**

ACTIVE INGREDIENT:	**% Weight**
1,2-Benzisothiazolin-3(2H)-One	**19.18%**
INERT INGREDIENTS	**80.82%**
TOTAL	**100.0%**

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:
[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

®MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

APPLICATION RATE: Mergal®BIT 20 is an effective preservative for most aqueous applications. Mergal®BIT 20 is suggested for use in aqueous or water-containing products and systems, including industrial and institutional products to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% wt/wt of Mergal®BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of Mergal®BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below.

FOR FOOD-CONTACT PAPER AND PAPERBOARD COATINGS: Follow the FDA clearances cited below. Use of Mergal®BIT 20 must not exceed 0.21 mg/in^2 (0.0326 mg/cm^2) of finished paper and paperboard intended for contact with dry foods and 0.11 mg/in^2 (0.0168 mg/cm^2) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal®BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 -	Components for Adhesives
21 CFR 176.170 –	Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 –	Components of Paper and Paperboard in contact with dry food
21 CFR 176-300 –	Slimicides (in the manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 –	Rubber articles intended for repeated use: follow instructions in paragraph (c)(4)(1X)

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polymer and micellar/polymer waterfloods: Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
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Natan R. Chavez (English and Spanish)
Field Research Associate
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Thomas F. Moate (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or paint products; if you have psoriasis, eczema, sores or open cuts on your skin; if you have severe diabetes; if you have a suppressed immune system such as with an organ transplant or active chemotherapy; or if you have heart or breathing problems.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, or the laboratory General Manager, Thomas Moate, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long

johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own sex will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The research will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits

You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates Independent Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of each informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

You may contact the *Schulman Associates Independent Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA-??: Interior Latex Paint Application with Brush and Roller Scenario

Part I: *Interview questions*	Q/NQ
1. Do you have any skin conditions on your hands (psoriasis, eczema, etc.)? ☐Yes ☐No	
2. Do you have difficulty breathing? Moderate or severe asthma or emphysema? ☐Yes ☐No	
3. Do you have Cardiovascular disease? Have you ever had a myocardial infarct, stroke, or congestive heart failure? Do you have uncontrolled high blood pressure? ☐Yes ☐No	
4. Do you have severe diabetes? ☐Yes ☐No	
5. Are you immunologically suppressed? Have you ever had a transplant? Chemotherapy? ☐Yes ☐No	
6. Are you employed by or married to an employee of an AEATF company, GPL, a paint manufacturer or the ACC (interviewer to explain initials of various entities)? ☐Yes ☐No	

Part II: *To be filled out by candidate*			
7. Name		10. Weight: lbs	
8. Address		11. Height: ft in	
		12. Shirt size: ☐**S** ☐**M** ☐**L** ☐**XL** ☐**XXL** ☐**XXXL**	
9. City, ST, Zip		13. Waist: ☐24-28 in ☐28-32 in ☐32-36 in ☐36-40 in ☐40-44 in ☐44-50 in	
14. Telephone(s)			
15. Age in years =	16. DOB:	17. Sex ☐M ☐F	
18. Resident in Fresno County? ☐Yes ☐No		19. Have you painted with a brush and roller in the past 5 years? ☐Yes ☐No	
		20. Have you worked as a professional painter in the past 10 years? ☐Yes ☐No	
21. Preferred Language: ☐English ☐Spanish		22. Reads: ☐English ☐Spanish	
23. Are you pregnant? ☐NA ☐Yes ☐No		24. Are you nursing a baby? ☐NA ☐Yes ☐No	
25. Do you consider your general health good enough to participate in this study as described? ☐Yes ☐No			
26. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐No			
27. Are you bothered by rubbing alcohol or soap on your skin more than family or friends? ☐Yes ☐No			
Interviewer ID age verification: ☐Yes ☐No _____ Subject Signature _____ Date			
Language of interview: : ☐English ☐Spanish	Interviewer Name:		
Interview date:	Interviewer Signature:		

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
*for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	Cristobalite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	Calcium Carbonate		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	Titanium Dioxide		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.
EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.
SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

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SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

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SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable
CONDITIONS TO AVOID
None known.
INCOMPATIBILITY
None known.
HAZARDOUS DECOMPOSITION PRODUCTS
By fire: Carbon Dioxide, Carbon Monoxide
HAZARDOUS POLYMERIZATION
Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS
Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.
IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD
Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.
Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

A87W151

SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 2/27/2013

Spanish advertisement here after translation of approved English version

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply one-half to two and one-half gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.

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Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:
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1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description

Antimicrobial Exposure Assessment Task Force II (AEATF II)

INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN

October 25, 2013

Revision Date: 10/25/2013

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INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN

1. Introduction

This document summarizes the rationale for critical elements of the design of the AEATF II interior latex paint application with brush and roller monitoring study. Brush and roller application of interior latex paint represents an exposure scenario being addressed as part of the overall AEATF II monitoring program. Airless sprayer application of interior latex paint represents another exposure scenario which will be addressed by AEATF II in a separate study as part of the overall AEATF II monitoring program. AEATF II in consultation with EPA made the decision to separate the brush and roller, and airless sprayer, interior latex paint application studies after a careful evaluation was made of the appropriate study designs. AEATF II proposes to conduct the brush and roller study using consumer applicators (without experience as professional painters), as use by typical consumer painters is likely to result in higher exposure than would be seen using professional painters as applicators. In contrast, AEATF II proposes to conduct a separate airless sprayer study using applicators with recent experience as professional painters using airless spray equipment. AEATF II anticipates that the level of training and experience necessary to safely operate commercial airless spraying equipment necessitates the use of experienced professional painters. Since the pool of potential subjects is separate for these two painting scenarios, AEATF II intends to perform each scenario as a separate study.

2. Scenario definition

A scenario is defined as a set of related tasks, pesticide formulations, equipment, engineering controls, and worker and/or consumer practices. For the purposes of the AEATF II Monitoring Program, the **interior latex paint application with brush and roller scenario** is defined as the hand-held application using a paint brush and/or paint roller of a formulated interior latex paint containing an antimicrobial chemical. This includes the task of actual painting for purposes of protection and beautification of architectural and other surfaces. The application of paint with a brush and roller represents a common application method by consumers, and is also used by commercial painters, as an alternative to a paint spray system. The interior latex paint application with brush and roller scenario is being used to address potential exposures to paint products in general, including latex paints, acrylic paints, epoxy paints, stains, sealants, etc. The interior latex paint was selected to represent this group of paint products because it is a commonly used product type, the application process (brush and roller) is similar across all paint product types, and all paint categories are considered similar for exposure purposes (*Standard Operating Procedures (SOPs) for Residential Exposure Assessment,* US Environmental Protection Agency, 2012).

Revision Date: 10/25/2013

In practice, paint application may or may not involve follow-on tasks, such as cleaning of the painting equipment, removing protective barriers from non-target surfaces, etc. Only the actual paint application is covered by this scenario. Applicator exposure associated with cleaning painting equipment is likely to result in a decrease in residues on the applicator's hands as washing equipment with water will also wash the applicator's hands. Cleaning of equipment may result in increased residues on the applicator's clothing due to splashing, however this may be less than any reduction in hand residues. In addition, applicators may not clean their equipment after each days use. As a result, AEATF II feels the more conservative approach is to monitor only the actual painting.

The AEATF II study restricts the paint application with brush and roller scenario to consumer applicators only. This focus on consumer applicators is considered the more conservative approach, given that consumer painters are expected to be less skilled than professional painters. A less skilled painter is more likely to expose themselves to drips and paint spills. It is expected that consumer painter exposure will be above the limits of quantification/detection of the analytical method. The amount of product handled per task, and per day can be used to extrapolate potential exposure to professional painters.

Thus, the AEATF II exposure data for brush and roller paint application of antimicrobial pesticides would be 'conservative' (i.e., would over-predict) if used to describe professional application exposure. However, it would be reasonable for regulatory agencies using the data to assume that exposure levels for professional applicators, when normalized for the amount of active ingredient handled, are not greater than those for consumer applicators.

3. Existing paint application with brush and roller exposure data

3.1. PHED studies

Since 1992 the EPA has conducted professional and consumer mixer/loader and applicator exposure and risk assessments relying primarily on the exposure data in PHED. PHED version 1.01 was initially released in February 1992, followed by PHED version 1.1 in February 1995. PHED version 1.1 was described by the Agency as an incremental improvement over the 1.01 version (Pesticide Handlers Exposure Database, User's Guide Version 1.1, Health Canada, U.S. Environmental Protection Agency, American Crop Protection Association, February 1995). PHED does include one study conducted using paintbrush application methods, but the data does not include paint roller application. Relevant characteristics of this study are summarized in Table 1.

Table 1: Summary of Paintbrush Application Studies in PHED

Study Design	Study 467
Active Ingredient:	Surrogate
Type of Use:	Paintbrush application
Monitoring Events (ME):	15
Product Applied:	~0.05 lb a.i.
Location:	MD
Analytical Grade(s)	AB (hands), C (dermal, inhalation)

Unfortunately, this study has limitations that reduce its value for an antimicrobial-oriented generic database. This study monitors paintbrush application only, but is being used to extrapolate to application with brush and roller combined. It appears that every ME within the study applied an identical amount of product. Thus, there is no variation in amount of a.i. handled within the study. In addition, both the dermal and inhalation exposure data from study 467 have only an analytical quality grade of C. To support the registration of a pesticide, the data should have an analytical grade of A or B. As a result, study 467 has limitations for use in regulatory exposure assessments.

3.2. Gijsbers study

In addition to PHED, a review of published literature was made to look for studies evaluating exposure to non-volatile paint components. Although numerous studies were available evaluating exposure to paint solvents, only one suitable study was located which studied a non-volatile chemical (Gijsbers et. al., 2004).

This study was a comprehensive investigation including dermal exposure from painting with a brush/roller conducted in The Netherlands to provide data to the European risk assessment database (RISKODERM). The study evaluated subject exposure to DEGBE (2-(2-Butoxyethoxy)ethanol) which was a component of the latex paint used at concentrations ranging from 0.4-3.2%. Subjects painted surfaces at construction sites primarily with a brush and sometimes a roller. Dermal and hand exposure were evaluated. However, this study was found to be lacking in several key areas.

1) No mention was made of good laboratory practices, quality assurance reviews, or other regulatory standards being followed.

2) No evaluation was made of potential inhalation exposure to DEGBE.

3) Non-hand dermal samples were only collected from 12 monitoring events.

4) Field recoveries were unacceptable due to background contamination at multiple sites, reducing the number of data points available.

5) The same subject was used for up to four monitoring events with most subjects monitored twice resulting in less than 12 valid and unique monitoring events for hand residues.

3.3. Removal efficiency studies

A review of published literature was made to look for studies evaluating removal efficiency of the proposed active ingredient, benzisothiazoline-3-one (BIT), from human skin. No studies were found which addressed this issue. A pilot experiment conducted at Golden Pacific Laboratories using mannequin hands as a surrogate recovered 88% of BIT applied in latex paint. AEATF II proposes conducting a separate study for the purpose of determining removal efficiency from human skin of BIT at two application levels in latex paint and solvent (n=10 hands per group). These subjects would have a small volume of latex paint containing BIT, or BIT in isopropyl alcohol, applied to the palmar surfaces of each hand and allowed to dry. Following 30 minutes drying time the paint would be removed using the technique developed with mannequin hands: scrubbing the hand with dressing sponges wetted with isopropyl alcohol/water (1/1) followed by rinsing with the same solvent. Each hand would be evaluated separately to increase sample size while minimizing the number of subjects.

4. Goal of the AEATF II paint application with brush and roller monitoring study

The AEATF II program, as described in the Governing Document (2008), intends to develop a database of exposure monitoring data that can be used to support practical regulatory decisions about future exposures for different (including currently nonexistent) active ingredients and their associated products. The database needs to address a variety of exposure scenarios for which no or limited data currently exist. The paint application with brush and roller scenario is an important component of the AEATF II program and the focus of this protocol. As noted in the previous section, existing monitoring data for this scenario are considered inadequate.

The primary purpose of the paint application with brush and roller monitoring study is to develop more accurate information on potential consumer and worker exposures to antimicrobials. These data will consist of dermal and inhalation exposure estimates derived from monitoring subjects under conditions constructed to broadly represent those expected for the future application of arbitrary antimicrobial pesticides. AEATF II

anticipates the resulting database will contain sufficient data to support exposure assessments for paint application with brush and roller.

For the paint application with brush and roller scenario (as is true for all AEATF II scenarios) only a small number of expensive experimentally-obtained monitoring events (MEs) are possible. Each ME represents the exposure possible for a single future handler-day. Although it is only a single task, paint application with a brush and roller still encompasses more handling conditions than any small number of MEs can practically include in a single study. For example, there are many possible active ingredients (ai), different application equipment used, multiple concentrations of active ingredient used, different volumes of product used, different workers and their associated behaviors, and multiple environmental and other handling conditions. All of these are expected to affect exposure to varying degrees.

In view of this limitation, a practical goal for this study is that the small sample of paint application with brush and roller MEs be biased towards increased diversity of handling conditions. As a result, the diverse sample of MEs is expected to at least cover the middle portion of the future exposure distribution, cover the upper portion of the future exposure distribution, and capture the range of exposure variation that is expected to exist. It is important to recognize that some degree of overestimation bias is inherent in any study if the exposures measured on the inner dosimeters from MEs are less than limit of quantitation (LOQ). This is more likely to occur in the lower exposure groups, although AEATF II is making every effort to obtain measurable exposures at all intervals. Another potential source of inherent overestimation bias in the study design described in this document and the associated protocol is reusing the same rooms for multiple painters. The residue remaining from prior uses represents a source of potential contamination for subsequent users, and will require adequate drying time and background monitoring to mitigate. A final source of overestimation bias in the study design is the use of an indoor site. AEATF II feels that an indoor painting environment is likely to increase dermal exposure over an outdoor painting environment due to the painting of ceiling surfaces which represent a significant source for drips and splatter. The AEATF II also feels that an indoor painting environment has a higher potential for inhalation exposure due to the limited air exchanges compared to an outdoor painting environment. The AEATF II does not foresee significant sources of underestimation bias for exposure estimates derived from data resulting from the proposed study.

The successful use of a small sample of MEs to represent the diversity in the target population of future 'painting-days' is aided by the following:

1. Dermal and inhalation exposure to the chemicals are considered generic (i.e., independent of the particular active ingredient used). This *generic principle* permits use of a small set of surrogate active ingredients to predict exposure for other active ingredients;
2. The *principle of proportionality* of exposure to the true amount of active ingredient contact. If a diverse amount of active ingredient handled (AaiH) is used across MEs, then exposures measured for one level of AaiH can be used to predict different levels of AaiH; and

3. *Expert knowledge* of possible handler conditions expected throughout the scenario permits re-construction (and/or selection) of synthetic MEs that represent a diverse set of future paint application with brush and roller conditions.

5. Diversity selection of monitoring events

A diversity selection approach is being used by the AEATF II to implement the paint application with brush and roller study. In the AEATF II approach, instances of possible handler-day conditions under the scenario are synthetically constructed and handler-day exposures measured using surrogate painters. These conditions (including painters) are either purposively or randomly chosen in such a manner that the synthetic handler-days (i.e., monitoring events, or "MEs") span the diversity of conditions in the scenario. The ME construction approach used by the AEATF II achieves diversity by:

1. Using multiple application dates within purpose built painting rooms in the study area (Fresno Co., CA);
2. Varying the levels of potential AI contact; and
3. Using different workers for each ME rather than repeated use of the same worker.

Diversifying these three 'meta-characteristics' indirectly varies many known and unknown handling-conditions. Purposively varying other minor handling-conditions, such as the sequence of surfaces painted, can further reduce homogeneity of MEs within the single site.

The AEATF II has determined, in consultation with the U.S. EPA, Health Canada, and California EPA, that a purposive diversity selection (PDS) approach is appropriate considering the regulatory purpose of the data and feasibility. A PDS approach is one that is primarily purposive but can be coupled with random choice elements when feasible to reduce intentional selection bias. The AEATF II Governing Document (2008) describes diversity and purposive diversity selection more generally in the context of the AEATF II Monitoring Program.

5.1. Painting rooms and equipment

The paint application with brush and roller monitoring study will be conducted in purpose built monitoring rooms inside a vacant building in Fresno County, CA. This particular geographic area was selected given its proximity to the analytical laboratory. Fresno County also contains a moderately large metropolitan area and offers a population of over 1,000,000 persons. Consequently, there is a substantial pool of possible subjects and a large number of vacant commercial buildings that are potentially acceptable for monitoring activities.

The use of a single geographic area and site is based on the premise that indoor paint application with brush and roller tasks being performed at a site in one geographical

area will not differ substantially from a similar array of tasks being performed at sites in another geographical area. That is, the variation in exposure associated with paint application with brush and roller inside of a building in Fresno County, CA would not be expected to differ substantially if another building in Fresno County, or in another metropolitan area were used or multiple cities over the country were spanned. This premise is supported by the Popendorf et al. (1992) antimicrobial exposure monitoring study which concluded that variability in dermal and inhalation exposures across workers was primarily influenced by the application method and by implication, each individual worker's implementation of that application method (i.e., their work practices and behavior), rather than the location or setting in which the application method is performed. This implies that monitoring multiple subjects and capturing diversity in indoor paint application with brush and roller conditions that might influence behavior is more important than geographic or site diversity.

Geographic differences in exposure that have been observed in some agricultural cohorts are not expected for paint application with brush and rollers. For example, in harvesters, climatic conditions that influence the degree of dustiness, the rate of dissipation of foliar pesticide residues, or the amount of perspiration may influence exposure. Those differences cannot really be considered regional, but rather environmental. In the case of painting services conducted indoors, the environmental conditions are constrained by heating, ventilating and air conditioning systems that control dustiness, temperature, humidity and airflow. Therefore, these conditions are expected to be similar throughout the country. Further the majority of exposure from painting is expected to be dermal due to drips and spills. This type of exposure is expected to be most associated with equipment and application technique.

Limited standardization of painting practices is another factor that is expected to lessen the importance of geographic area. Consumer painters may receive informal training in brush and roller application techniques from multiple sources. Some of these sources include: instruction from staff at paint sales outlets, instruction from other consumers with painting experience, and watching of home improvement television shows. This helps to insure that painting tasks are conducted somewhat uniformly across the country.

Lastly, there is increased efficiency, convenience, and cost savings associated with the use of a single site location near the analytical laboratory. The use of buildings located over multiple geographical locations would be especially costly. The cost of selecting both buildings and subjects would increase at least in proportion to the number of geographic locations due to construction, field team logistics and resources required. For the reasons outlined above, there would appear to be little benefit from such an increase in cost.

Monitoring will always be conducted inside purpose built rooms within a vacant commercial building or vacant areas and rooms within this building. The purpose built rooms will include walls, ceiling, door with frame, window frame, and baseboards. These rooms will be built to represent a "typical" residential room and provide a

combination of trim surfaces to be painted with a brush plus flat surfaces to be painted with a roller. The purpose in conducting these studies in a vacant building/area is to be free from personal interferences with non-subjects and the potential contamination from other sources of a commonly-used active ingredient (i.e., BIT). It also makes it easier to design monitoring events that focus on paint application with brush and roller only as opposed to the broad range of painting activities a subject might engage in that could also involve the active ingredient. Using vacant buildings also offers greater control of the scheduling of monitoring events. This combination of facility (building or building complex) and monitoring period (i.e. dates) is termed a 'site'. Only a single site will be used for this study.

Monitoring events will use a single type of application equipment (brush and roller). Generically speaking the type of equipment used will represent the most commonly used consumer equipment. The "most commonly used" designation was determined by AEATF II from available "top seller" lists on websites of national home improvement stores, and from conversations with paint store personnel. The equipment is defined by materials and techniques used in the construction of the roller and brush. The equipment used will be recommended by the manufacturer for use with indoor latex paint. For example the following set of painting equipment would be considered appropriate:

Table 2: Example brush and roller selection

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

Common materials used in constructing paint rollers including medium density polyester, high density polyester, microfiber, lambswool, and others including combinations. The roller nap generally ranges from 1/4" to 3/4", but can also be smooth foam. The construction material and nap length determine how much paint the roller holds, how well it spreads, the ability to penetrate rough surfaces, and the smoothness of the applied paint. The 3/8" nap high density polyester is the most commonly used roller cover and is considered appropriate for semi-rough to smooth surfaces such as interior walls. A longer nap would be appropriate for rough surfaces such as exterior stucco. Paintbrushes for home painting are typically 1 to 5" in width and either straight or angled. The most common sizes are 2 to 3" and both straight and angled brushes are commonly sold. Paintbrush materials include various synthetic and natural fibers, with synthetic fibers generally being more common and less expensive. AEATF II has selected a 3" straight polyester brush as a common design which is a Home Depot best seller. AEATF II is not aware of any studies relating roller or paintbrush construction with painter exposure.

As part of the painting task, painters will be allowed the use of dry "painter's rags." These rags will be used by surrogate painters to wipe excessive liquid paint drips and spills. AEATF II believes that the use of painter's rags represents standard practice for both consumer and professional painters, and is a practical necessity to deal with spills and large drips while painting.

5.2. Varying concentration of product applied

The second key diversity meta-parameter controlled by diversity selection for the paint application with brush and roller study is the amount of active ingredient handled (AaiH) per workday. All MEs in the study will use the same active ingredient, benzisothiazoline-3-one (BIT), at one of three concentrations using pre-formulated latex paint. The target concentrations of BIT in the paint will be 120 ppm (mg/Kg), 400 ppm and 600 ppm. The selected target concentrations are the expected native level of BIT in the manufactured paint, a concentration 5X the lowest concentration, and an intermediate level. The paint concentrations are expected to be sufficient to allow good method sensitivity, but include a safety margin to ensure BIT does not exceed safe levels. AEATF II feels that use of three concentrations of BIT is appropriate since the primary exposure medium is paint. Consequently, AaiH will be directly proportional to the concentration times the total amount of paint applied over the entire workday. To determine the amount of paint applied, some reasonable value for the expected range of this meta-parameter among painters is needed.

Table 3 summarizes information on the frequency and amount of paint applied by consumers annually. These data were obtained from the Exposure Factors Handbook (EPA 2011).

Table 3: The amount of latex paint applied for consumer painters.

Applicator Type	Mean number of painting events per year	Mean Annual Latex Paint Use	90th Percentile Annual Latex Paint Use
Consumer	4	371 oz	857 oz

A household survey of interior painters (Westat, 1987) reported a mean of 4 painting events per year with latex paint, and a mean of 4 gallons of paint used. It was unclear from the Westat question if respondents were indicating gallons per year or per event.

Using Table 3 the amount of paint applied by consumers per painting event has a mean of 0.7 gallons and a 90th percentile value of 1.7 gallons. The actual amount will vary from room to room, from day to day, and from person to person. However, this amount

is not expected to vary independently. There will certainly be some degree of correlation for all rooms painted by the same individual. There is likely to be correlation between different painters as well, since the goal of all painters is to cover the painted surface completely but avoid drips. In order to accomplish this goal the paint needs to be applied to a similar coating thickness by all painters.

For the AEATF II paint application with brush and roller study, the analytical method LOQ sets a practical lower limit on the amount of paint that should be used for an ME. Obviously it is desirable to obtain actual measurements, rather than non-detects, beneath normal work clothing. For this scenario, it is felt that an application of approximately 2 gallons (target range 1.75 to 2.25 gallons) per ME will achieve detectable levels of active ingredients on dosimetry matrices.

The time spent applying paint with a brush and roller will also limit the number of gallons applied. The Exposure Factors Handbook lists the mean time painting for consumer painters as 3 hours correlated with a mean volume of paint applied of 0.7 gallons. Although there are no preparation and cleanup tasks required for painters in the paint application with brush and roller study, it is expected that the application of approximately 2 gallons of paint will take multiple hours. The time spent painting will be recorded and reported for each ME, but no specific time will be required as volume of paint applied will be the primary parameter.

Thus, these results suggest that reasonable diversity in AaiH among MEs could be obtained by varying the concentration of paint applied with a fixed volume of approximately 2 gallons. Each ME will be randomly assigned to one of the three concentration strata.

5.3. Varying surrogate painters

The final meta-characteristic that is formally varied is the surrogate painter. These are consumers without professional painting experience, who are available and consent to perform these tasks at/in appropriate facilities on the specified dates. These are referred to as surrogate painters because they are not viewed as any sample from an existing population of painters. Rather they are viewed simply as another component of the synthetic ME that is being constructed to predict a single instance of a future day's exposure to an arbitrary antimicrobial pesticide. Each surrogate painter provides his/her unique set of behaviors to the painting task. Use of the same painter for all monitoring events would over-represent a single type of behavior. As a result, diversification of painter behavior among MEs is accomplished by simply requiring that each ME be based on a different surrogate painter.

Surrogate painters will all be consumers with at least one residential painting experience in the past 5 years, but no professional painting experience, who reside in the Fresno CA metropolitan area. AEATF II intends to require painting experience as an inclusion criterion since a completely inexperienced painter will require instruction.

Subjects with prior painting experience may have obtained instruction from a variety of sources including friends, paint supply stores, how-to articles, etc. AEATF II feels it important to maintain diversity by requiring subjects have this prior experience, rather than receiving instruction from study personnel. Advertisements soliciting subjects will be posted in the major local newspaper, the Fresno Bee, as well as newspapers circulating in the Spanish speaking community and the African-American community. Individuals who express a desire to participate in the study within a fixed period of time will be contacted and screened in random order. Individuals who meet the study requirements will be recruited until the required number of surrogate painters is obtained. Surrogate painters are randomly assigned to MEs. As a precaution, more participants are recruited than are expected to be needed.

This process results in a simple random sample of qualifying subjects from the volunteer pool. Note, however, that is not the same as a random sample from the existing population of non-professional consumer painters. By definition, volunteers are self-selected and could have different characteristics than non-volunteers. Such distinctions have no relevance in this case, however. There is no particular need to obtain a random sample from the Fresno consumer painter population. This existing population is not the target population for the study. The MEs are synthetic constructs that attempt to predict aspects of a future handler-day population. It is purposive by definition. Thus, a random sample of just one ME component (e.g. subject) from a subpopulation (e.g. Fresno County) provides no statistical advantage. In fact, a random sample of subjects from the volunteer pool is not the only possibility. For example, a more diverse sample of surrogate painters from this pool could also be acceptable if a clear diversifying characteristic were available for all painters. Lacking this, the paint application with brush and roller study uses the reasonable default option of a random sample from the volunteer pool.

6. Sample size determination

The sample size of this study will be 18 MEs, with 6 MEs randomly assigned to each AI concentration strata. The number of MEs was determined by EPA in discussion with AEATF II to be appropriate to achieve the benchmark objective in studies of this general design type. For the paint application with brush and roller study, the benchmark objective is that sample estimates of the arithmetic mean and 95th percentile of normalized exposure are accurate to within 3-fold 95% of the time. The EPA, in discussion with AEATF II, determined that this benchmark is sufficient for regulatory purposes. If the benchmark objective is not achieved after completion of the 18 MEs AEATF II will consult with EPA to determine if additional MEs are required.

7. References

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. American Chemistry Council, Arlington, VA.

AHETF (Agricultural Handlers Exposure Task Force). 2007. Governing Document Document for A Multi-Year Pesticide Handler Worker Exposure Monitoring Program. 2007. Draft Report. Agricultural Handlers Exposure Task Force. Johnson Management & Consulting, LLC, Macon, MO.

Aklam and Associates Inc. and the National Food Laboratory. 2006. AEJV "Amount Used" Study. Prepared for the Antimicrobial Exposure Joint Venture, Chemical Specialty Products Association, Washington, DC.

EPA (U.S. Environmental Protection Agency). 1998. PHED Surrogate Exposure Guide, Estimates of Worker Exposure from the Pesticide Handler Exposure Database, Version 1.1, August (1988).

EPA (U.S. Environmental Protection Agency). 2007. SAP Minutes No. 2007-03. A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Review of Worker Exposure Assessment Methods. January 9 – 12, 2007. FIFRA Scientific Advisory Panel Meeting. U.S. EPA, Arlington, VA.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol.* Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Jacobs, L. and L. Juster. (2006). ANTIMICROBIAL EXPOSURE JOINT VENTURE NATIONAL ANTIMICROBIAL USE SURVEY: DIARY STUDY (PHASE II). Prepared for the Antimicrobial Exposure Joint Venture, Chemical Specialty Products Association, Washington, DC. Prepared by TNO NFO, Chicago, IL.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa.

Westat Inc., 1987. *National Household Survey of Interior Painters.* Final Report.

Robert Testman

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Wednesday, October 30, 2013 7:22 AM
To: Robert Testman
Subject: RE: New protocol for review

Robert,

Thanks for the heads up. I will send this protocol out for review today.

Don

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, October 28, 2013 3:05 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: New protocol for review

Hi Don,

Please see attached a new protocol involving human subjects that will be conducted in California, and the associated scenario design document. The protocol was submitted to EPA for preliminary technical comments from EPA and CDPR, and incorporates those comments. We will also be submitting the protocol for IRB review. Please let me know if you have any questions, etc.

Thanks,
Rob

P.S. – as a heads up Megan will have an additional protocol later this week for a removal efficiency study that supports this study (waiting for EPA comments).

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Robert Testman
Sent: Tuesday, December 10, 2013 7:48 AM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: RE: New protocol for review

Hi Don,

Could you give me a status update on the study review for the two GPL studies? The one I submitted will be six weeks tomorrow, and Megan Boatwright's was a few days later. EPA is pushing us to get those studies turned in.

Thanks,
Rob

From: Richmond, Don@CDPR [mailto:Don.Richmond@cdpr.ca.gov]
Sent: Wednesday, October 30, 2013 7:22 AM
To: Robert Testman
Subject: RE: New protocol for review

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Sent: Monday, October 28, 2013 3:05 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
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Rob

P.S. – as a heads up Megan will have an additional protocol later this week for a removal efficiency study that supports this study (waiting for EPA comments).

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Megan Boatwright

From: Robert Testman
Sent: Friday, December 20, 2013 1:49 PM
To: Megan Boatwright
Subject: FW: protocol for the study "A Study for Measurement of Potential ....."
Attachments: ny12-19.pdf

Hi Megan,

Attached is the review for brush and roller from CDPR. You should have received the removal efficiency review as well, can you forward a copy?

Thanks,
Rob

From: Escobar, Olga@CDPR [mailto:Olga.Escobar@cdpr.ca.gov]
Sent: Thursday, December 19, 2013 2:37 PM
To: Robert Testman
Cc: McKenzie, Jenna@CDPR; Nonato, Yvette@CDPR; Richmond, Don@CDPR; Beauvais, Sheryl@CDPR; Ross, Lisa@CDPR; Fan, Anna@OEHHA; Salocks, Charles@OEHHA; Wisniewski, Joy@OEHHA
Subject: protocol for the study "A Study for Measurement of Potential ....."

Mr. Testman:

Attached please find the correspondence to you from Nino Yanga concerning protocol for the study "A Study for Measurement of Potential Dermal and Inhalation Exposure during Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting.

Please contact him directly should you have and questions or concerns.

Note to cc's: A hard copy will not be provided unless requested.

Thank you.

Olga Escobar
Worker Health and Safety Branch
Department of Pesticide Regulation
916-324-8849

Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

December 19, 2013

Robert Testman
Golden Pacific Laboratories, LLC (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, CA 93722

Dear Mr. Testman:

On October 28, 2013, the Department of Pesticide Regulation (DPR) received the protocol for the study **"A Study for Measurement of Potential Dermal and Inhalation Exposure during Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting."** Title 3, California Code of Regulations (3 CCR) Section 6710 requires Department of Pesticide Regulation (DPR) review and approval of pesticide exposure study protocols involving human subjects for studies conducted in California. 3 CCR Section 6710 also requires a concurrent review by the Office of Environmental Health Hazard Assessment (OEHHA).

Below is our review of the study protocol, Informed Consent Form (ICF), and Experimental Subject's Bill of Rights (BOR). Please incorporate the revisions listed in the Human Subject Protection/Ethical Considerations section. Please respond to comments in *General Review* and *Exposure Assessment* sections by either adopting them or providing further explanation to address review comments. Response to Editorial Comments is at your discretion. Once DPR receives your revised study protocol, ICF, and BOR, we will review them and, if acceptable, grant provisional approval of your proposed pesticide exposure study.

Institutional Review Board (IRB) Approval

After making the required revisions to the study protocol and receiving provisional determination of acceptability from DPR, please submit the study protocol, ICF, and BOR to an institutional review board (IRB) for approval. Once you receive the IRB approval, submit the IRB-approved documents to DPR's Worker Health and Safety Branch for approval.

Final DPR Approval

The DPR Director's final decision regarding approval or denial to conduct the proposed study, and the basis for the decision, will be determined once you have secured IRB approval of your revised protocol, ICF, and BOR. Please submit all revised documents to DPR electronically.

Review of Subject Proposal

Our review focused on the following four aspects as summarized below:

I. General Review: The appropriateness of the study design to achieve study objectives,
II. Exposure Assessment: The adequacy of the protocol for exposure assessment purposes,
III. Human Subjects Protection/Ethical Considerations: The adequacy of protective equipment and other measures in preventing over-exposure of study subjects and in conducting a study in accordance with ethical principles, and
IV. Editorial Comments.

I. General Review

The study involves the antimicrobial chemical 1,2-Benzisothiazol-3(2H)-one (BIT)

Protocol

- *Section 5, Oversight of Ethical Conduct – page 12.*
  - Note that protocol amendments involving potential health effects of participants must be reviewed and approved by DPR.
  - Unanticipated problems involving risks to human subjects: report any that occur as soon as possible to DPR.
- *Section 6E, Balance of Risks and Benefits, Alternative Data Sources – page 15.* The protocol states that "biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low." However, within the Reregistration Eligibility Decision for BIT, a dermal penetration value is listed as 40.6%. Even though this is based on a rat study after 72 hours of exposure, it is still relevant.
- *Section 7A, Test Substance, Test Substance Identification – page 16.* The protocol states that a minimal volume of paint colorant will be added to approximately half of the paint used during the ME. Does the colorant also contain BIT? If so, BIT concentrations should be confirmed after the colorant is added.
- *Section 7C, Test Substance, Safety Precautions – page 17.* One reviewer suggested the researchers review the Material Safety Data Sheet for BIT with the subjects so they are aware of any toxic effects and health risks.
- *Section 7E, Test Substance, Application Parameters and Amount Applied – page 19.* The study design allows for evaluation of exposure of participants while painting. Cleaning of the paint brush, roller, and other painting equipment after the end of the application is not included as part of the exposure study. One reviewer stated this will likely underestimate the exposure since cleaning the painting equipment is a common practice. Consider having the participants clean the equipment as part of the study or conducting a separate monitoring study for cleaning of the equipment.
- *Section 8B, Monitoring Site – page 20, paragraph 2.* The protocol states that analysis of background samples taken in each painting room will be analyzed at the discretion of the Study Director. Since the protocol allows the reuse of the rooms multiple times during the study, it is important to analyze the background samples for the presence of BIT at the beginning each monitoring event.

- *Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 24, paragraph 2*. The protocol states "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR." Revise to "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study." DPR does not require verification of identity, but requires verification of age (at least 18 years of age) for inclusion in the study.
- *Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 25, last paragraph*. The protocol states that final enrollment for potential female subjects will be determined on each study day following a pregnancy test. The protocol should specify that potential female subjects may enroll in the study after the recruitment meeting, but participation in the study will be determined after they take a pregnancy test on the study day.
- *Section 9B, Subject Recruitment Number – page 27, paragraph 1*. The protocol indicates 24 people will be enrolled in the study with the first 18 assigned to ME01 to ME18; the second sequential group of eight will be assigned as primary alternates. The 18 enrolled in the first group and 8 enrolled in the second group equal 26. Revise numbers to equal 24.
- *Section 9B, Subject Sequence Number – page 27; and Section 13A, Field Records – page 44*. Clarify storage of records. Section 9B states Golden Pacific Laboratories will retain subject's records indefinitely while Section 13A states the raw data files will be kept in secure files until transferred to a permanent location selected by the Sponsor.
- Section 9D, Stop Criteria and Medical Management – page 29. The protocol needs to identify who will pay for the medical costs of research-related injuries. This information is appropriately included in the Informed Consent Form.
- *Section 10C, Monitoring Event Procedures, ME Activities #3 – page 32*. When the subject moves from one room to another room, specify who will move the paint and painting supplies.
- *Section 10D, Monitoring Event Procedures, Sample Collection #1c – page 33*. The procedure for rinsing the hands in unclear (e.g., hands submerged in the rinsing solution, solution poured over the hands and the solution collected). Describe how the rinsing will occur.
- *Section 10D, Monitoring Event Procedures, Sample Collection #4, page 34*. The protocol states "The high solubility of BIT in both IPA and water..." Since BIT is soluble in both water and isopropyl alcohol (IPA), provide rationale for using a 50% water/50% IPA mixture versus the use of water alone for removing paint with BIT. Water would be less irritating to the skin than the 50% water/50% IPA mixture.
- *Section 10D, Monitoring Event Procedures, Sample Collection #6 – Outer and Inner Dosimeter* Samples, *page 35*. The protocol states "The dressing area will be cleaned with cleaning agents appropriate for the study between subjects." Cleaning agents may contain BIT. The protocol should specify the use of BIT-free cleaning agents.

Informed Consent Form (ICF)

- *Protocol section 9b, Subject Sequence Number, page 27,* states the subject may obtain copies of their own records from the Principal Investigator on request. This information should also be included in the ICF.
- *Study Procedure 6 – page 62*. Protocol section 10B7 states "The subjects must wear the safety glasses and hat while applying..." The ICF states "You must wear the safety glasses while painting with brush and roller." Revise the ICF to include the requirement that the subjects must wear the hats while applying.
- *Study Procedure 10 – page 62*. The procedure states "We will turn on your air pumps and ask you to put on your safety glasses" The protocol requires wearing a painter's hat so this procedure should include putting on the hat.

Qualification Worksheet

- In addition to the "once in 5 years" painting requirement, would it be relevant to the study to ask the participants how often they paint?

II. Exposure Assessment

- None

III. Human Subject Protection/Ethical Considerations

Protocol

- *Section 10C, Monitoring Event Procedures, ME Activities #1, page 31*. The protocol states that ceiling ventilation fans will be turned off while the ME is conducted in a room. However, section 8 of the MSDS for the paint covers Exposure Controls and Personal Protection. This section includes the precaution "Use only with adequate ventilation." Under the Ventilation subheading, the MSDS states "Local exhaust preferable. General exhaust acceptable if exposure to materials in Section 2 is maintained below acceptable exposure limits" and refers to an OSHA standard. With the ceiling exhaust fans turned off, add information about how the work environment will be maintained to keep exposure levels below acceptable exposure limits.
- *Risks 1 – page 63.* In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.

Informed Consent Form (ICF)

- The inclusion criteria include the ability to speak and read English or Spanish. The protocol package does not include a Spanish translation of the ICF and Experimental Subjects Bill of Rights. These documents must be submitted before DPR approves the protocol.
- If the Informed Consent is conducted in Spanish by a Spanish-speaking researcher, the researcher needs to sign the ICF, in addition to the Principal Investigator.

IV. Editorial Comments

- Define acronyms when first used: HVAC (page 20), LOQ (page 16), TBA (page 40), NA (page 41), and MD (AEATF Rationale document, page 5).
- The following references listed on p. 14 of the AEATF II Rationale document are not cited in the text: Jacobs (2006); AHETF (2007); Aklam (2006), and EPA (1998). Likewise, Popendorf (1992) is listed in the references but not cited in the BIT exposure protocol.

Protocol

- *Section 6A, Balance of Risks and Benefits – page 13, Line 1:* Add a comma so the sentence reads "... available to EPA from the PHED, the Agency..."
- *Section 9Aii*, Recruitment of Surrogate Workers – page 23, paragraph 4.
  - Revise first mention of Appendix D form title to "Subject Self-Reporting Demographic Form."
  - The second sentence states the investigator will ask the subject the health questions on the Subject Self-Reporting Demographic Form. The next sentence states "The investigator will answer any questions. Revise this sentence to read "The investigator will answer any questions the subject may have."
- *Section 9Aii, Recruitment of Surrogate Workers – page 24, paragraph 4*. Suggested Revising the first sentence to read: The recruitment process will terminate at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited, ...Bill of Rights Form. The revision includes deleting the space before the period at the end of the sentence.
- *Section 9D, Stop Criteria and Medical Management – page 28, paragraph 2, 3rd sentence*. Add a comma after *If instructed* so the sentence will read "If instructed, research staff..."
- *Section 10, Monitoring Event Procedures, page 29*. This sections mentions sampling trains, but does not describe what the sampling trains consist of. The term is described in a parenthetical on page 32 in Section 10C #2. Suggest moving the parenthetical to page 29 where sampling train is first mentioned.
- *Section 10H, Field Recovery Evaluation – page 38 Table*. Units of measure have been included for all fortification levels. Although the units of measure (ng/mL) are the same for the fortification levels for handwipes/washes, suggest adding the unit of measure after 4.0 to ensure clarity.
- *Section 11A, Sample Identification* – page 39. This section lists various codes to help identify samples. The outer and inner dosimeters will be sectioned into upper and lower arms, front and back torso, and upper and lower legs (page 35). The codes identifying samples do not include codes for the upper arms, front and back torso, and upper and lower legs.
- *Section 12B, Analytical Methods – page 41*. The protocol states: "The HPLC/MS/MS methods will be validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits." The subjects' exposures are

not minimized by low detection limits, but by use of PPE and very low levels of BIT in paint, or other exposure parameters.

Informed Consent Form (ICF)

- *Subject Selection – page 60, paragraph 3*. Suggest revising the second sentence by replacing 'anyone' with 'someone' so the sentence will read: We will sign up a few more people than we need, in case someone can't participate on the day of the test.
- *Study Procedure 3 – page 61, paragraph 4:*
  - *Line 2*. Add a comma so the sentence reads "...day of the test, each female volunteer…"
  - *Line 5*. Add a comma so the sentence reads "...give yourself the test, we will ask you…"
- *Study Procedures 12e – page 63*. This item should read "The researcher will help..."
- *Questions about this Study – page 65, paragraph 1.* Suggest revising the sentence to: "If you have any questions, you may ask Robert Testman or any other member of the research team at any time – before, during, or after the study."
- *Questions about the Study – page 65.* : Revise the name of the IRB to Schulman Associates Institutional Review Board.
- *Costs and payments – page 66, paragraph 2*. The second sentence reads like the subjects have more than one consent interview. Suggest revising to "At the end of the informed consent interview..."

Experimental Subject's Bill of Rights

- *Page 66.* Revise the name of the IRB to Schulman Associates Institutional Review Board.

Please submit your revised protocol to DPR electronically so that we can determine provisional acceptability of the study. If you have any questions, please contact Don Richmond of my staff at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov, or myself, at the number listed below.

Sincerely,

(original signed by N. Yanga)

Saturnino "Nino" Yanga, DVM, MPVM, MS
Environmental Program Manager I
Worker Health and Safety Branch
(916) 445-6387

cc: Anna M. Fan, Ph.D., Chief, Pesticide and Environmental Toxicology Branch (PETB), Office of Environmental Health hazard Assessment (OEHHA)
Charles Salocks, Ph.D., Senior Toxicologist, Chief, Pesticide Epidemiology Section, PETB, OEHHA
Joy A. Wisniewski, Ph.D., Staff Toxicologist, PETB, OEHHA
Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Sheryl Beauvais, Ph.D., Senior Toxicologist, WHS, DPR
Jenna McKenzie, Ph.D., Associate Toxicologist, WHS, DPR
Don Richmond, Research Scientist II, WHS, DPR
Dr. Yvette Nonato, Research Scientist I, WHS, DPR

Megan Boatwright

From: Robert Testman
Sent: Friday, January 24, 2014 12:51 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: FW: protocol for the study "A Study for Measurement of Potential ....."
Attachments: CDPR letter 22Jan2014.pdf; AEATF Brush Roller Draft Protocol 22Jan2014 redline.docx

Hi Don,

Attached is a letter with responses to the CDPR comments on the brush and roller study, as well as a redlined version of the revised protocol. The revised protocol incorporates IRB and CDPR comments and is now being submitted to the EPA for HSRB review. Once we receive and incorporate their comments we will route it back to you for approval. I appreciate your help with this process.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

From: Escobar, Olga@CDPR [mailto:Olga.Escobar@cdpr.ca.gov]
Sent: Thursday, December 19, 2013 2:37 PM
To: Robert Testman
Cc: McKenzie, Jenna@CDPR; Nonato, Yvette@CDPR; Richmond, Don@CDPR; Beauvais, Sheryl@CDPR; Ross, Lisa@CDPR; Fan, Anna@OEHHA; Salocks, Charles@OEHHA; Wisniewski, Joy@OEHHA
Subject: protocol for the study "A Study for Measurement of Potential ....."

Mr. Testman:

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Please contact him directly should you have and questions or concerns.

Note to cc's: A hard copy will not be provided unless requested.

Thank you.

Olga Escobar
Worker Health and Safety Branch
Department of Pesticide Regulation
916-324-8849

Golden Pacific
LABORATORIES

January 22, 2014

Dr. Saturnino Yanga
California Dept. of Pesticide Regulation
1001 I Street
Sacramento, CA 95812

Dear Dr. Yanga:

I have received and carefully studied the review comments dated December 19, 2013 for the protocol "A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting." The Protocol and Informed Consent form (ICF) have been updated and a "track changes" version submitted electronically with this letter. I have attached a table addressing the review comments from DPR and the responses/edits to each comment.

The protocol has received preliminary approval from an IRB and is now being submitted to the EPA for review by the Human Studies Review Board. Following their review we will incorporate their comments and submit the modified version to the IRB and DPR for final approvals.

Please feel free to contact me with any questions. I can be reached at (949)939-3585 or rtestman@gplabs.com.

Sincerely,

Rob Testman

Robert Testman
Principal Investigator

cc: Don Richmond

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

CA DPR Comments	GPL Response	Protocol Modifications
Section 5, Oversight of Ethical Conduct – page 12. - Note that protocol amendments involving potential health effects of participants must be reviewed and approved by DPR. - Unanticipated problems involving risks to human subjects: report any that occur as soon as possible to DPR.	Section 19, Protocol Changes – page 47. The requirement for notification and/or approval of IRB and DPR is contained in this section of the protocol.	N/A
Section 6E, Balance of Risks and Benefits, Alternative Data Sources – page 15. The protocol states that "biological monitoring is not reasonable with BIT, because dermal penetration has been shown to be low." However, within the Reregistration Eligibility Decision for BIT, a dermal penetration value is listed as 40.6%. Even though this is based on a rat study after 72 hours of exposure, it is still relevant.	The statement re low dermal penetration will be deleted.	Modified Section 6.E to remove referenced statement.
Section 7A, Test Substance, Test Substance Identification – page 16. The protocol states that a minimal volume of paint colorant will be added to approximately half of the paint used during the ME. Does the colorant also contain BIT? If so, BIT concentrations should be confirmed after the colorant is added.	BIT concentration will be determined for each batch of paint to be used, including after addition of any colorant. Method development work did not show any contribution to BIT from the colorant.	Modified Section 7.A to clarify that testing will be post-addition of colorant.

CA DPR Comments	GPL Response	Protocol Modifications
Section 7C, Test Substance, Safety Precautions – page 17. One reviewer suggested the researchers review the Material Safety Data Sheet for BIT with the subjects so they are aware of any toxic effects and health risks.	Researchers will review the Informed Consent document with subjects. As part of that review the MSDS will be available and offered to subjects. Researchers will be available to answer any subject questions regarding the MSDS.	N/A
Section 7E, Test Substance, Application Parameters and Amount Applied – page 19. The study design allows for evaluation of exposure of participants while painting. Cleaning of the paint brush, roller, and other painting equipment after the end of the application is not included as part of the exposure study. One reviewer stated this will likely underestimate the exposure since cleaning the painting equipment is a common practice. Consider having the participants clean the equipment as part of the study or conducting a separate monitoring study for cleaning of the equipment.	The inclusion or exclusion of equipment cleaning was reviewed and discussed as part of the Joint Committee review of the study protocol, which included EPA and CDPR. The decision was made that excluding cleanup was the worst case scenario, as residues added from contact or splashing during cleaning activities would likely be outweighed by removal of paint from the hands.	N/A
Section 8B, Monitoring Site – page 20, paragraph 2. The protocol states that analysis of background samples taken in each painting room will be analyzed at the discretion of the Study Director. Since the protocol allows the reuse of the rooms multiple times during the study, it is important to analyze the background samples for the presence of BIT at the beginning each monitoring event.	The background samples are being collected in recognition of the potential issue of cross-contamination. There may be cases where analysis is unnecessary; for example if the subject air tubes do not contain BIT above the LOQ, then background samples would not need to be analyzed. This is why it was left to the Study Director's discretion.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 24, paragraph 2. The protocol states "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify identity as required by California DPR." Revise to "The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study." DPR does not require verification of identity, but requires verification of age (at least 18 years of age) for inclusion in the study.	Protocol will be updated.	Section 9.A.ii was updated.
Section 9Aii, Subject Recruitment, Recruitment of Surrogate Workers – page 25, last paragraph. The protocol states that final enrollment for potential female subjects will be determined on each study day following a pregnancy test. The protocol should specify that potential female subjects may enroll in the study after the recruitment meeting, but participation in the study will be determined after they take a pregnancy test on the study day.	Current wording of 9Aii states, "For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test." This wording appears to reflect this comment already.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 9B, Subject Recruitment Number – page 27, paragraph 1. The protocol indicates 24 people will be enrolled in the study with the first 18 assigned to ME01 to ME18; the second sequential group of eight will be assigned as primary alternates. The 18 enrolled in the first group and 8 enrolled in the second group equal 26. Revise numbers to equal 24.	Typo corrected.	Corrected.
Section 9B, Subject Sequence Number – page 27; and Section 13A, Field Records – page 44. Clarify storage of records. Section 9B states Golden Pacific Laboratories will retain subject's records indefinitely while Section 13A states the raw data files will be kept in secure files until transferred to a permanent location selected by the Sponsor.	Modified section 13.A to clarify that subject personal information is not included with other raw data files or transferred to Sponsor.	Section 13.A was updated.
Section 9D, Stop Criteria and Medical Management – page 29. The protocol needs to identify who will pay for the medical costs of research-related injuries. This information is appropriately included in the Informed Consent Form.	Added payment information to Section 9.D.	Added the following language from the Informed Consent to section 9.D, "The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered."

CA DPR Comments	GPL Response	Protocol Modifications
Section 10C, Monitoring Event Procedures, ME Activities #3 – page 32. When the subject moves from one room to another room, specify who will move the paint and painting supplies.	Clarified section 10.C.	Added the following language to section 10.C, "Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff."
Section 10D, Monitoring Event Procedures, Sample Collection #1c – page 33. The procedure for rinsing the hands in unclear (e.g., hands submerged in the rinsing solution, solution poured over the hands and the solution collected). Describe how the rinsing will occur.	The description in the protocol was reviewed and found to be clear. Hands are held above bowl, scrubbed with gauze pads wetted with IPA/water and rinsed with IPA/water.	N/A
Section 10D, Monitoring Event Procedures, Sample Collection #4, page 34. The protocol states "The high solubility of BIT in both IPA and water..." Since BIT is soluble in both water and isopropyl alcohol (IPA), provide rationale for using a 50% water/50% IPA mixture versus the use of water alone for removing paint with BIT. Water would be less irritating to the skin than the 50% water/50% IPA mixture.	Removal of test substances from the hands is a more complex system than dissolving neat compounds. Due to the interaction with the skin and skin oils hands are normally washed/rinsed with a surfactant or a mild alcohol along with water. The IPA/water mix is more likely to result in a high percentage removal of BIT from skin than water alone. Surfactants are avoided due to the potential negative influence on sample analysis.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 10D, Monitoring Event Procedures, Sample Collection #6 – Outer and Inner Dosimeter Samples, page 35. The protocol states "The dressing area will be cleaned with cleaning agents appropriate for the study between subjects." Cleaning agents may contain BIT. The protocol should specify the use of BIT-free cleaning agents.	Avoiding the use of cleaning agents containing BIT is important. However, this requirement is the reason for the generic "appropriate for the study" designation. Cleaning agents will be screened for BIT prior to use.	N/A
Protocol section 9b, Subject Sequence Number, page 27, states the subject may obtain copies of their own records from the Principal Investigator on request. This information should also be included in the ICF.	Added language to Informed Consent form (ICF).	Added the following language to ICF, "You may obtain a copy of your own records from the Principal Investigator upon request."
Study Procedure 6 – page 62. Protocol section 10B7 states "The subjects must wear the safety glasses and hat while applying..." The ICF states "You must wear the safety glasses while painting with brush and roller." Revise the ICF to include the requirement that the subjects must wear the hats while applying.	Updated ICF.	Added "and hat" to ICF Study Procedure Item 6.
Study Procedure 10 – page 62. The procedure states "We will turn on your air pumps and ask you to put on your safety glasses" The protocol requires wearing a painter's hat so this procedure should include putting on the hat.	Updated ICF.	Added "hat and" to ICF Procedure Item 10.

CA DPR Comments	GPL Response	Protocol Modifications
In addition to the "once in 5 years" painting requirement, would it be relevant to the study to ask the participants how often they paint?	The purpose of the question is to establish that the subject has at least minimal experience so that training in how to paint will not be needed.	N/A
Section 10C, Monitoring Event Procedures, ME Activities #1, page 31. The protocol states that ceiling ventilation fans will be turned off while the ME is conducted in a room. However, section 8 of the MSDS for the paint covers Exposure Controls and Personal Protection. This section includes the precaution "Use only with adequate ventilation." Under the Ventilation subheading, the MSDS states "Local exhaust preferable. General exhaust acceptable if exposure to materials in Section 2 is maintained below acceptable exposure limits" and refers to an OSHA standard. With the ceiling exhaust fans turned off, add information about how the work environment will be maintained to keep exposure levels below acceptable exposure limits.	The use of the exhaust fan during painting was discussed with the JRC during protocol design. In response to this question EPA has deferred until receiving guidance as part of the HSRB process.	To be determined.
Risks 1 – page 63. In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.	Updated ICF.	Modified ICF - Risks 1 as follows, "...You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher."

CA DPR Comments	GPL Response	Protocol Modifications
The inclusion criteria include the ability to speak and read English or Spanish. The protocol package does not include a Spanish translation of the ICF and Experimental Subjects Bill of Rights. These documents must be submitted before DPR approves the protocol.	The Spanish translation of the ICF/Experimental Subjects Bill of Rights, and recruiting materials will be performed by SAIRB after regulatory reviews of the protocol are completed and the English version is finalized.	To be determined (Spanish translation to be added by IRB after reviews complete).
If the Informed Consent is conducted in Spanish by a Spanish-speaking researcher, the researcher needs to sign the ICF, in addition to the Principal Investigator.	Added to ICF.	Added to ICF Consent and Signature page.
Editorial comments	Reviewed and updated as appropriate.	Updated as appropriate.

***DRAFT* PROTOCOL**

~~04 November 2013~~22 January 2014

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

May 2014

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEA09

GPL Study Number

120463

Total Number of Pages: 131~~77~~

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No: AEA09
GPL Study No: 120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date: May 2014

Proposed Experimental Termination Date: August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
7B.1	Test, Control, and Reference Substances Labeling	12.0
7C.1	Disposal of Test, Control, and Reference Substances	17.0
7D.1	Test, Control, and Reference Substances Chain of Custody	13.0
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Field Location:	Fresno County, CA
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2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 400 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 400 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all personal protective equipment (PPE, i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable,

thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as

outlined in section 4 of the scenario design document. Generally, from a regulatory perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is little incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: *(954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its

risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish.

Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California Department of Pesticide Review (DPR) and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity

profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations, and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data available to EPA from the PHED, the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or isopropyl alcohol (IPA) will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own sex. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that

apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because ~~dermal penetration has been shown to be low (Bartels, 2013), and~~ the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 400 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 400 ppm and 600 ppm.

~~GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study.~~

A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study for each preparation of the test substance including colorant.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantitation of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint types. The table below lists the proposed limit of quantitation (LOQ) for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample
Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue. Subjects will be provided dry cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at ambient room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary the amount of active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for

MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).

Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 8 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 10 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The AiAH will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Applicators to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates. At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24 initially selected are required, randomized subject 25 will be contacted

followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate applicators (or 'workers') for the MEs. This includes the planned 18 surrogate painters needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Subject Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire about the health of the subject. The investigator will answer any questions the subject may have. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time

during this process as well as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify ~~identity as required by California DP~~Rage for inclusion in the study, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate ~~when~~ at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form~~.~~. If fewer than 24 subjects have been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in

7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and Subject Self-Reporting Demographic Form

- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies to latex paint, soaps or isopropyl alcohol
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential applicators of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study

sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of six will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the

Principal Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed, research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink.

The on-site health professional will immediately be contacted for further medical management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure

monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same sex. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be

cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer dosimeter shirt will be tucked into the pants. A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation, and the subject will retain the key during their ME.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections.

Ceiling ventilation fans will be turned off while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be provided additional test substance until they have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks. Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the

private area with a researcher of the same sex. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

a. The researcher will help subjects take off the painter's hat and save it for analysis.

b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse with the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

f. The researcher will help subjects take off the long underwear, and save it for analysis.

g. When all samples have been collected, subjects will dress again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat will be removed with the assistance of a researcher (study team member) of the same sex, placed in a pre-labeled glass jar and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing, sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™ filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same sex and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in "gross violation" or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.

3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.
5. Prepare field fortification samples.
6. Monitor temperature and humidity, ensure room vent fans are off during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site (e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 ng/mL and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at ≤ -10° C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	TBA
Purity:	TBA
Date Received:	TBA
Expiration Date:	TBA

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. ~~The HPLC/MS/MS methods will be validated by GPL and are extremely sensitive and selective, thus minimizing subjects' exposure by allowing for very low detection limits.~~ The limit of ~~quantification~~ quantitation (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the remaining samples. Any sample not bracketed by the standard curve concentrations will be re-diluted and re-analyzed unless it is below the LOQ when at the minimum method dilution.

Each analytical set will include two laboratory fortified matrix samples, a solvent blank and an unfortified matrix control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantitation

Chromatographic quantitation (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);

12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study, except study subject personal information, will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be ~~kept~~ maintained in a separate location at GPL and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts (Appendix H), and an executive summary of EPA's REDs for BIT

summarizing their risk assessment conclusions (Appendix H). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the quality assurance unit (QAU). The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Principal Investigator and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.

9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.
13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with California DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing

to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, California 93722
Telephone: 559-275-9091
Fax: 559-275-1810
E-mail: rtestman@gplabs.com

B. Quality Assurance Unit

Anantdeep K. Kang, M.S.
ASK GLP Consulting
1577 Dartmouth Ave.
Clovis, California 93619
Telephone: 559-960-6164

*A.K. Kang will report directly to the GPL Board of Directors, i.e., independent of any involvement of the Study Director or other investigators.

C. Field Coordinators

Megan T. Boatwright
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D. Analytical Coordinator

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Fresno, California 93722
Telephone: 559-275-9091
E-mail: kacedo@gplabs.com

19. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Robert J. Testman, M.B.A. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Megan T. Boatwright, B.S. Date
Field Coordinator (English)
Golden Pacific Laboratories, LLC

Kimon P. Acedo, B.S. Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Anantdeep K. Kang, M.S. Date
Quality Assurance
ASK GLP Consulting

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

~~Bartels, 2013. Personal Communication. Abstract of Determination of The In-Vitro Dermal Absorption of 1,2-Benzisothiazolin-3-one.~~

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol.* Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012, Complies with:			
OTC	Yes	LEED® 09 CI	Yes
SCAQMD	Yes	LEED® 09 NC	Yes
CARB	Yes	LEED® 09 CS	Yes
CARB SCM 2007	Yes	LEED® 09 H	Yes
MPI #	53	MGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer
Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry
Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent
Flash Point: N/A
Finish: 0-5 units @ 85°
Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic
A86W00151
VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12
Volume Solids: 43 ± 2%
Weight Solids: 61 ± 2%
Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

continued on back

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE. Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
HOTW 03/25/2013 A86W00151 09 47

The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet

Spanish product label here after translation of approved English version

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or absorbed through skin. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles or faceshield), long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-30 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Hydrocarbon pneumonitis, circulatory shock, respiratory depression, and convulsion may be seeded.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latex Adhesive And Sealant Formulations, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Car Care Products Including Car Washes, Car Waxes, Automotive Finishes, Home Care Products Including Hard Surface Cleaners, Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	**5383-121**
EPA Establishment Number	**5383-NJ-1**

ACTIVE INGREDIENT:	**% Weight**
1,2-Benzisothiazolin-3(2H)-One	**19.18%**
INERT INGREDIENTS	**80.82%**
TOTAL	**100.0%**

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:
[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

©MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

GENERAL INFORMATION

APPLICATION RATE: Mergal® BIT 20 is an effective preservative for most aqueous applications. Mergal® BIT 20 is suggested for use in aqueous or water-containing products and systems, including 0.25% when used at Mergal® BIT 20 levels to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% of Mergal® BIT 20 as received product. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below. **RESTRICTIONS FOR USE IN FOOD CONTACT APPLICATIONS:** Follow the FDA clearances cited below. Use of Mergal® BIT 20 must not exceed 0.21 mg/in² (0.0325 mg/cm²) of finished paper and paperboard intended for contact with dry foods and 0.11mg/in² (0.0168 mg/cm²) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal® BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 –	Components for Adhesives
21 CFR 176.170 –	Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 –	Components of Paper and Paperboard in contact with dry food
21 CFR 176.300 –	Slimicides (for manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 –	Rubber articles intended for repeated use: follow instructions in conditions of use

Oil RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as produced water, brine, seawater, and freshwater systems. Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows. Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution. Stand container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank. Repeat this procedure two more times. Then offer for recycling or reconditioning if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

INFORMED CONSENT FORM

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator:
Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
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Natan R. Chavez (English and Spanish)
Field Research Associate
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Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations:
(Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

Subject Selection

To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, or paint products; if you have psoriasis, eczema, sores or open cuts on your skin; if you have severe diabetes; if you have a suppressed immune system such as with an organ transplant or active chemotherapy; or if you have heart or breathing problems.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment

Today you are meeting with the Principal Investigator, Robert Testman, or the laboratory General Manager, Thomas Moate, or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own sex will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on cotton long underwear (long

johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

9. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will ask if you have any questions.

10. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces or tattoos in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

11. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

12. When you finish painting, a researcher of your own sex will take you back to the changing area and collect samples:

a. The researcher will remove the painter's hat, air sampling pumps and equipment;

b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

d. The researcher will help you remove your shoes (and socks if you wish);

e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

f. The researcher will help you take off the long underwear, and will save it for analysis.

When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy, or if you think you may have gotten some of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

4. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

5. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own sex, and will be the only other person with you. You will wear your own underwear all the time.

6. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks

Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries

If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive any of your legal rights by signing this form.

Alternatives to Participation

If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits

You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. This may indirectly benefit you and others when you do painting. You may also benefit if you ask for your own results from this study, so you can learn how much paint

got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

This study was reviewed by Schulman Associates ~~Independent~~ Institutional Review Board, Inc. (SAIRB). If you have any questions about your rights as a volunteer, or to report a problem in the study, please call SAIRB toll free at 1- (888) 557-2472. You can reach them from 5 am to 3 pm Pacific Time, Monday through Friday. SAIRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the SAIRB, Inc. website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of ~~each~~ the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually tested.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face.

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

| You may contact the *Schulman Associates ~~Independent~~ Institutional Review Board (SAIRB), toll free at (888) 557-2472 from 5 am to 3 pm Pacific Time*, if you have a question about your rights as a research subject.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Spanish Informed Consent Form with Subject's Bill of Rights here after translation of approved English version

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA09: Interior Latex Paint Application with Brush and Roller Scenario

Part I: *Interview questions*	Q/NQ
1. Do you have any skin conditions on your hands (psoriasis, eczema, etc.)? ☐Yes ☐No	
2. Do you have difficulty breathing? Moderate or severe asthma or emphysema? ☐Yes ☐No	
3. Do you have Cardiovascular disease? Have you ever had a myocardial infarct, stroke, or congestive heart failure? Do you have uncontrolled high blood pressure? ☐Yes ☐No	
4. Do you have severe diabetes? ☐Yes ☐No	
5. Are you immunologically suppressed? Have you ever had a transplant? Chemotherapy? ☐Yes ☐No	
6. Are you employed by or married to an employee of an AEATF company, GPL, a paint manufacturer or the ACC (interviewer to explain initials of various entities)? ☐Yes ☐No	

Part II: *To be filled out by candidate*			
7. Name		10. Weight: lbs	
8. Address		11. Height: ft in	
		12. Shirt size: ☐**S** ☐**M** ☐**L** ☐**XL** ☐**XXL** ☐**XXXL**	
9. City, ST, Zip		13. Waist: ☐24-28 in ☐28-32 in ☐32-36 in	
14. Telephone(s)		☐36-40 in ☐40-44 in ☐44-50 in	
15. Age in years =	16. DOB:	17. Sex ☐M ☐F	
18. Resident in Fresno County? ☐Yes ☐No		19. Have you painted with a brush and roller in the past 5 years? ☐Yes ☐No	
		20. Have you worked as a professional painter in the past 10 years? ☐Yes ☐No	
21. Preferred Language: ☐English ☐Spanish		22. Reads: ☐English ☐Spanish	
23. Are you pregnant? ☐NA ☐Yes ☐No		24. Are you nursing a baby? ☐NA ☐Yes ☐No	
25. Do you consider your general health good enough to participate in this study as described? ☐Yes ☐No			
26. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐No			
27. Are you bothered by rubbing alcohol or soap on your skin more than family or friends? ☐Yes ☐No			
Interviewer ID age verification: ☐Yes ☐No _____ _____ Subject Signature Date			

Language of interview: : ☐English ☐Spanish	Interviewer Name:
Interview date:	Interviewer Signature:

Spanish Subject Self-Reporting Demographic Form here after translation of approved English version

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
*for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	**Cristobalite**		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	**Calcium Carbonate**		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	**Titanium Dioxide**		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.
EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.
SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

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SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

A87W151

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable
CONDITIONS TO AVOID
None known.
INCOMPATIBILITY
None known.
HAZARDOUS DECOMPOSITION PRODUCTS
By fire: Carbon Dioxide, Carbon Monoxide
HAZARDOUS POLYMERIZATION
Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS
Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.
IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD
Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.
Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

A87W151

SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

Spanish Material Safety Data Sheet for Sherwin-Williams Latex Paint here after translation of approved English version

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APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

Spanish advertisement here after translation of approved English version

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

Spanish Subject Invitation to Participate Script here after translation of approved English version

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.

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Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:

1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA09-BRS-01-PH	Brush and Roller Worker Sample, ME 01, Painter's Hat
AEA09-BRS-01-AR	Brush and Roller Worker Sample, ME 01, Air Sampling Tube
AEA09-BRS-01-RES-01	Brush and Roller Worker Sample, ME 01, RespiCon™ 100 µm
AEA09-BRS-01-RES-02	Brush and Roller Worker Sample, ME 01, RespiCon™ 10 µm
AEA09-BRS-01-RES-03	Brush and Roller Worker Sample, ME 01, RespiCon™ 2.5 µm
AEA09-BRS-01-HW-01	Brush and Roller Worker Sample, ME 01, Hand Wash
AEA09-BRS-01-FW-01	Brush and Roller Worker Sample, ME 01, Face and Neck Wipe
AEA09-BRS-01-ID-UA	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Upper Arm
AEA09-BRS-01-ID-LA	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Lower Arm
AEA09-BRS-01-ID-FT	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Front Torso
AEA09-BRS-01-ID-RT	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Rear Torso
AEA09-BRS-01-ID-UL	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Upper Leg
AEA09-BRS-01-ID-LL	Brush and Roller Worker Sample, ME 01, Inner Dosimter, Lower Leg
AEA09-BRS-01-OD-UA	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Upper Arm
AEA09-BRS-01-OD-LA	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Lower Arm
AEA09-BRS-01-OD-FT	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Front Torso
AEA09-BRS-01-OD-RT	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Rear Torso
AEA09-BRS-01-OD-UL	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Upper Leg
AEA09-BRS-01-OD-LL	Brush and Roller Worker Sample, ME 01, Outer Dosimter, Lower Leg
AEA09-BRS-02-PH	Brush and Roller Worker Sample, ME 02, Painter's Hat
AEA09-BRS-02-AR	Brush and Roller Worker Sample, ME 02, Air Sampling Tube
AEA09-BRS-02-RES-01	Brush and Roller Worker Sample, ME 02, RespiCon™ 100 µm
AEA09-BRS-02-RES-02	Brush and Roller Worker Sample, ME 02, RespiCon™ 10 µm
AEA09-BRS-02-RES-03	Brush and Roller Worker Sample, ME 02, RespiCon™ 2.5 µm
AEA09-BRS-02-HW-01	Brush and Roller Worker Sample, ME 02, Hand Wash
AEA09-BRS-02-FW-01	Brush and Roller Worker Sample, ME 02, Face and Neck Wipe
AEA09-BRS-02-ID-UA	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Upper Arm
AEA09-BRS-02-ID-LA	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Lower Arm
AEA09-BRS-02-ID-FT	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Front Torso
AEA09-BRS-02-ID-RT	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-02-ID-UL	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Upper Leg
AEA09-BRS-02-ID-LL	Brush and Roller Worker Sample, ME 02, Inner Dosimter, Lower Leg
AEA09-BRS-02-OD-UA	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Upper Arm
AEA09-BRS-02-OD-LA	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Lower Arm
AEA09-BRS-02-OD-FT	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Front Torso
AEA09-BRS-02-OD-RT	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Rear Torso
AEA09-BRS-02-OD-UL	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Upper Leg
AEA09-BRS-02-OD-LL	Brush and Roller Worker Sample, ME 02, Outer Dosimter, Lower Leg
AEA09-BRS-03-PH	Brush and Roller Worker Sample, ME 03, Painter's Hat
AEA09-BRS-03-AR	Brush and Roller Worker Sample, ME 03, Air Sampling Tube
AEA09-BRS-03-RES-01	Brush and Roller Worker Sample, ME 03, RespiCon™ 100 µm
AEA09-BRS-03-RES-02	Brush and Roller Worker Sample, ME 03, RespiCon™ 10 µm
AEA09-BRS-03-RES-03	Brush and Roller Worker Sample, ME 03, RespiCon™ 2.5 µm
AEA09-BRS-03-HW-01	Brush and Roller Worker Sample, ME 03, Hand Wash
AEA09-BRS-03-FW-01	Brush and Roller Worker Sample, ME 03, Face and Neck Wipe
AEA09-BRS-03-ID-UA	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Upper Arm
AEA09-BRS-03-ID-LA	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Lower Arm
AEA09-BRS-03-ID-FT	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Front Torso
AEA09-BRS-03-ID-RT	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Rear Torso
AEA09-BRS-03-ID-UL	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Upper Leg
AEA09-BRS-03-ID-LL	Brush and Roller Worker Sample, ME 03, Inner Dosimter, Lower Leg
AEA09-BRS-03-OD-UA	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Upper Arm
AEA09-BRS-03-OD-LA	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Lower Arm
AEA09-BRS-03-OD-FT	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Front Torso
AEA09-BRS-03-OD-RT	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Rear Torso
AEA09-BRS-03-OD-UL	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Upper Leg
AEA09-BRS-03-OD-LL	Brush and Roller Worker Sample, ME 03, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-04-PH	Brush and Roller Worker Sample, ME 04, Painter's Hat
AEA09-BRS-04-AR	Brush and Roller Worker Sample, ME 04, Air Sampling Tube
AEA09-BRS-04-RES-01	Brush and Roller Worker Sample, ME 04, RespiCon™ 100 µm
AEA09-BRS-04-RES-02	Brush and Roller Worker Sample, ME 04, RespiCon™ 10 µm
AEA09-BRS-04-RES-03	Brush and Roller Worker Sample, ME 04, RespiCon™ 2.5 µm
AEA09-BRS-04-HW-01	Brush and Roller Worker Sample, ME 04, Hand Wash
AEA09-BRS-04-FW-01	Brush and Roller Worker Sample, ME 04, Face and Neck Wipe
AEA09-BRS-04-ID-UA	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Upper Arm
AEA09-BRS-04-ID-LA	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Lower Arm
AEA09-BRS-04-ID-FT	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Front Torso
AEA09-BRS-04-ID-RT	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Rear Torso
AEA09-BRS-04-ID-UL	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Upper Leg
AEA09-BRS-04-ID-LL	Brush and Roller Worker Sample, ME 04, Inner Dosimter, Lower Leg
AEA09-BRS-04-OD-UA	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Upper Arm
AEA09-BRS-04-OD-LA	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Lower Arm
AEA09-BRS-04-OD-FT	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Front Torso
AEA09-BRS-04-OD-RT	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Rear Torso
AEA09-BRS-04-OD-UL	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Upper Leg
AEA09-BRS-04-OD-LL	Brush and Roller Worker Sample, ME 04, Outer Dosimter, Lower Leg
AEA09-BRS-05-PH	Brush and Roller Worker Sample, ME 05, Painter's Hat
AEA09-BRS-05-AR	Brush and Roller Worker Sample, ME 05, Air Sampling Tube
AEA09-BRS-05-RES-01	Brush and Roller Worker Sample, ME 05, RespiCon™ 100 µm
AEA09-BRS-05-RES-02	Brush and Roller Worker Sample, ME 05, RespiCon™ 10 µm
AEA09-BRS-05-RES-03	Brush and Roller Worker Sample, ME 05, RespiCon™ 2.5 µm
AEA09-BRS-05-HW-01	Brush and Roller Worker Sample, ME 05, Hand Wash
AEA09-BRS-05-FW-01	Brush and Roller Worker Sample, ME 05, Face and Neck Wipe
AEA09-BRS-05-ID-UA	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Upper Arm
AEA09-BRS-05-ID-LA	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Lower Arm
AEA09-BRS-05-ID-FT	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Front Torso
AEA09-BRS-05-ID-RT	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-05-ID-UL	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Upper Leg
AEA09-BRS-05-ID-LL	Brush and Roller Worker Sample, ME 05, Inner Dosimter, Lower Leg
AEA09-BRS-05-OD-UA	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Upper Arm
AEA09-BRS-05-OD-LA	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Lower Arm
AEA09-BRS-05-OD-FT	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Front Torso
AEA09-BRS-05-OD-RT	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Rear Torso
AEA09-BRS-05-OD-UL	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Upper Leg
AEA09-BRS-05-OD-LL	Brush and Roller Worker Sample, ME 05, Outer Dosimter, Lower Leg
AEA09-BRS-06-PH	Brush and Roller Worker Sample, ME 06, Painter's Hat
AEA09-BRS-06-AR	Brush and Roller Worker Sample, ME 06, Air Sampling Tube
AEA09-BRS-06-RES-01	Brush and Roller Worker Sample, ME 06, RespiCon™ 100 µm
AEA09-BRS-06-RES-02	Brush and Roller Worker Sample, ME 06, RespiCon™ 10 µm
AEA09-BRS-06-RES-03	Brush and Roller Worker Sample, ME 06, RespiCon™ 2.5 µm
AEA09-BRS-06-HW-01	Brush and Roller Worker Sample, ME 06, Hand Wash
AEA09-BRS-06-FW-01	Brush and Roller Worker Sample, ME 06, Face and Neck Wipe
AEA09-BRS-06-ID-UA	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Upper Arm
AEA09-BRS-06-ID-LA	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Lower Arm
AEA09-BRS-06-ID-FT	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Front Torso
AEA09-BRS-06-ID-RT	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Rear Torso
AEA09-BRS-06-ID-UL	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Upper Leg
AEA09-BRS-06-ID-LL	Brush and Roller Worker Sample, ME 06, Inner Dosimter, Lower Leg
AEA09-BRS-06-OD-UA	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Upper Arm
AEA09-BRS-06-OD-LA	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Lower Arm
AEA09-BRS-06-OD-FT	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Front Torso
AEA09-BRS-06-OD-RT	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Rear Torso
AEA09-BRS-06-OD-UL	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Upper Leg
AEA09-BRS-06-OD-LL	Brush and Roller Worker Sample, ME 06, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-07-PH	Brush and Roller Worker Sample, ME 07, Painter's Hat
AEA09-BRS-07-AR	Brush and Roller Worker Sample, ME 07, Air Sampling Tube
AEA09-BRS-07-RES-01	Brush and Roller Worker Sample, ME 07, RespiCon™ 100 µm
AEA09-BRS-07-RES-02	Brush and Roller Worker Sample, ME 07, RespiCon™ 10 µm
AEA09-BRS-07-RES-03	Brush and Roller Worker Sample, ME 07, RespiCon™ 2.5 µm
AEA09-BRS-07-HW-01	Brush and Roller Worker Sample, ME 07, Hand Wash
AEA09-BRS-07-FW-01	Brush and Roller Worker Sample, ME 07, Face and Neck Wipe
AEA09-BRS-07-ID-UA	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Upper Arm
AEA09-BRS-07-ID-LA	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Lower Arm
AEA09-BRS-07-ID-FT	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Front Torso
AEA09-BRS-07-ID-RT	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Rear Torso
AEA09-BRS-07-ID-UL	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Upper Leg
AEA09-BRS-07-ID-LL	Brush and Roller Worker Sample, ME 07, Inner Dosimter, Lower Leg
AEA09-BRS-07-OD-UA	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Upper Arm
AEA09-BRS-07-OD-LA	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Lower Arm
AEA09-BRS-07-OD-FT	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Front Torso
AEA09-BRS-07-OD-RT	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Rear Torso
AEA09-BRS-07-OD-UL	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Upper Leg
AEA09-BRS-07-OD-LL	Brush and Roller Worker Sample, ME 07, Outer Dosimter, Lower Leg
AEA09-BRS-08-PH	Brush and Roller Worker Sample, ME 08, Painter's Hat
AEA09-BRS-08-AR	Brush and Roller Worker Sample, ME 08, Air Sampling Tube
AEA09-BRS-08-RES-01	Brush and Roller Worker Sample, ME 08, RespiCon™ 100 µm
AEA09-BRS-08-RES-02	Brush and Roller Worker Sample, ME 08, RespiCon™ 10 µm
AEA09-BRS-08-RES-03	Brush and Roller Worker Sample, ME 08, RespiCon™ 2.5 µm
AEA09-BRS-08-HW-01	Brush and Roller Worker Sample, ME 08, Hand Wash
AEA09-BRS-08-FW-01	Brush and Roller Worker Sample, ME 08, Face and Neck Wipe
AEA09-BRS-08-ID-UA	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Upper Arm
AEA09-BRS-08-ID-LA	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Lower Arm
AEA09-BRS-08-ID-FT	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Front Torso
AEA09-BRS-08-ID-RT	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-08-ID-UL	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Upper Leg
AEA09-BRS-08-ID-LL	Brush and Roller Worker Sample, ME 08, Inner Dosimter, Lower Leg
AEA09-BRS-08-OD-UA	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Upper Arm
AEA09-BRS-08-OD-LA	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Lower Arm
AEA09-BRS-08-OD-FT	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Front Torso
AEA09-BRS-08-OD-RT	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Rear Torso
AEA09-BRS-08-OD-UL	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Upper Leg
AEA09-BRS-08-OD-LL	Brush and Roller Worker Sample, ME 08, Outer Dosimter, Lower Leg
AEA09-BRS-09-PH	Brush and Roller Worker Sample, ME 09, Painter's Hat
AEA09-BRS-09-AR	Brush and Roller Worker Sample, ME 09, Air Sampling Tube
AEA09-BRS-09-RES-01	Brush and Roller Worker Sample, ME 09, RespiCon™ 100 µm
AEA09-BRS-09-RES-02	Brush and Roller Worker Sample, ME 09, RespiCon™ 10 µm
AEA09-BRS-09-RES-03	Brush and Roller Worker Sample, ME 09, RespiCon™ 2.5 µm
AEA09-BRS-09-HW-01	Brush and Roller Worker Sample, ME 09, Hand Wash
AEA09-BRS-09-FW-01	Brush and Roller Worker Sample, ME 09, Face and Neck Wipe
AEA09-BRS-09-ID-UA	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Upper Arm
AEA09-BRS-09-ID-LA	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Lower Arm
AEA09-BRS-09-ID-FT	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Front Torso
AEA09-BRS-09-ID-RT	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Rear Torso
AEA09-BRS-09-ID-UL	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Upper Leg
AEA09-BRS-09-ID-LL	Brush and Roller Worker Sample, ME 09, Inner Dosimter, Lower Leg
AEA09-BRS-09-OD-UA	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Upper Arm
AEA09-BRS-09-OD-LA	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Lower Arm
AEA09-BRS-09-OD-FT	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Front Torso
AEA09-BRS-09-OD-RT	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Rear Torso
AEA09-BRS-09-OD-UL	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Upper Leg
AEA09-BRS-09-OD-LL	Brush and Roller Worker Sample, ME 09, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-10-PH	Brush and Roller Worker Sample, ME 10, Painter's Hat
AEA09-BRS-10-AR	Brush and Roller Worker Sample, ME 10, Air Sampling Tube
AEA09-BRS-10-RES-01	Brush and Roller Worker Sample, ME 10, RespiCon™ 100 µm
AEA09-BRS-10-RES-02	Brush and Roller Worker Sample, ME 10, RespiCon™ 10 µm
AEA09-BRS-10-RES-03	Brush and Roller Worker Sample, ME 10, RespiCon™ 2.5 µm
AEA09-BRS-10-HW-01	Brush and Roller Worker Sample, ME 10, Hand Wash
AEA09-BRS-10-FW-01	Brush and Roller Worker Sample, ME 10, Face and Neck Wipe
AEA09-BRS-10-ID-UA	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Upper Arm
AEA09-BRS-10-ID-LA	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Lower Arm
AEA09-BRS-10-ID-FT	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Front Torso
AEA09-BRS-10-ID-RT	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Rear Torso
AEA09-BRS-10-ID-UL	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Upper Leg
AEA09-BRS-10-ID-LL	Brush and Roller Worker Sample, ME 10, Inner Dosimter, Lower Leg
AEA09-BRS-10-OD-UA	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Upper Arm
AEA09-BRS-10-OD-LA	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Lower Arm
AEA09-BRS-10-OD-FT	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Front Torso
AEA09-BRS-10-OD-RT	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Rear Torso
AEA09-BRS-10-OD-UL	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Upper Leg
AEA09-BRS-10-OD-LL	Brush and Roller Worker Sample, ME 10, Outer Dosimter, Lower Leg
AEA09-BRS-11-PH	Brush and Roller Worker Sample, ME 11, Painter's Hat
AEA09-BRS-11-AR	Brush and Roller Worker Sample, ME 11, Air Sampling Tube
AEA09-BRS-11-RES-01	Brush and Roller Worker Sample, ME 11, RespiCon™ 100 µm
AEA09-BRS-11-RES-02	Brush and Roller Worker Sample, ME 11, RespiCon™ 10 µm
AEA09-BRS-11-RES-03	Brush and Roller Worker Sample, ME 11, RespiCon™ 2.5 µm
AEA09-BRS-11-HW-01	Brush and Roller Worker Sample, ME 11, Hand Wash
AEA09-BRS-11-FW-01	Brush and Roller Worker Sample, ME 11, Face and Neck Wipe
AEA09-BRS-11-ID-UA	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Upper Arm
AEA09-BRS-11-ID-LA	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Lower Arm
AEA09-BRS-11-ID-FT	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Front Torso
AEA09-BRS-11-ID-RT	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-11-ID-UL	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Upper Leg
AEA09-BRS-11-ID-LL	Brush and Roller Worker Sample, ME 11, Inner Dosimter, Lower Leg
AEA09-BRS-11-OD-UA	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Upper Arm
AEA09-BRS-11-OD-LA	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Lower Arm
AEA09-BRS-11-OD-FT	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Front Torso
AEA09-BRS-11-OD-RT	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Rear Torso
AEA09-BRS-11-OD-UL	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Upper Leg
AEA09-BRS-11-OD-LL	Brush and Roller Worker Sample, ME 11, Outer Dosimter, Lower Leg
AEA09-BRS-12-PH	Brush and Roller Worker Sample, ME 12, Painter's Hat
AEA09-BRS-12-AR	Brush and Roller Worker Sample, ME 12, Air Sampling Tube
AEA09-BRS-12-RES-01	Brush and Roller Worker Sample, ME 12, RespiCon™ 100 µm
AEA09-BRS-12-RES-02	Brush and Roller Worker Sample, ME 12, RespiCon™ 10 µm
AEA09-BRS-12-RES-03	Brush and Roller Worker Sample, ME 12, RespiCon™ 2.5 µm
AEA09-BRS-12-HW-01	Brush and Roller Worker Sample, ME 12, Hand Wash
AEA09-BRS-12-FW-01	Brush and Roller Worker Sample, ME 12, Face and Neck Wipe
AEA09-BRS-12-ID-UA	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Upper Arm
AEA09-BRS-12-ID-LA	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Lower Arm
AEA09-BRS-12-ID-FT	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Front Torso
AEA09-BRS-12-ID-RT	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Rear Torso
AEA09-BRS-12-ID-UL	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Upper Leg
AEA09-BRS-12-ID-LL	Brush and Roller Worker Sample, ME 12, Inner Dosimter, Lower Leg
AEA09-BRS-12-OD-UA	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Upper Arm
AEA09-BRS-12-OD-LA	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Lower Arm
AEA09-BRS-12-OD-FT	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Front Torso
AEA09-BRS-12-OD-RT	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Rear Torso
AEA09-BRS-12-OD-UL	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Upper Leg
AEA09-BRS-12-OD-LL	Brush and Roller Worker Sample, ME 12, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-13-PH	Brush and Roller Worker Sample, ME 13, Painter's Hat
AEA09-BRS-13-AR	Brush and Roller Worker Sample, ME 13, Air Sampling Tube
AEA09-BRS-13-RES-01	Brush and Roller Worker Sample, ME 13, RespiCon™ 100 µm
AEA09-BRS-13-RES-02	Brush and Roller Worker Sample, ME 13, RespiCon™ 10 µm
AEA09-BRS-13-RES-03	Brush and Roller Worker Sample, ME 13, RespiCon™ 2.5 µm
AEA09-BRS-13-HW-01	Brush and Roller Worker Sample, ME 13, Hand Wash
AEA09-BRS-13-FW-01	Brush and Roller Worker Sample, ME 13, Face and Neck Wipe
AEA09-BRS-13-ID-UA	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Upper Arm
AEA09-BRS-13-ID-LA	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Lower Arm
AEA09-BRS-13-ID-FT	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Front Torso
AEA09-BRS-13-ID-RT	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Rear Torso
AEA09-BRS-13-ID-UL	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Upper Leg
AEA09-BRS-13-ID-LL	Brush and Roller Worker Sample, ME 13, Inner Dosimter, Lower Leg
AEA09-BRS-13-OD-UA	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Upper Arm
AEA09-BRS-13-OD-LA	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Lower Arm
AEA09-BRS-13-OD-FT	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Front Torso
AEA09-BRS-13-OD-RT	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Rear Torso
AEA09-BRS-13-OD-UL	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Upper Leg
AEA09-BRS-13-OD-LL	Brush and Roller Worker Sample, ME 13, Outer Dosimter, Lower Leg
AEA09-BRS-14-PH	Brush and Roller Worker Sample, ME 14, Painter's Hat
AEA09-BRS-14-AR	Brush and Roller Worker Sample, ME 14, Air Sampling Tube
AEA09-BRS-14-RES-01	Brush and Roller Worker Sample, ME 14, RespiCon™ 100 µm
AEA09-BRS-14-RES-02	Brush and Roller Worker Sample, ME 14, RespiCon™ 10 µm
AEA09-BRS-14-RES-03	Brush and Roller Worker Sample, ME 14, RespiCon™ 2.5 µm
AEA09-BRS-14-HW-01	Brush and Roller Worker Sample, ME 14, Hand Wash
AEA09-BRS-14-FW-01	Brush and Roller Worker Sample, ME 14, Face and Neck Wipe
AEA09-BRS-14-ID-UA	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Upper Arm
AEA09-BRS-14-ID-LA	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Lower Arm
AEA09-BRS-14-ID-FT	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Front Torso
AEA09-BRS-14-ID-RT	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-14-ID-UL	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Upper Leg
AEA09-BRS-14-ID-LL	Brush and Roller Worker Sample, ME 14, Inner Dosimter, Lower Leg
AEA09-BRS-14-OD-UA	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Upper Arm
AEA09-BRS-14-OD-LA	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Lower Arm
AEA09-BRS-14-OD-FT	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Front Torso
AEA09-BRS-14-OD-RT	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Rear Torso
AEA09-BRS-14-OD-UL	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Upper Leg
AEA09-BRS-14-OD-LL	Brush and Roller Worker Sample, ME 14, Outer Dosimter, Lower Leg
AEA09-BRS-15-PH	Brush and Roller Worker Sample, ME 15, Painter's Hat
AEA09-BRS-15-AR	Brush and Roller Worker Sample, ME 15, Air Sampling Tube
AEA09-BRS-15-RES-01	Brush and Roller Worker Sample, ME 15, RespiCon™ 100 µm
AEA09-BRS-15-RES-02	Brush and Roller Worker Sample, ME 15, RespiCon™ 10 µm
AEA09-BRS-15-RES-03	Brush and Roller Worker Sample, ME 15, RespiCon™ 2.5 µm
AEA09-BRS-15-HW-01	Brush and Roller Worker Sample, ME 15, Hand Wash
AEA09-BRS-15-FW-01	Brush and Roller Worker Sample, ME 15, Face and Neck Wipe
AEA09-BRS-15-ID-UA	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Upper Arm
AEA09-BRS-15-ID-LA	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Lower Arm
AEA09-BRS-15-ID-FT	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Front Torso
AEA09-BRS-15-ID-RT	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Rear Torso
AEA09-BRS-15-ID-UL	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Upper Leg
AEA09-BRS-15-ID-LL	Brush and Roller Worker Sample, ME 15, Inner Dosimter, Lower Leg
AEA09-BRS-15-OD-UA	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Upper Arm
AEA09-BRS-15-OD-LA	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Lower Arm
AEA09-BRS-15-OD-FT	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Front Torso
AEA09-BRS-15-OD-RT	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Rear Torso
AEA09-BRS-15-OD-UL	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Upper Leg
AEA09-BRS-15-OD-LL	Brush and Roller Worker Sample, ME 15, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-BRS-16-PH	Brush and Roller Worker Sample, ME 16, Painter's Hat
AEA09-BRS-16-AR	Brush and Roller Worker Sample, ME 16, Air Sampling Tube
AEA09-BRS-16-RES-01	Brush and Roller Worker Sample, ME 16, RespiCon™ 100 µm
AEA09-BRS-16-RES-02	Brush and Roller Worker Sample, ME 16, RespiCon™ 10 µm
AEA09-BRS-16-RES-03	Brush and Roller Worker Sample, ME 16, RespiCon™ 2.5 µm
AEA09-BRS-16-HW-01	Brush and Roller Worker Sample, ME 16, Hand Wash
AEA09-BRS-16-FW-01	Brush and Roller Worker Sample, ME 16, Face and Neck Wipe
AEA09-BRS-16-ID-UA	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Upper Arm
AEA09-BRS-16-ID-LA	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Lower Arm
AEA09-BRS-16-ID-FT	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Front Torso
AEA09-BRS-16-ID-RT	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Rear Torso
AEA09-BRS-16-ID-UL	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Upper Leg
AEA09-BRS-16-ID-LL	Brush and Roller Worker Sample, ME 16, Inner Dosimter, Lower Leg
AEA09-BRS-16-OD-UA	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Upper Arm
AEA09-BRS-16-OD-LA	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Lower Arm
AEA09-BRS-16-OD-FT	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Front Torso
AEA09-BRS-16-OD-RT	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Rear Torso
AEA09-BRS-16-OD-UL	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Upper Leg
AEA09-BRS-16-OD-LL	Brush and Roller Worker Sample, ME 16, Outer Dosimter, Lower Leg
AEA09-BRS-17-PH	Brush and Roller Worker Sample, ME 17, Painter's Hat
AEA09-BRS-17-AR	Brush and Roller Worker Sample, ME 17, Air Sampling Tube
AEA09-BRS-17-RES-01	Brush and Roller Worker Sample, ME 17, RespiCon™ 100 µm
AEA09-BRS-17-RES-02	Brush and Roller Worker Sample, ME 17, RespiCon™ 10 µm
AEA09-BRS-17-RES-03	Brush and Roller Worker Sample, ME 17, RespiCon™ 2.5 µm
AEA09-BRS-17-HW-01	Brush and Roller Worker Sample, ME 17, Hand Wash
AEA09-BRS-17-FW-01	Brush and Roller Worker Sample, ME 17, Face and Neck Wipe
AEA09-BRS-17-ID-UA	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Upper Arm
AEA09-BRS-17-ID-LA	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Lower Arm
AEA09-BRS-17-ID-FT	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Front Torso
AEA09-BRS-17-ID-RT	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Rear Torso

Sample ID Number	Description
AEA09-BRS-17-ID-UL	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Upper Leg
AEA09-BRS-17-ID-LL	Brush and Roller Worker Sample, ME 17, Inner Dosimter, Lower Leg
AEA09-BRS-17-OD-UA	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Upper Arm
AEA09-BRS-17-OD-LA	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Lower Arm
AEA09-BRS-17-OD-FT	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Front Torso
AEA09-BRS-17-OD-RT	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Rear Torso
AEA09-BRS-17-OD-UL	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Upper Leg
AEA09-BRS-17-OD-LL	Brush and Roller Worker Sample, ME 17, Outer Dosimter, Lower Leg
AEA09-BRS-18-PH	Brush and Roller Worker Sample, ME 18, Painter's Hat
AEA09-BRS-18-AR	Brush and Roller Worker Sample, ME 18, Air Sampling Tube
AEA09-BRS-18-RES-01	Brush and Roller Worker Sample, ME 18, RespiCon™ 100 µm
AEA09-BRS-18-RES-02	Brush and Roller Worker Sample, ME 18, RespiCon™ 10 µm
AEA09-BRS-18-RES-03	Brush and Roller Worker Sample, ME 18, RespiCon™ 2.5 µm
AEA09-BRS-18-HW-01	Brush and Roller Worker Sample, ME 18, Hand Wash
AEA09-BRS-18-FW-01	Brush and Roller Worker Sample, ME 18, Face and Neck Wipe
AEA09-BRS-18-ID-UA	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Upper Arm
AEA09-BRS-18-ID-LA	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Lower Arm
AEA09-BRS-18-ID-FT	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Front Torso
AEA09-BRS-18-ID-RT	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Rear Torso
AEA09-BRS-18-ID-UL	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Upper Leg
AEA09-BRS-18-ID-LL	Brush and Roller Worker Sample, ME 18, Inner Dosimter, Lower Leg
AEA09-BRS-18-OD-UA	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Upper Arm
AEA09-BRS-18-OD-LA	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Lower Arm
AEA09-BRS-18-OD-FT	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Front Torso
AEA09-BRS-18-OD-RT	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Rear Torso
AEA09-BRS-18-OD-UL	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Upper Leg
AEA09-BRS-18-OD-LL	Brush and Roller Worker Sample, ME 18, Outer Dosimter, Lower Leg

Sample ID Number	Description
AEA09-FF-01-PH-C1	Fortification Sample, ME 01, Painter's Hat, 1st Control
AEA09-FF-01-PH-C2	Fortification Sample, ME 01, Painter's Hat, 2nd Control
AEA09-FF-01-PH-L1	Fortification Sample, ME 01, Painter's Hat, 1st Low Level
AEA09-FF-01-PH-L2	Fortification Sample, ME 01, Painter's Hat, 2nd Low Level
AEA09-FF-01-PH-L3	Fortification Sample, ME 01, Painter's Hat, 3rd Low Level
AEA09-FF-01-PH-H1	Fortification Sample, ME 01, Painter's Hat, 1st High Level
AEA09-FF-01-PH-H2	Fortification Sample, ME 01, Painter's Hat, 2nd High Level
AEA09-FF-01-PH-H3	Fortification Sample, ME 01, Painter's Hat, 3rd High Level
AEA09-FF-01-AR-C1	Fortification Sample, ME 01, Air Sampling Tube, 1st Control
AEA09-FF-01-AR-C2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Control
AEA09-FF-01-AR-L1	Fortification Sample, ME 01, Air Sampling Tube, 1st Low Level
AEA09-FF-01-AR-L2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Low Level
AEA09-FF-01-AR-L3	Fortification Sample, ME 01, Air Sampling Tube, 3rd Low Level
AEA09-FF-01-AR-H1	Fortification Sample, ME 01, Air Sampling Tube, 1st High Level
AEA09-FF-01-AR-H2	Fortification Sample, ME 01, Air Sampling Tube, 2nd High Level
AEA09-FF-01-AR-H3	Fortification Sample, ME 01, Air Sampling Tube, 3rd High Level
AEA09-FF-01-RES-C1	Fortification Sample, ME 01, RespiCon, 1st Control
AEA09-FF-01-RES-C2	Fortification Sample, ME 01, RespiCon, 2nd Control
AEA09-FF-01-RES-L1	Fortification Sample, ME 01, RespiCon, 1st Low Level
AEA09-FF-01-RES-L2	Fortification Sample, ME 01, RespiCon, 2nd Low Level
AEA09-FF-01-RES-L3	Fortification Sample, ME 01, RespiCon, 3rd Low Level
AEA09-FF-01-RES-H1	Fortification Sample, ME 01, RespiCon, 1st High Level
AEA09-FF-01-RES-H2	Fortification Sample, ME 01, RespiCon, 2nd High Level
AEA09-FF-01-RES-H3	Fortification Sample, ME 01, RespiCon, 3rd High Level
AEA09-FF-01-HW-C1	Fortification Sample, ME 01, Hand Wash, 1st Control
AEA09-FF-01-HW-C2	Fortification Sample, ME 01, Hand Wash, 2nd Control
AEA09-FF-01-HW-L1	Fortification Sample, ME 01, Hand Wash, 1st Low Level
AEA09-FF-01-HW-L2	Fortification Sample, ME 01, Hand Wash, 2nd Low Level
AEA09-FF-01-HW-L3	Fortification Sample, ME 01, Hand Wash, 3rd Low Level
AEA09-FF-01-HW-H1	Fortification Sample, ME 01, Hand Wash, 1st High Level
AEA09-FF-01-HW-H2	Fortification Sample, ME 01, Hand Wash, 2nd High Level
AEA09-FF-01-HW-H3	Fortification Sample, ME 01, Hand Wash, 3rd High Level
AEA09-FF-01-FW-C1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Control
AEA09-FF-01-FW-C2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Control
AEA09-FF-01-FW-L1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Low Level
AEA09-FF-01-FW-L2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Low Level
AEA09-FF-01-FW-L3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd Low Level
AEA09-FF-01-FW-H1	Fortification Sample, ME 01, Face and Neck Wipe, 1st High Level
AEA09-FF-01-FW-H2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd High Level
AEA09-FF-01-FW-H3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd High Level

Sample ID Number	Description
AEA09-FF-01-ID-C1	Fortification Sample, ME 01, Inner Dosimeter, 1st Control
AEA09-FF-01-ID-C2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Control
AEA09-FF-01-ID-L1	Fortification Sample, ME 01, Inner Dosimeter, 1st Low Level
AEA09-FF-01-ID-L2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Low Level
AEA09-FF-01-ID-L3	Fortification Sample, ME 01, Inner Dosimeter, 3rd Low Level
AEA09-FF-01-ID-H1	Fortification Sample, ME 01, Inner Dosimeter, 1st High Level
AEA09-FF-01-ID-H2	Fortification Sample, ME 01, Inner Dosimeter, 2nd High Level
AEA09-FF-01-ID-H3	Fortification Sample, ME 01, Inner Dosimeter, 3rd High Level
AEA09-FF-01-OD-C1	Fortification Sample, ME 01, Outer Dosimeter, 1st Control
AEA09-FF-01-OD-C2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Control
AEA09-FF-01-OD-L1	Fortification Sample, ME 01, Outer Dosimeter, 1st Low Level
AEA09-FF-01-OD-L2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Low Level
AEA09-FF-01-OD-L3	Fortification Sample, ME 01, Outer Dosimeter, 3rd Low Level
AEA09-FF-01-OD-H1	Fortification Sample, ME 01, Outer Dosimeter, 1st High Level
AEA09-FF-01-OD-H2	Fortification Sample, ME 01, Outer Dosimeter, 2nd High Level
AEA09-FF-01-OD-H3	Fortification Sample, ME 01, Outer Dosimeter, 3rd High Level
AEA09-FF-02-PH-C1	Fortification Sample, ME 02, Painter's Hat, 1st Control
AEA09-FF-02-PH-C2	Fortification Sample, ME 02, Painter's Hat, 2nd Control
AEA09-FF-02-PH-L1	Fortification Sample, ME 02, Painter's Hat, 1st Low Level
AEA09-FF-02-PH-L2	Fortification Sample, ME 02, Painter's Hat, 2nd Low Level
AEA09-FF-02-PH-L3	Fortification Sample, ME 02, Painter's Hat, 3rd Low Level
AEA09-FF-02-PH-H1	Fortification Sample, ME 02, Painter's Hat, 1st High Level
AEA09-FF-02-PH-H2	Fortification Sample, ME 02, Painter's Hat, 2nd High Level
AEA09-FF-02-PH-H3	Fortification Sample, ME 02, Painter's Hat, 3rd High Level
AEA09-FF-02-AR-C1	Fortification Sample, ME 02, Air Sampling Tube, 1st Control
AEA09-FF-02-AR-C2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Control
AEA09-FF-02-AR-L1	Fortification Sample, ME 02, Air Sampling Tube, 1st Low Level
AEA09-FF-02-AR-L2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Low Level
AEA09-FF-02-AR-L3	Fortification Sample, ME 02, Air Sampling Tube, 3rd Low Level
AEA09-FF-02-AR-H1	Fortification Sample, ME 02, Air Sampling Tube, 1st High Level
AEA09-FF-02-AR-H2	Fortification Sample, ME 02, Air Sampling Tube, 2nd High Level
AEA09-FF-02-AR-H3	Fortification Sample, ME 02, Air Sampling Tube, 3rd High Level
AEA09-FF-02-RES-C1	Fortification Sample, ME 02, RespiCon, 1st Control
AEA09-FF-02-RES-C2	Fortification Sample, ME 02, RespiCon, 2nd Control
AEA09-FF-02-RES-L1	Fortification Sample, ME 02, RespiCon, 1st Low Level
AEA09-FF-02-RES-L2	Fortification Sample, ME 02, RespiCon, 2nd Low Level
AEA09-FF-02-RES-L3	Fortification Sample, ME 02, RespiCon, 3rd Low Level
AEA09-FF-02-RES-H1	Fortification Sample, ME 02, RespiCon, 1st High Level
AEA09-FF-02-RES-H2	Fortification Sample, ME 02, RespiCon, 2nd High Level
AEA09-FF-02-RES-H3	Fortification Sample, ME 02, RespiCon, 3rd High Level
AEA09-FF-02-HW-C1	Fortification Sample, ME 02, Hand Wash, 1st Control
AEA09-FF-02-HW-C2	Fortification Sample, ME 02, Hand Wash, 2nd Control
AEA09-FF-02-HW-L1	Fortification Sample, ME 02, Hand Wash, 1st Low Level
AEA09-FF-02-HW-L2	Fortification Sample, ME 02, Hand Wash, 2nd Low Level
AEA09-FF-02-HW-L3	Fortification Sample, ME 02, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-02-HW-H1	Fortification Sample, ME 02, Hand Wash, 1st High Level
AEA09-FF-02-HW-H2	Fortification Sample, ME 02, Hand Wash, 2nd High Level
AEA09-FF-02-HW-H3	Fortification Sample, ME 02, Hand Wash, 3rd High Level
AEA09-FF-02-FW-C1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Control
AEA09-FF-02-FW-C2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Control
AEA09-FF-02-FW-L1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Low Level
AEA09-FF-02-FW-L2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Low Level
AEA09-FF-02-FW-L3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd Low Level
AEA09-FF-02-FW-H1	Fortification Sample, ME 02, Face and Neck Wipe, 1st High Level
AEA09-FF-02-FW-H2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd High Level
AEA09-FF-02-FW-H3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd High Level
AEA09-FF-02-ID-C1	Fortification Sample, ME 02, Inner Dosimeter, 1st Control
AEA09-FF-02-ID-C2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Control
AEA09-FF-02-ID-L1	Fortification Sample, ME 02, Inner Dosimeter, 1st Low Level
AEA09-FF-02-ID-L2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Low Level
AEA09-FF-02-ID-L3	Fortification Sample, ME 02, Inner Dosimeter, 3rd Low Level
AEA09-FF-02-ID-H1	Fortification Sample, ME 02, Inner Dosimeter, 1st High Level
AEA09-FF-02-ID-H2	Fortification Sample, ME 02, Inner Dosimeter, 2nd High Level
AEA09-FF-02-ID-H3	Fortification Sample, ME 02, Inner Dosimeter, 3rd High Level
AEA09-FF-02-OD-C1	Fortification Sample, ME 02, Outer Dosimeter, 1st Control
AEA09-FF-02-OD-C2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Control
AEA09-FF-02-OD-L1	Fortification Sample, ME 02, Outer Dosimeter, 1st Low Level
AEA09-FF-02-OD-L2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Low Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-02-OD-H1	Fortification Sample, ME 02, Outer Dosimeter, 1st High Level
AEA09-FF-02-OD-H2	Fortification Sample, ME 02, Outer Dosimeter, 2nd High Level
AEA09-FF-02-OD-H3	Fortification Sample, ME 02, Outer Dosimeter, 3rd High Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-03-PH-C1	Fortification Sample, ME 03, Painter's Hat, 1st Control
AEA09-FF-03-PH-C2	Fortification Sample, ME 03, Painter's Hat, 2nd Control
AEA09-FF-03-PH-L1	Fortification Sample, ME 03, Painter's Hat, 1st Low Level
AEA09-FF-03-PH-L2	Fortification Sample, ME 03, Painter's Hat, 2nd Low Level
AEA09-FF-03-PH-L3	Fortification Sample, ME 03, Painter's Hat, 3rd Low Level
AEA09-FF-03-PH-H1	Fortification Sample, ME 03, Painter's Hat, 1st High Level
AEA09-FF-03-PH-H2	Fortification Sample, ME 03, Painter's Hat, 2nd High Level
AEA09-FF-03-PH-H3	Fortification Sample, ME 03, Painter's Hat, 3rd High Level
AEA09-FF-03-AR-C1	Fortification Sample, ME 03, Air Sampling Tube, 1st Control
AEA09-FF-03-AR-C2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Control
AEA09-FF-03-AR-L1	Fortification Sample, ME 03, Air Sampling Tube, 1st Low Level
AEA09-FF-03-AR-L2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Low Level
AEA09-FF-03-AR-L3	Fortification Sample, ME 03, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-AR-H1	Fortification Sample, ME 03, Air Sampling Tube, 1st High Level
AEA09-FF-03-AR-H2	Fortification Sample, ME 03, Air Sampling Tube, 2nd High Level
AEA09-FF-03-AR-H3	Fortification Sample, ME 03, Air Sampling Tube, 3rd High Level
AEA09-FF-03-RES-C1	Fortification Sample, ME 03, RespiCon, 1st Control
AEA09-FF-03-RES-C2	Fortification Sample, ME 03, RespiCon, 2nd Control
AEA09-FF-03-RES-L1	Fortification Sample, ME 03, RespiCon, 1st Low Level
AEA09-FF-03-RES-L2	Fortification Sample, ME 03, RespiCon, 2nd Low Level
AEA09-FF-03-RES-L3	Fortification Sample, ME 03, RespiCon, 3rd Low Level
AEA09-FF-03-RES-H1	Fortification Sample, ME 03, RespiCon, 1st High Level
AEA09-FF-03-RES-H2	Fortification Sample, ME 03, RespiCon, 2nd High Level
AEA09-FF-03-RES-H3	Fortification Sample, ME 03, RespiCon, 3rd High Level
AEA09-FF-03-HW-C1	Fortification Sample, ME 03, Hand Wash, 1st Control
AEA09-FF-03-HW-C2	Fortification Sample, ME 03, Hand Wash, 2nd Control
AEA09-FF-03-HW-L1	Fortification Sample, ME 03, Hand Wash, 1st Low Level
AEA09-FF-03-HW-L2	Fortification Sample, ME 03, Hand Wash, 2nd Low Level
AEA09-FF-03-HW-L3	Fortification Sample, ME 03, Hand Wash, 3rd Low Level
AEA09-FF-03-HW-H1	Fortification Sample, ME 03, Hand Wash, 1st High Level
AEA09-FF-03-HW-H2	Fortification Sample, ME 03, Hand Wash, 2nd High Level
AEA09-FF-03-HW-H3	Fortification Sample, ME 03, Hand Wash, 3rd High Level
AEA09-FF-03-FW-C1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Control
AEA09-FF-03-FW-C2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Control
AEA09-FF-03-FW-L1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Low Level
AEA09-FF-03-FW-L2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Low Level
AEA09-FF-03-FW-L3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd Low Level
AEA09-FF-03-FW-H1	Fortification Sample, ME 03, Face and Neck Wipe, 1st High Level
AEA09-FF-03-FW-H2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd High Level
AEA09-FF-03-FW-H3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd High Level
AEA09-FF-03-ID-C1	Fortification Sample, ME 03, Inner Dosimeter, 1st Control
AEA09-FF-03-ID-C2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Control
AEA09-FF-03-ID-L1	Fortification Sample, ME 03, Inner Dosimeter, 1st Low Level
AEA09-FF-03-ID-L2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Low Level
AEA09-FF-03-ID-L3	Fortification Sample, ME 03, Inner Dosimeter, 3rd Low Level
AEA09-FF-03-ID-H1	Fortification Sample, ME 03, Inner Dosimeter, 1st High Level
AEA09-FF-03-ID-H2	Fortification Sample, ME 03, Inner Dosimeter, 2nd High Level
AEA09-FF-03-ID-H3	Fortification Sample, ME 03, Inner Dosimeter, 3rd High Level
AEA09-FF-03-OD-C1	Fortification Sample, ME 03, Outer Dosimeter, 1st Control
AEA09-FF-03-OD-C2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Control
AEA09-FF-03-OD-L1	Fortification Sample, ME 03, Outer Dosimeter, 1st Low Level
AEA09-FF-03-OD-L2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Low Level
AEA09-FF-03-OD-L3	Fortification Sample, ME 03, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-OD-H1	Fortification Sample, ME 03, Outer Dosimeter, 1st High Level
AEA09-FF-03-OD-H2	Fortification Sample, ME 03, Outer Dosimeter, 2nd High Level
AEA09-FF-03-OD-H3	Fortification Sample, ME 03, Outer Dosimeter, 3rd High Level
AEA09-FF-04-PH-C1	Fortification Sample, ME 04, Painter's Hat, 1st Control
AEA09-FF-04-PH-C2	Fortification Sample, ME 04, Painter's Hat, 2nd Control
AEA09-FF-04-PH-L1	Fortification Sample, ME 04, Painter's Hat, 1st Low Level
AEA09-FF-04-PH-L2	Fortification Sample, ME 04, Painter's Hat, 2nd Low Level
AEA09-FF-04-PH-L3	Fortification Sample, ME 04, Painter's Hat, 3rd Low Level
AEA09-FF-04-PH-H1	Fortification Sample, ME 04, Painter's Hat, 1st High Level
AEA09-FF-04-PH-H2	Fortification Sample, ME 04, Painter's Hat, 2nd High Level
AEA09-FF-04-PH-H3	Fortification Sample, ME 04, Painter's Hat, 3rd High Level
AEA09-FF-04-AR-C1	Fortification Sample, ME 04, Air Sampling Tube, 1st Control
AEA09-FF-04-AR-C2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Control
AEA09-FF-04-AR-L1	Fortification Sample, ME 04, Air Sampling Tube, 1st Low Level
AEA09-FF-04-AR-L2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Low Level
AEA09-FF-04-AR-L3	Fortification Sample, ME 04, Air Sampling Tube, 3rd Low Level
AEA09-FF-04-AR-H1	Fortification Sample, ME 04, Air Sampling Tube, 1st High Level
AEA09-FF-04-AR-H2	Fortification Sample, ME 04, Air Sampling Tube, 2nd High Level
AEA09-FF-04-AR-H3	Fortification Sample, ME 04, Air Sampling Tube, 3rd High Level
AEA09-FF-04-RES-C1	Fortification Sample, ME 04, RespiCon, 1st Control
AEA09-FF-04-RES-C2	Fortification Sample, ME 04, RespiCon, 2nd Control
AEA09-FF-04-RES-L1	Fortification Sample, ME 04, RespiCon, 1st Low Level
AEA09-FF-04-RES-L2	Fortification Sample, ME 04, RespiCon, 2nd Low Level
AEA09-FF-04-RES-L3	Fortification Sample, ME 04, RespiCon, 3rd Low Level
AEA09-FF-04-RES-H1	Fortification Sample, ME 04, RespiCon, 1st High Level
AEA09-FF-04-RES-H2	Fortification Sample, ME 04, RespiCon, 2nd High Level
AEA09-FF-04-RES-H3	Fortification Sample, ME 04, RespiCon, 3rd High Level
AEA09-FF-04-HW-C1	Fortification Sample, ME 04, Hand Wash, 1st Control
AEA09-FF-04-HW-C2	Fortification Sample, ME 04, Hand Wash, 2nd Control
AEA09-FF-04-HW-L1	Fortification Sample, ME 04, Hand Wash, 1st Low Level
AEA09-FF-04-HW-L2	Fortification Sample, ME 04, Hand Wash, 2nd Low Level
AEA09-FF-04-HW-L3	Fortification Sample, ME 04, Hand Wash, 3rd Low Level
AEA09-FF-04-HW-H1	Fortification Sample, ME 04, Hand Wash, 1st High Level
AEA09-FF-04-HW-H2	Fortification Sample, ME 04, Hand Wash, 2nd High Level
AEA09-FF-04-HW-H3	Fortification Sample, ME 04, Hand Wash, 3rd High Level
AEA09-FF-04-FW-C1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Control
AEA09-FF-04-FW-C2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Control
AEA09-FF-04-FW-L1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Low Level
AEA09-FF-04-FW-L2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Low Level
AEA09-FF-04-FW-L3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd Low Level
AEA09-FF-04-FW-H1	Fortification Sample, ME 04, Face and Neck Wipe, 1st High Level
AEA09-FF-04-FW-H2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd High Level

Sample ID Number	Description
AEA09-FF-04-FW-H3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd High Level
AEA09-FF-04-ID-C1	Fortification Sample, ME 04, Inner Dosimeter, 1st Control
AEA09-FF-04-ID-C2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Control
AEA09-FF-04-ID-L1	Fortification Sample, ME 04, Inner Dosimeter, 1st Low Level
AEA09-FF-04-ID-L2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Low Level
AEA09-FF-04-ID-L3	Fortification Sample, ME 04, Inner Dosimeter, 3rd Low Level
AEA09-FF-04-ID-H1	Fortification Sample, ME 04, Inner Dosimeter, 1st High Level
AEA09-FF-04-ID-H2	Fortification Sample, ME 04, Inner Dosimeter, 2nd High Level
AEA09-FF-04-ID-H3	Fortification Sample, ME 04, Inner Dosimeter, 3rd High Level
AEA09-FF-04-OD-C1	Fortification Sample, ME 04, Outer Dosimeter, 1st Control
AEA09-FF-04-OD-C2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Control
AEA09-FF-04-OD-L1	Fortification Sample, ME 04, Outer Dosimeter, 1st Low Level
AEA09-FF-04-OD-L2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Low Level
AEA09-FF-04-OD-L3	Fortification Sample, ME 04, Outer Dosimeter, 3rd Low Level
AEA09-FF-04-OD-H1	Fortification Sample, ME 04, Outer Dosimeter, 1st High Level
AEA09-FF-04-OD-H2	Fortification Sample, ME 04, Outer Dosimeter, 2nd High Level
AEA09-FF-04-OD-H3	Fortification Sample, ME 04, Outer Dosimeter, 3rd High Level
AEA09-FF-05-PH-C1	Fortification Sample, ME 05, Painter's Hat, 1st Control
AEA09-FF-05-PH-C2	Fortification Sample, ME 05, Painter's Hat, 2nd Control
AEA09-FF-05-PH-L1	Fortification Sample, ME 05, Painter's Hat, 1st Low Level
AEA09-FF-05-PH-L2	Fortification Sample, ME 05, Painter's Hat, 2nd Low Level
AEA09-FF-05-PH-L3	Fortification Sample, ME 05, Painter's Hat, 3rd Low Level
AEA09-FF-05-PH-H1	Fortification Sample, ME 05, Painter's Hat, 1st High Level
AEA09-FF-05-PH-H2	Fortification Sample, ME 05, Painter's Hat, 2nd High Level
AEA09-FF-05-PH-H3	Fortification Sample, ME 05, Painter's Hat, 3rd High Level
AEA09-FF-05-AR-C1	Fortification Sample, ME 05, Air Sampling Tube, 1st Control
AEA09-FF-05-AR-C2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Control
AEA09-FF-05-AR-L1	Fortification Sample, ME 05, Air Sampling Tube, 1st Low Level
AEA09-FF-05-AR-L2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Low Level
AEA09-FF-05-AR-L3	Fortification Sample, ME 05, Air Sampling Tube, 3rd Low Level
AEA09-FF-05-AR-H1	Fortification Sample, ME 05, Air Sampling Tube, 1st High Level
AEA09-FF-05-AR-H2	Fortification Sample, ME 05, Air Sampling Tube, 2nd High Level
AEA09-FF-05-AR-H3	Fortification Sample, ME 05, Air Sampling Tube, 3rd High Level
AEA09-FF-05-RES-C1	Fortification Sample, ME 05, RespiCon, 1st Control
AEA09-FF-05-RES-C2	Fortification Sample, ME 05, RespiCon, 2nd Control
AEA09-FF-05-RES-L1	Fortification Sample, ME 05, RespiCon, 1st Low Level
AEA09-FF-05-RES-L2	Fortification Sample, ME 05, RespiCon, 2nd Low Level
AEA09-FF-05-RES-L3	Fortification Sample, ME 05, RespiCon, 3rd Low Level
AEA09-FF-05-RES-H1	Fortification Sample, ME 05, RespiCon, 1st High Level
AEA09-FF-05-RES-H2	Fortification Sample, ME 05, RespiCon, 2nd High Level
AEA09-FF-05-RES-H3	Fortification Sample, ME 05, RespiCon, 3rd High Level
AEA09-FF-05-HW-C1	Fortification Sample, ME 05, Hand Wash, 1st Control
AEA09-FF-05-HW-C2	Fortification Sample, ME 05, Hand Wash, 2nd Control
AEA09-FF-05-HW-L1	Fortification Sample, ME 05, Hand Wash, 1st Low Level
AEA09-FF-05-HW-L2	Fortification Sample, ME 05, Hand Wash, 2nd Low Level
AEA09-FF-05-HW-L3	Fortification Sample, ME 05, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-05-HW-H1	Fortification Sample, ME 05, Hand Wash, 1st High Level
AEA09-FF-05-HW-H2	Fortification Sample, ME 05, Hand Wash, 2nd High Level
AEA09-FF-05-HW-H3	Fortification Sample, ME 05, Hand Wash, 3rd High Level
AEA09-FF-05-FW-C1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Control
AEA09-FF-05-FW-C2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Control
AEA09-FF-05-FW-L1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Low Level
AEA09-FF-05-FW-L2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Low Level
AEA09-FF-05-FW-L3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd Low Level
AEA09-FF-05-FW-H1	Fortification Sample, ME 05, Face and Neck Wipe, 1st High Level
AEA09-FF-05-FW-H2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd High Level
AEA09-FF-05-FW-H3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd High Level
AEA09-FF-05-ID-C1	Fortification Sample, ME 05, Inner Dosimeter, 1st Control
AEA09-FF-05-ID-C2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Control
AEA09-FF-05-ID-L1	Fortification Sample, ME 05, Inner Dosimeter, 1st Low Level
AEA09-FF-05-ID-L2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Low Level
AEA09-FF-05-ID-L3	Fortification Sample, ME 05, Inner Dosimeter, 3rd Low Level
AEA09-FF-05-ID-H1	Fortification Sample, ME 05, Inner Dosimeter, 1st High Level
AEA09-FF-05-ID-H2	Fortification Sample, ME 05, Inner Dosimeter, 2nd High Level
AEA09-FF-05-ID-H3	Fortification Sample, ME 05, Inner Dosimeter, 3rd High Level
AEA09-FF-05-OD-C1	Fortification Sample, ME 05, Outer Dosimeter, 1st Control
AEA09-FF-05-OD-C2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Control
AEA09-FF-05-OD-L1	Fortification Sample, ME 05, Outer Dosimeter, 1st Low Level
AEA09-FF-05-OD-L2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Low Level
AEA09-FF-05-OD-L3	Fortification Sample, ME 05, Outer Dosimeter, 3rd Low Level
AEA09-FF-05-OD-H1	Fortification Sample, ME 05, Outer Dosimeter, 1st High Level
AEA09-FF-05-OD-H2	Fortification Sample, ME 05, Outer Dosimeter, 2nd High Level
AEA09-FF-05-OD-H3	Fortification Sample, ME 05, Outer Dosimeter, 3rd High Level
AEA09-FF-06-PH-C1	Fortification Sample, ME 06, Painter's Hat, 1st Control
AEA09-FF-06-PH-C2	Fortification Sample, ME 06, Painter's Hat, 2nd Control
AEA09-FF-06-PH-L1	Fortification Sample, ME 06, Painter's Hat, 1st Low Level
AEA09-FF-06-PH-L2	Fortification Sample, ME 06, Painter's Hat, 2nd Low Level
AEA09-FF-06-PH-L3	Fortification Sample, ME 06, Painter's Hat, 3rd Low Level
AEA09-FF-06-PH-H1	Fortification Sample, ME 06, Painter's Hat, 1st High Level
AEA09-FF-06-PH-H2	Fortification Sample, ME 06, Painter's Hat, 2nd High Level
AEA09-FF-06-PH-H3	Fortification Sample, ME 06, Painter's Hat, 3rd High Level
AEA09-FF-06-AR-C1	Fortification Sample, ME 06, Air Sampling Tube, 1st Control
AEA09-FF-06-AR-C2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Control
AEA09-FF-06-AR-L1	Fortification Sample, ME 06, Air Sampling Tube, 1st Low Level
AEA09-FF-06-AR-L2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Low Level
AEA09-FF-06-AR-L3	Fortification Sample, ME 06, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-AR-H1	Fortification Sample, ME 06, Air Sampling Tube, 1st High Level
AEA09-FF-06-AR-H2	Fortification Sample, ME 06, Air Sampling Tube, 2nd High Level
AEA09-FF-06-AR-H3	Fortification Sample, ME 06, Air Sampling Tube, 3rd High Level
AEA09-FF-06-RES-C1	Fortification Sample, ME 06, RespiCon, 1st Control
AEA09-FF-06-RES-C2	Fortification Sample, ME 06, RespiCon, 2nd Control
AEA09-FF-06-RES-L1	Fortification Sample, ME 06, RespiCon, 1st Low Level
AEA09-FF-06-RES-L2	Fortification Sample, ME 06, RespiCon, 2nd Low Level
AEA09-FF-06-RES-L3	Fortification Sample, ME 06, RespiCon, 3rd Low Level
AEA09-FF-06-RES-H1	Fortification Sample, ME 06, RespiCon, 1st High Level
AEA09-FF-06-RES-H2	Fortification Sample, ME 06, RespiCon, 2nd High Level
AEA09-FF-06-RES-H3	Fortification Sample, ME 06, RespiCon, 3rd High Level
AEA09-FF-06-HW-C1	Fortification Sample, ME 06, Hand Wash, 1st Control
AEA09-FF-06-HW-C2	Fortification Sample, ME 06, Hand Wash, 2nd Control
AEA09-FF-06-HW-L1	Fortification Sample, ME 06, Hand Wash, 1st Low Level
AEA09-FF-06-HW-L2	Fortification Sample, ME 06, Hand Wash, 2nd Low Level
AEA09-FF-06-HW-L3	Fortification Sample, ME 06, Hand Wash, 3rd Low Level
AEA09-FF-06-HW-H1	Fortification Sample, ME 06, Hand Wash, 1st High Level
AEA09-FF-06-HW-H2	Fortification Sample, ME 06, Hand Wash, 2nd High Level
AEA09-FF-06-HW-H3	Fortification Sample, ME 06, Hand Wash, 3rd High Level
AEA09-FF-06-FW-C1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Control
AEA09-FF-06-FW-C2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Control
AEA09-FF-06-FW-L1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Low Level
AEA09-FF-06-FW-L2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Low Level
AEA09-FF-06-FW-L3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd Low Level
AEA09-FF-06-FW-H1	Fortification Sample, ME 06, Face and Neck Wipe, 1st High Level
AEA09-FF-06-FW-H2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd High Level
AEA09-FF-06-FW-H3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd High Level
AEA09-FF-06-ID-C1	Fortification Sample, ME 06, Inner Dosimeter, 1st Control
AEA09-FF-06-ID-C2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Control
AEA09-FF-06-ID-L1	Fortification Sample, ME 06, Inner Dosimeter, 1st Low Level
AEA09-FF-06-ID-L2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Low Level
AEA09-FF-06-ID-L3	Fortification Sample, ME 06, Inner Dosimeter, 3rd Low Level
AEA09-FF-06-ID-H1	Fortification Sample, ME 06, Inner Dosimeter, 1st High Level
AEA09-FF-06-ID-H2	Fortification Sample, ME 06, Inner Dosimeter, 2nd High Level
AEA09-FF-06-ID-H3	Fortification Sample, ME 06, Inner Dosimeter, 3rd High Level
AEA09-FF-06-OD-C1	Fortification Sample, ME 06, Outer Dosimeter, 1st Control
AEA09-FF-06-OD-C2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Control
AEA09-FF-06-OD-L1	Fortification Sample, ME 06, Outer Dosimeter, 1st Low Level
AEA09-FF-06-OD-L2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Low Level
AEA09-FF-06-OD-L3	Fortification Sample, ME 06, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-OD-H1	Fortification Sample, ME 06, Outer Dosimeter, 1st High Level
AEA09-FF-06-OD-H2	Fortification Sample, ME 06, Outer Dosimeter, 2nd High Level
AEA09-FF-06-OD-H3	Fortification Sample, ME 06, Outer Dosimeter, 3rd High Level
AEA09-FF-07-PH-C1	Fortification Sample, ME 07, Painter's Hat, 1st Control
AEA09-FF-07-PH-C2	Fortification Sample, ME 07, Painter's Hat, 2nd Control
AEA09-FF-07-PH-L1	Fortification Sample, ME 07, Painter's Hat, 1st Low Level
AEA09-FF-07-PH-L2	Fortification Sample, ME 07, Painter's Hat, 2nd Low Level
AEA09-FF-07-PH-L3	Fortification Sample, ME 07, Painter's Hat, 3rd Low Level
AEA09-FF-07-PH-H1	Fortification Sample, ME 07, Painter's Hat, 1st High Level
AEA09-FF-07-PH-H2	Fortification Sample, ME 07, Painter's Hat, 2nd High Level
AEA09-FF-07-PH-H3	Fortification Sample, ME 07, Painter's Hat, 3rd High Level
AEA09-FF-07-AR-C1	Fortification Sample, ME 07, Air Sampling Tube, 1st Control
AEA09-FF-07-AR-C2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Control
AEA09-FF-07-AR-L1	Fortification Sample, ME 07, Air Sampling Tube, 1st Low Level
AEA09-FF-07-AR-L2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Low Level
AEA09-FF-07-AR-L3	Fortification Sample, ME 07, Air Sampling Tube, 3rd Low Level
AEA09-FF-07-AR-H1	Fortification Sample, ME 07, Air Sampling Tube, 1st High Level
AEA09-FF-07-AR-H2	Fortification Sample, ME 07, Air Sampling Tube, 2nd High Level
AEA09-FF-07-AR-H3	Fortification Sample, ME 07, Air Sampling Tube, 3rd High Level
AEA09-FF-07-RES-C1	Fortification Sample, ME 07, RespiCon, 1st Control
AEA09-FF-07-RES-C2	Fortification Sample, ME 07, RespiCon, 2nd Control
AEA09-FF-07-RES-L1	Fortification Sample, ME 07, RespiCon, 1st Low Level
AEA09-FF-07-RES-L2	Fortification Sample, ME 07, RespiCon, 2nd Low Level
AEA09-FF-07-RES-L3	Fortification Sample, ME 07, RespiCon, 3rd Low Level
AEA09-FF-07-RES-H1	Fortification Sample, ME 07, RespiCon, 1st High Level
AEA09-FF-07-RES-H2	Fortification Sample, ME 07, RespiCon, 2nd High Level
AEA09-FF-07-RES-H3	Fortification Sample, ME 07, RespiCon, 3rd High Level
AEA09-FF-07-HW-C1	Fortification Sample, ME 07, Hand Wash, 1st Control
AEA09-FF-07-HW-C2	Fortification Sample, ME 07, Hand Wash, 2nd Control
AEA09-FF-07-HW-L1	Fortification Sample, ME 07, Hand Wash, 1st Low Level
AEA09-FF-07-HW-L2	Fortification Sample, ME 07, Hand Wash, 2nd Low Level
AEA09-FF-07-HW-L3	Fortification Sample, ME 07, Hand Wash, 3rd Low Level
AEA09-FF-07-HW-H1	Fortification Sample, ME 07, Hand Wash, 1st High Level
AEA09-FF-07-HW-H2	Fortification Sample, ME 07, Hand Wash, 2nd High Level
AEA09-FF-07-HW-H3	Fortification Sample, ME 07, Hand Wash, 3rd High Level
AEA09-FF-07-FW-C1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Control
AEA09-FF-07-FW-C2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Control
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Low Level
AEA09-FF-07-FW-L3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd Low Level
AEA09-FF-07-FW-H1	Fortification Sample, ME 07, Face and Neck Wipe, 1st High Level

Sample ID Number	Description
AEA09-FF-07-FW-H2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd High Level
AEA09-FF-07-FW-H3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd High Level
AEA09-FF-07-ID-C1	Fortification Sample, ME 07, Inner Dosimeter, 1st Control
AEA09-FF-07-ID-C2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Control
AEA09-FF-07-ID-L1	Fortification Sample, ME 07, Inner Dosimeter, 1st Low Level
AEA09-FF-07-ID-L2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Low Level
AEA09-FF-07-ID-L3	Fortification Sample, ME 07, Inner Dosimeter, 3rd Low Level
AEA09-FF-07-ID-H1	Fortification Sample, ME 07, Inner Dosimeter, 1st High Level
AEA09-FF-07-ID-H2	Fortification Sample, ME 07, Inner Dosimeter, 2nd High Level
AEA09-FF-07-ID-H3	Fortification Sample, ME 07, Inner Dosimeter, 3rd High Level
AEA09-FF-07-OD-C1	Fortification Sample, ME 07, Outer Dosimeter, 1st Control
AEA09-FF-07-OD-C2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Control
AEA09-FF-07-OD-L1	Fortification Sample, ME 07, Outer Dosimeter, 1st Low Level
AEA09-FF-07-OD-L2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Low Level
AEA09-FF-07-OD-L3	Fortification Sample, ME 07, Outer Dosimeter, 3rd Low Level
AEA09-FF-07-OD-H1	Fortification Sample, ME 07, Outer Dosimeter, 1st High Level
AEA09-FF-07-OD-H2	Fortification Sample, ME 07, Outer Dosimeter, 2nd High Level
AEA09-FF-07-OD-H3	Fortification Sample, ME 07, Outer Dosimeter, 3rd High Level
AEA09-FF-08-PH-C1	Fortification Sample, ME 08, Painter's Hat, 1st Control
AEA09-FF-08-PH-C2	Fortification Sample, ME 08, Painter's Hat, 2nd Control
AEA09-FF-08-PH-L1	Fortification Sample, ME 08, Painter's Hat, 1st Low Level
AEA09-FF-08-PH-L2	Fortification Sample, ME 08, Painter's Hat, 2nd Low Level
AEA09-FF-08-PH-L3	Fortification Sample, ME 08, Painter's Hat, 3rd Low Level
AEA09-FF-08-PH-H1	Fortification Sample, ME 08, Painter's Hat, 1st High Level
AEA09-FF-08-PH-H2	Fortification Sample, ME 08, Painter's Hat, 2nd High Level
AEA09-FF-08-PH-H3	Fortification Sample, ME 08, Painter's Hat, 3rd High Level
AEA09-FF-08-AR-C1	Fortification Sample, ME 08, Air Sampling Tube, 1st Control
AEA09-FF-08-AR-C2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Control
AEA09-FF-08-AR-L1	Fortification Sample, ME 08, Air Sampling Tube, 1st Low Level
AEA09-FF-08-AR-L2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Low Level
AEA09-FF-08-AR-L3	Fortification Sample, ME 08, Air Sampling Tube, 3rd Low Level
AEA09-FF-08-AR-H1	Fortification Sample, ME 08, Air Sampling Tube, 1st High Level
AEA09-FF-08-AR-H2	Fortification Sample, ME 08, Air Sampling Tube, 2nd High Level
AEA09-FF-08-AR-H3	Fortification Sample, ME 08, Air Sampling Tube, 3rd High Level
AEA09-FF-08-RES-C1	Fortification Sample, ME 08, RespiCon, 1st Control
AEA09-FF-08-RES-C2	Fortification Sample, ME 08, RespiCon, 2nd Control
AEA09-FF-08-RES-L1	Fortification Sample, ME 08, RespiCon, 1st Low Level
AEA09-FF-08-RES-L2	Fortification Sample, ME 08, RespiCon, 2nd Low Level
AEA09-FF-08-RES-L3	Fortification Sample, ME 08, RespiCon, 3rd Low Level
AEA09-FF-08-RES-H1	Fortification Sample, ME 08, RespiCon, 1st High Level
AEA09-FF-08-RES-H2	Fortification Sample, ME 08, RespiCon, 2nd High Level
AEA09-FF-08-RES-H3	Fortification Sample, ME 08, RespiCon, 3rd High Level
AEA09-FF-08-HW-C1	Fortification Sample, ME 08, Hand Wash, 1st Control
AEA09-FF-08-HW-C2	Fortification Sample, ME 08, Hand Wash, 2nd Control

Sample ID Number	Description
AEA09-FF-08-HW-L1	Fortification Sample, ME 08, Hand Wash, 1st Low Level
AEA09-FF-08-HW-L2	Fortification Sample, ME 08, Hand Wash, 2nd Low Level
AEA09-FF-08-HW-L3	Fortification Sample, ME 08, Hand Wash, 3rd Low Level
AEA09-FF-08-HW-H1	Fortification Sample, ME 08, Hand Wash, 1st High Level
AEA09-FF-08-HW-H2	Fortification Sample, ME 08, Hand Wash, 2nd High Level
AEA09-FF-08-HW-H3	Fortification Sample, ME 08, Hand Wash, 3rd High Level
AEA09-FF-08-FW-C1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Control
AEA09-FF-08-FW-C2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Control
AEA09-FF-08-FW-L1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Low Level
AEA09-FF-08-FW-L2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Low Level
AEA09-FF-08-FW-L3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd Low Level
AEA09-FF-08-FW-H1	Fortification Sample, ME 08, Face and Neck Wipe, 1st High Level
AEA09-FF-08-FW-H2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd High Level
AEA09-FF-08-FW-H3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd High Level
AEA09-FF-08-ID-C1	Fortification Sample, ME 08, Inner Dosimeter, 1st Control
AEA09-FF-08-ID-C2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Control
AEA09-FF-08-ID-L1	Fortification Sample, ME 08, Inner Dosimeter, 1st Low Level
AEA09-FF-08-ID-L2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Low Level
AEA09-FF-08-ID-L3	Fortification Sample, ME 08, Inner Dosimeter, 3rd Low Level
AEA09-FF-08-ID-H1	Fortification Sample, ME 08, Inner Dosimeter, 1st High Level
AEA09-FF-08-ID-H2	Fortification Sample, ME 08, Inner Dosimeter, 2nd High Level
AEA09-FF-08-ID-H3	Fortification Sample, ME 08, Inner Dosimeter, 3rd High Level
AEA09-FF-08-OD-C1	Fortification Sample, ME 08, Outer Dosimeter, 1st Control
AEA09-FF-08-OD-C2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Control
AEA09-FF-08-OD-L1	Fortification Sample, ME 08, Outer Dosimeter, 1st Low Level
AEA09-FF-08-OD-L2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Low Level
AEA09-FF-08-OD-L3	Fortification Sample, ME 08, Outer Dosimeter, 3rd Low Level
AEA09-FF-08-OD-H1	Fortification Sample, ME 08, Outer Dosimeter, 1st High Level
AEA09-FF-08-OD-H2	Fortification Sample, ME 08, Outer Dosimeter, 2nd High Level
AEA09-FF-08-OD-H3	Fortification Sample, ME 08, Outer Dosimeter, 3rd High Level
AEA09-FF-09-PH-C1	Fortification Sample, ME 09, Painter's Hat, 1st Control
AEA09-FF-09-PH-C2	Fortification Sample, ME 09, Painter's Hat, 2nd Control
AEA09-FF-09-PH-L1	Fortification Sample, ME 09, Painter's Hat, 1st Low Level
AEA09-FF-09-PH-L2	Fortification Sample, ME 09, Painter's Hat, 2nd Low Level
AEA09-FF-09-PH-L3	Fortification Sample, ME 09, Painter's Hat, 3rd Low Level
AEA09-FF-09-PH-H1	Fortification Sample, ME 09, Painter's Hat, 1st High Level
AEA09-FF-09-PH-H2	Fortification Sample, ME 09, Painter's Hat, 2nd High Level
AEA09-FF-09-PH-H3	Fortification Sample, ME 09, Painter's Hat, 3rd High Level
AEA09-FF-09-AR-C1	Fortification Sample, ME 09, Air Sampling Tube, 1st Control
AEA09-FF-09-AR-C2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Control

Sample ID Number	Description
AEA09-FF-09-AR-L1	Fortification Sample, ME 09, Air Sampling Tube, 1st Low Level
AEA09-FF-09-AR-L2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Low Level
AEA09-FF-09-AR-L3	Fortification Sample, ME 09, Air Sampling Tube, 3rd Low Level
AEA09-FF-09-AR-H1	Fortification Sample, ME 09, Air Sampling Tube, 1st High Level
AEA09-FF-09-AR-H2	Fortification Sample, ME 09, Air Sampling Tube, 2nd High Level
AEA09-FF-09-AR-H3	Fortification Sample, ME 09, Air Sampling Tube, 3rd High Level
AEA09-FF-09-RES-C1	Fortification Sample, ME 09, RespiCon, 1st Control
AEA09-FF-09-RES-C2	Fortification Sample, ME 09, RespiCon, 2nd Control
AEA09-FF-09-RES-L1	Fortification Sample, ME 09, RespiCon, 1st Low Level
AEA09-FF-09-RES-L2	Fortification Sample, ME 09, RespiCon, 2nd Low Level
AEA09-FF-09-RES-L3	Fortification Sample, ME 09, RespiCon, 3rd Low Level
AEA09-FF-09-RES-H1	Fortification Sample, ME 09, RespiCon, 1st High Level
AEA09-FF-09-RES-H2	Fortification Sample, ME 09, RespiCon, 2nd High Level
AEA09-FF-09-RES-H3	Fortification Sample, ME 09, RespiCon, 3rd High Level
AEA09-FF-09-HW-C1	Fortification Sample, ME 09, Hand Wash, 1st Control
AEA09-FF-09-HW-C2	Fortification Sample, ME 09, Hand Wash, 2nd Control
AEA09-FF-09-HW-L1	Fortification Sample, ME 09, Hand Wash, 1st Low Level
AEA09-FF-09-HW-L2	Fortification Sample, ME 09, Hand Wash, 2nd Low Level
AEA09-FF-09-HW-L3	Fortification Sample, ME 09, Hand Wash, 3rd Low Level
AEA09-FF-09-HW-H1	Fortification Sample, ME 09, Hand Wash, 1st High Level
AEA09-FF-09-HW-H2	Fortification Sample, ME 09, Hand Wash, 2nd High Level
AEA09-FF-09-HW-H3	Fortification Sample, ME 09, Hand Wash, 3rd High Level
AEA09-FF-09-FW-C1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Control
AEA09-FF-09-FW-C2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Control
AEA09-FF-09-FW-L1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Low Level
AEA09-FF-09-FW-L2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Low Level
AEA09-FF-09-FW-L3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd Low Level
AEA09-FF-09-FW-H1	Fortification Sample, ME 09, Face and Neck Wipe, 1st High Level
AEA09-FF-09-FW-H2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd High Level
AEA09-FF-09-FW-H3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd High Level
AEA09-FF-09-ID-C1	Fortification Sample, ME 09, Inner Dosimeter, 1st Control
AEA09-FF-09-ID-C2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Control
AEA09-FF-09-ID-L1	Fortification Sample, ME 09, Inner Dosimeter, 1st Low Level
AEA09-FF-09-ID-L2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Low Level
AEA09-FF-09-ID-L3	Fortification Sample, ME 09, Inner Dosimeter, 3rd Low Level
AEA09-FF-09-ID-H1	Fortification Sample, ME 09, Inner Dosimeter, 1st High Level
AEA09-FF-09-ID-H2	Fortification Sample, ME 09, Inner Dosimeter, 2nd High Level
AEA09-FF-09-ID-H3	Fortification Sample, ME 09, Inner Dosimeter, 3rd High Level
AEA09-FF-09-OD-C1	Fortification Sample, ME 09, Outer Dosimeter, 1st Control
AEA09-FF-09-OD-C2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Control

Sample ID Number	Description
AEA09-FF-09-OD-L1	Fortification Sample, ME 09, Outer Dosimeter, 1st Low Level
AEA09-FF-09-OD-L2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Low Level
AEA09-FF-09-OD-L3	Fortification Sample, ME 09, Outer Dosimeter, 3rd Low Level
AEA09-FF-09-OD-H1	Fortification Sample, ME 09, Outer Dosimeter, 1st High Level
AEA09-FF-09-OD-H2	Fortification Sample, ME 09, Outer Dosimeter, 2nd High Level
AEA09-FF-09-OD-H3	Fortification Sample, ME 09, Outer Dosimeter, 3rd High Level
AEA09-FF-10-PH-C1	Fortification Sample, ME 10, Painter's Hat, 1st Control
AEA09-FF-10-PH-C2	Fortification Sample, ME 10, Painter's Hat, 2nd Control
AEA09-FF-10-PH-L1	Fortification Sample, ME 10, Painter's Hat, 1st Low Level
AEA09-FF-10-PH-L2	Fortification Sample, ME 10, Painter's Hat, 2nd Low Level
AEA09-FF-10-PH-L3	Fortification Sample, ME 10, Painter's Hat, 3rd Low Level
AEA09-FF-10-PH-H1	Fortification Sample, ME 10, Painter's Hat, 1st High Level
AEA09-FF-10-PH-H2	Fortification Sample, ME 10, Painter's Hat, 2nd High Level
AEA09-FF-10-PH-H3	Fortification Sample, ME 10, Painter's Hat, 3rd High Level
AEA09-FF-10-AR-C1	Fortification Sample, ME 10, Air Sampling Tube, 1st Control
AEA09-FF-10-AR-C2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Control
AEA09-FF-10-AR-L1	Fortification Sample, ME 10, Air Sampling Tube, 1st Low Level
AEA09-FF-10-AR-L2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Low Level
AEA09-FF-10-AR-L3	Fortification Sample, ME 10, Air Sampling Tube, 3rd Low Level
AEA09-FF-10-AR-H1	Fortification Sample, ME 10, Air Sampling Tube, 1st High Level
AEA09-FF-10-AR-H2	Fortification Sample, ME 10, Air Sampling Tube, 2nd High Level
AEA09-FF-10-AR-H3	Fortification Sample, ME 10, Air Sampling Tube, 3rd High Level
AEA09-FF-10-RES-C1	Fortification Sample, ME 10, RespiCon, 1st Control
AEA09-FF-10-RES-C2	Fortification Sample, ME 10, RespiCon, 2nd Control
AEA09-FF-10-RES-L1	Fortification Sample, ME 10, RespiCon, 1st Low Level
AEA09-FF-10-RES-L2	Fortification Sample, ME 10, RespiCon, 2nd Low Level
AEA09-FF-10-RES-L3	Fortification Sample, ME 10, RespiCon, 3rd Low Level
AEA09-FF-10-RES-H1	Fortification Sample, ME 10, RespiCon, 1st High Level
AEA09-FF-10-RES-H2	Fortification Sample, ME 10, RespiCon, 2nd High Level
AEA09-FF-10-RES-H3	Fortification Sample, ME 10, RespiCon, 3rd High Level
AEA09-FF-10-HW-C1	Fortification Sample, ME 10, Hand Wash, 1st Control
AEA09-FF-10-HW-C2	Fortification Sample, ME 10, Hand Wash, 2nd Control
AEA09-FF-10-HW-L1	Fortification Sample, ME 10, Hand Wash, 1st Low Level
AEA09-FF-10-HW-L2	Fortification Sample, ME 10, Hand Wash, 2nd Low Level
AEA09-FF-10-HW-L3	Fortification Sample, ME 10, Hand Wash, 3rd Low Level
AEA09-FF-10-HW-H1	Fortification Sample, ME 10, Hand Wash, 1st High Level
AEA09-FF-10-HW-H2	Fortification Sample, ME 10, Hand Wash, 2nd High Level
AEA09-FF-10-HW-H3	Fortification Sample, ME 10, Hand Wash, 3rd High Level
AEA09-FF-10-FW-C1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Control
AEA09-FF-10-FW-C2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Control
AEA09-FF-10-FW-L1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Low Level
AEA09-FF-10-FW-L2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Low Level
AEA09-FF-10-FW-L3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-10-FW-H1	Fortification Sample, ME 10, Face and Neck Wipe, 1st High Level
AEA09-FF-10-FW-H2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd High Level
AEA09-FF-10-FW-H3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd High Level
AEA09-FF-10-ID-C1	Fortification Sample, ME 10, Inner Dosimeter, 1st Control
AEA09-FF-10-ID-C2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Control
AEA09-FF-10-ID-L1	Fortification Sample, ME 10, Inner Dosimeter, 1st Low Level
AEA09-FF-10-ID-L2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Low Level
AEA09-FF-10-ID-L3	Fortification Sample, ME 10, Inner Dosimeter, 3rd Low Level
AEA09-FF-10-ID-H1	Fortification Sample, ME 10, Inner Dosimeter, 1st High Level
AEA09-FF-10-ID-H2	Fortification Sample, ME 10, Inner Dosimeter, 2nd High Level
AEA09-FF-10-ID-H3	Fortification Sample, ME 10, Inner Dosimeter, 3rd High Level
AEA09-FF-10-OD-C1	Fortification Sample, ME 10, Outer Dosimeter, 1st Control
AEA09-FF-10-OD-C2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Control
AEA09-FF-10-OD-L1	Fortification Sample, ME 10, Outer Dosimeter, 1st Low Level
AEA09-FF-10-OD-L2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Low Level
AEA09-FF-10-OD-L3	Fortification Sample, ME 10, Outer Dosimeter, 3rd Low Level
AEA09-FF-10-OD-H1	Fortification Sample, ME 10, Outer Dosimeter, 1st High Level
AEA09-FF-10-OD-H2	Fortification Sample, ME 10, Outer Dosimeter, 2nd High Level
AEA09-FF-10-OD-H3	Fortification Sample, ME 10, Outer Dosimeter, 3rd High Level
AEA09-FF-11-PH-C1	Fortification Sample, ME 11, Painter's Hat, 1st Control
AEA09-FF-11-PH-C2	Fortification Sample, ME 11, Painter's Hat, 2nd Control
AEA09-FF-11-PH-L1	Fortification Sample, ME 11, Painter's Hat, 1st Low Level
AEA09-FF-11-PH-L2	Fortification Sample, ME 11, Painter's Hat, 2nd Low Level
AEA09-FF-11-PH-L3	Fortification Sample, ME 11, Painter's Hat, 3rd Low Level
AEA09-FF-11-PH-H1	Fortification Sample, ME 11, Painter's Hat, 1st High Level
AEA09-FF-11-PH-H2	Fortification Sample, ME 11, Painter's Hat, 2nd High Level
AEA09-FF-11-PH-H3	Fortification Sample, ME 11, Painter's Hat, 3rd High Level
AEA09-FF-11-AR-C1	Fortification Sample, ME 11, Air Sampling Tube, 1st Control
AEA09-FF-11-AR-C2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Control
AEA09-FF-11-AR-L1	Fortification Sample, ME 11, Air Sampling Tube, 1st Low Level
AEA09-FF-11-AR-L2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Low Level
AEA09-FF-11-AR-L3	Fortification Sample, ME 11, Air Sampling Tube, 3rd Low Level
AEA09-FF-11-AR-H1	Fortification Sample, ME 11, Air Sampling Tube, 1st High Level
AEA09-FF-11-AR-H2	Fortification Sample, ME 11, Air Sampling Tube, 2nd High Level
AEA09-FF-11-AR-H3	Fortification Sample, ME 11, Air Sampling Tube, 3rd High Level
AEA09-FF-11-RES-C1	Fortification Sample, ME 11, RespiCon, 1st Control
AEA09-FF-11-RES-C2	Fortification Sample, ME 11, RespiCon, 2nd Control
AEA09-FF-11-RES-L1	Fortification Sample, ME 11, RespiCon, 1st Low Level
AEA09-FF-11-RES-L2	Fortification Sample, ME 11, RespiCon, 2nd Low Level
AEA09-FF-11-RES-L3	Fortification Sample, ME 11, RespiCon, 3rd Low Level
AEA09-FF-11-RES-H1	Fortification Sample, ME 11, RespiCon, 1st High Level
AEA09-FF-11-RES-H2	Fortification Sample, ME 11, RespiCon, 2nd High Level
AEA09-FF-11-RES-H3	Fortification Sample, ME 11, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-11-HW-C1	Fortification Sample, ME 11, Hand Wash, 1st Control
AEA09-FF-11-HW-C2	Fortification Sample, ME 11, Hand Wash, 2nd Control
AEA09-FF-11-HW-L1	Fortification Sample, ME 11, Hand Wash, 1st Low Level
AEA09-FF-11-HW-L2	Fortification Sample, ME 11, Hand Wash, 2nd Low Level
AEA09-FF-11-HW-L3	Fortification Sample, ME 11, Hand Wash, 3rd Low Level
AEA09-FF-11-HW-H1	Fortification Sample, ME 11, Hand Wash, 1st High Level
AEA09-FF-11-HW-H2	Fortification Sample, ME 11, Hand Wash, 2nd High Level
AEA09-FF-11-HW-H3	Fortification Sample, ME 11, Hand Wash, 3rd High Level
AEA09-FF-11-FW-C1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Control
AEA09-FF-11-FW-C2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Control
AEA09-FF-11-FW-L1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Low Level
AEA09-FF-11-FW-L2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Low Level
AEA09-FF-11-FW-L3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd Low Level
AEA09-FF-11-FW-H1	Fortification Sample, ME 11, Face and Neck Wipe, 1st High Level
AEA09-FF-11-FW-H2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd High Level
AEA09-FF-11-FW-H3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd High Level
AEA09-FF-11-ID-C1	Fortification Sample, ME 11, Inner Dosimeter, 1st Control
AEA09-FF-11-ID-C2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Control
AEA09-FF-11-ID-L1	Fortification Sample, ME 11, Inner Dosimeter, 1st Low Level
AEA09-FF-11-ID-L2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Low Level
AEA09-FF-11-ID-L3	Fortification Sample, ME 11, Inner Dosimeter, 3rd Low Level
AEA09-FF-11-ID-H1	Fortification Sample, ME 11, Inner Dosimeter, 1st High Level
AEA09-FF-11-ID-H2	Fortification Sample, ME 11, Inner Dosimeter, 2nd High Level
AEA09-FF-11-ID-H3	Fortification Sample, ME 11, Inner Dosimeter, 3rd High Level
AEA09-FF-11-OD-C1	Fortification Sample, ME 11, Outer Dosimeter, 1st Control
AEA09-FF-11-OD-C2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Control
AEA09-FF-11-OD-L1	Fortification Sample, ME 11, Outer Dosimeter, 1st Low Level
AEA09-FF-11-OD-L2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Low Level
AEA09-FF-11-OD-L3	Fortification Sample, ME 11, Outer Dosimeter, 3rd Low Level
AEA09-FF-11-OD-H1	Fortification Sample, ME 11, Outer Dosimeter, 1st High Level
AEA09-FF-11-OD-H2	Fortification Sample, ME 11, Outer Dosimeter, 2nd High Level
AEA09-FF-11-OD-H3	Fortification Sample, ME 11, Outer Dosimeter, 3rd High Level
AEA09-FF-12-PH-C1	Fortification Sample, ME 12, Painter's Hat, 1st Control
AEA09-FF-12-PH-C2	Fortification Sample, ME 12, Painter's Hat, 2nd Control
AEA09-FF-12-PH-L1	Fortification Sample, ME 12, Painter's Hat, 1st Low Level
AEA09-FF-12-PH-L2	Fortification Sample, ME 12, Painter's Hat, 2nd Low Level
AEA09-FF-12-PH-L3	Fortification Sample, ME 12, Painter's Hat, 3rd Low Level
AEA09-FF-12-PH-H1	Fortification Sample, ME 12, Painter's Hat, 1st High Level
AEA09-FF-12-PH-H2	Fortification Sample, ME 12, Painter's Hat, 2nd High Level
AEA09-FF-12-PH-H3	Fortification Sample, ME 12, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-AR-C1	Fortification Sample, ME 12, Air Sampling Tube, 1st Control
AEA09-FF-12-AR-C2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Control
AEA09-FF-12-AR-L1	Fortification Sample, ME 12, Air Sampling Tube, 1st Low Level
AEA09-FF-12-AR-L2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Low Level
AEA09-FF-12-AR-L3	Fortification Sample, ME 12, Air Sampling Tube, 3rd Low Level
AEA09-FF-12-AR-H1	Fortification Sample, ME 12, Air Sampling Tube, 1st High Level
AEA09-FF-12-AR-H2	Fortification Sample, ME 12, Air Sampling Tube, 2nd High Level
AEA09-FF-12-AR-H3	Fortification Sample, ME 12, Air Sampling Tube, 3rd High Level
AEA09-FF-12-RES-C1	Fortification Sample, ME 12, RespiCon, 1st Control
AEA09-FF-12-RES-C2	Fortification Sample, ME 12, RespiCon, 2nd Control
AEA09-FF-12-RES-L1	Fortification Sample, ME 12, RespiCon, 1st Low Level
AEA09-FF-12-RES-L2	Fortification Sample, ME 12, RespiCon, 2nd Low Level
AEA09-FF-12-RES-L3	Fortification Sample, ME 12, RespiCon, 3rd Low Level
AEA09-FF-12-RES-H1	Fortification Sample, ME 12, RespiCon, 1st High Level
AEA09-FF-12-RES-H2	Fortification Sample, ME 12, RespiCon, 2nd High Level
AEA09-FF-12-RES-H3	Fortification Sample, ME 12, RespiCon, 3rd High Level
AEA09-FF-12-HW-C1	Fortification Sample, ME 12, Hand Wash, 1st Control
AEA09-FF-12-HW-C2	Fortification Sample, ME 12, Hand Wash, 2nd Control
AEA09-FF-12-HW-L1	Fortification Sample, ME 12, Hand Wash, 1st Low Level
AEA09-FF-12-HW-L2	Fortification Sample, ME 12, Hand Wash, 2nd Low Level
AEA09-FF-12-HW-L3	Fortification Sample, ME 12, Hand Wash, 3rd Low Level
AEA09-FF-12-HW-H1	Fortification Sample, ME 12, Hand Wash, 1st High Level
AEA09-FF-12-HW-H2	Fortification Sample, ME 12, Hand Wash, 2nd High Level
AEA09-FF-12-HW-H3	Fortification Sample, ME 12, Hand Wash, 3rd High Level
AEA09-FF-12-FW-C1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Control
AEA09-FF-12-FW-C2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Control
AEA09-FF-12-FW-L1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Low Level
AEA09-FF-12-FW-L2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Low Level
AEA09-FF-12-FW-L3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd Low Level
AEA09-FF-12-FW-H1	Fortification Sample, ME 12, Face and Neck Wipe, 1st High Level
AEA09-FF-12-FW-H2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd High Level
AEA09-FF-12-FW-H3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd High Level
AEA09-FF-12-ID-C1	Fortification Sample, ME 12, Inner Dosimeter, 1st Control
AEA09-FF-12-ID-C2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Control
AEA09-FF-12-ID-L1	Fortification Sample, ME 12, Inner Dosimeter, 1st Low Level
AEA09-FF-12-ID-L2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Low Level
AEA09-FF-12-ID-L3	Fortification Sample, ME 12, Inner Dosimeter, 3rd Low Level
AEA09-FF-12-ID-H1	Fortification Sample, ME 12, Inner Dosimeter, 1st High Level
AEA09-FF-12-ID-H2	Fortification Sample, ME 12, Inner Dosimeter, 2nd High Level
AEA09-FF-12-ID-H3	Fortification Sample, ME 12, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-OD-C1	Fortification Sample, ME 12, Outer Dosimeter, 1st Control
AEA09-FF-12-OD-C2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Control
AEA09-FF-12-OD-L1	Fortification Sample, ME 12, Outer Dosimeter, 1st Low Level
AEA09-FF-12-OD-L2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Low Level
AEA09-FF-12-OD-L3	Fortification Sample, ME 12, Outer Dosimeter, 3rd Low Level
AEA09-FF-12-OD-H1	Fortification Sample, ME 12, Outer Dosimeter, 1st High Level
AEA09-FF-12-OD-H2	Fortification Sample, ME 12, Outer Dosimeter, 2nd High Level
AEA09-FF-12-OD-H3	Fortification Sample, ME 12, Outer Dosimeter, 3rd High Level
AEA09-FF-13-PH-C1	Fortification Sample, ME 13, Painter's Hat, 1st Control
AEA09-FF-13-PH-C2	Fortification Sample, ME 13, Painter's Hat, 2nd Control
AEA09-FF-13-PH-L1	Fortification Sample, ME 13, Painter's Hat, 1st Low Level
AEA09-FF-13-PH-L2	Fortification Sample, ME 13, Painter's Hat, 2nd Low Level
AEA09-FF-13-PH-L3	Fortification Sample, ME 13, Painter's Hat, 3rd Low Level
AEA09-FF-13-PH-H1	Fortification Sample, ME 13, Painter's Hat, 1st High Level
AEA09-FF-13-PH-H2	Fortification Sample, ME 13, Painter's Hat, 2nd High Level
AEA09-FF-13-PH-H3	Fortification Sample, ME 13, Painter's Hat, 3rd High Level
AEA09-FF-13-AR-C1	Fortification Sample, ME 13, Air Sampling Tube, 1st Control
AEA09-FF-13-AR-C2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Control
AEA09-FF-13-AR-L1	Fortification Sample, ME 13, Air Sampling Tube, 1st Low Level
AEA09-FF-13-AR-L2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Low Level
AEA09-FF-13-AR-L3	Fortification Sample, ME 13, Air Sampling Tube, 3rd Low Level
AEA09-FF-13-AR-H1	Fortification Sample, ME 13, Air Sampling Tube, 1st High Level
AEA09-FF-13-AR-H2	Fortification Sample, ME 13, Air Sampling Tube, 2nd High Level
AEA09-FF-13-AR-H3	Fortification Sample, ME 13, Air Sampling Tube, 3rd High Level
AEA09-FF-13-RES-C1	Fortification Sample, ME 13, RespiCon, 1st Control
AEA09-FF-13-RES-C2	Fortification Sample, ME 13, RespiCon, 2nd Control
AEA09-FF-13-RES-L1	Fortification Sample, ME 13, RespiCon, 1st Low Level
AEA09-FF-13-RES-L2	Fortification Sample, ME 13, RespiCon, 2nd Low Level
AEA09-FF-13-RES-L3	Fortification Sample, ME 13, RespiCon, 3rd Low Level
AEA09-FF-13-RES-H1	Fortification Sample, ME 13, RespiCon, 1st High Level
AEA09-FF-13-RES-H2	Fortification Sample, ME 13, RespiCon, 2nd High Level
AEA09-FF-13-RES-H3	Fortification Sample, ME 13, RespiCon, 3rd High Level
AEA09-FF-13-HW-C1	Fortification Sample, ME 13, Hand Wash, 1st Control
AEA09-FF-13-HW-C2	Fortification Sample, ME 13, Hand Wash, 2nd Control
AEA09-FF-13-HW-L1	Fortification Sample, ME 13, Hand Wash, 1st Low Level
AEA09-FF-13-HW-L2	Fortification Sample, ME 13, Hand Wash, 2nd Low Level
AEA09-FF-13-HW-L3	Fortification Sample, ME 13, Hand Wash, 3rd Low Level
AEA09-FF-13-HW-H1	Fortification Sample, ME 13, Hand Wash, 1st High Level
AEA09-FF-13-HW-H2	Fortification Sample, ME 13, Hand Wash, 2nd High Level
AEA09-FF-13-HW-H3	Fortification Sample, ME 13, Hand Wash, 3rd High Level
AEA09-FF-13-FW-C1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Control
AEA09-FF-13-FW-C2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Control
AEA09-FF-13-FW-L1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Low Level
AEA09-FF-13-FW-L2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Low Level
AEA09-FF-13-FW-L3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-13-FW-H1	Fortification Sample, ME 13, Face and Neck Wipe, 1st High Level
AEA09-FF-13-FW-H2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd High Level
AEA09-FF-13-FW-H3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd High Level
AEA09-FF-13-ID-C1	Fortification Sample, ME 13, Inner Dosimeter, 1st Control
AEA09-FF-13-ID-C2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Control
AEA09-FF-13-ID-L1	Fortification Sample, ME 13, Inner Dosimeter, 1st Low Level
AEA09-FF-13-ID-L2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Low Level
AEA09-FF-13-ID-L3	Fortification Sample, ME 13, Inner Dosimeter, 3rd Low Level
AEA09-FF-13-ID-H1	Fortification Sample, ME 13, Inner Dosimeter, 1st High Level
AEA09-FF-13-ID-H2	Fortification Sample, ME 13, Inner Dosimeter, 2nd High Level
AEA09-FF-13-ID-H3	Fortification Sample, ME 13, Inner Dosimeter, 3rd High Level
AEA09-FF-13-OD-C1	Fortification Sample, ME 13, Outer Dosimeter, 1st Control
AEA09-FF-13-OD-C2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Control
AEA09-FF-13-OD-L1	Fortification Sample, ME 13, Outer Dosimeter, 1st Low Level
AEA09-FF-13-OD-L2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Low Level
AEA09-FF-13-OD-L3	Fortification Sample, ME 13, Outer Dosimeter, 3rd Low Level
AEA09-FF-13-OD-H1	Fortification Sample, ME 13, Outer Dosimeter, 1st High Level
AEA09-FF-13-OD-H2	Fortification Sample, ME 13, Outer Dosimeter, 2nd High Level
AEA09-FF-13-OD-H3	Fortification Sample, ME 13, Outer Dosimeter, 3rd High Level
AEA09-FF-14-PH-C1	Fortification Sample, ME 14, Painter's Hat, 1st Control
AEA09-FF-14-PH-C2	Fortification Sample, ME 14, Painter's Hat, 2nd Control
AEA09-FF-14-PH-L1	Fortification Sample, ME 14, Painter's Hat, 1st Low Level
AEA09-FF-14-PH-L2	Fortification Sample, ME 14, Painter's Hat, 2nd Low Level
AEA09-FF-14-PH-L3	Fortification Sample, ME 14, Painter's Hat, 3rd Low Level
AEA09-FF-14-PH-H1	Fortification Sample, ME 14, Painter's Hat, 1st High Level
AEA09-FF-14-PH-H2	Fortification Sample, ME 14, Painter's Hat, 2nd High Level
AEA09-FF-14-PH-H3	Fortification Sample, ME 14, Painter's Hat, 3rd High Level
AEA09-FF-14-AR-C1	Fortification Sample, ME 14, Air Sampling Tube, 1st Control
AEA09-FF-14-AR-C2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Control
AEA09-FF-14-AR-L1	Fortification Sample, ME 14, Air Sampling Tube, 1st Low Level
AEA09-FF-14-AR-L2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Low Level
AEA09-FF-14-AR-L3	Fortification Sample, ME 14, Air Sampling Tube, 3rd Low Level
AEA09-FF-14-AR-H1	Fortification Sample, ME 14, Air Sampling Tube, 1st High Level
AEA09-FF-14-AR-H2	Fortification Sample, ME 14, Air Sampling Tube, 2nd High Level
AEA09-FF-14-AR-H3	Fortification Sample, ME 14, Air Sampling Tube, 3rd High Level
AEA09-FF-14-RES-C1	Fortification Sample, ME 14, RespiCon, 1st Control
AEA09-FF-14-RES-C2	Fortification Sample, ME 14, RespiCon, 2nd Control
AEA09-FF-14-RES-L1	Fortification Sample, ME 14, RespiCon, 1st Low Level
AEA09-FF-14-RES-L2	Fortification Sample, ME 14, RespiCon, 2nd Low Level
AEA09-FF-14-RES-L3	Fortification Sample, ME 14, RespiCon, 3rd Low Level
AEA09-FF-14-RES-H1	Fortification Sample, ME 14, RespiCon, 1st High Level
AEA09-FF-14-RES-H2	Fortification Sample, ME 14, RespiCon, 2nd High Level
AEA09-FF-14-RES-H3	Fortification Sample, ME 14, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-14-HW-C1	Fortification Sample, ME 14, Hand Wash, 1st Control
AEA09-FF-14-HW-C2	Fortification Sample, ME 14, Hand Wash, 2nd Control
AEA09-FF-14-HW-L1	Fortification Sample, ME 14, Hand Wash, 1st Low Level
AEA09-FF-14-HW-L2	Fortification Sample, ME 14, Hand Wash, 2nd Low Level
AEA09-FF-14-HW-L3	Fortification Sample, ME 14, Hand Wash, 3rd Low Level
AEA09-FF-14-HW-H1	Fortification Sample, ME 14, Hand Wash, 1st High Level
AEA09-FF-14-HW-H2	Fortification Sample, ME 14, Hand Wash, 2nd High Level
AEA09-FF-14-HW-H3	Fortification Sample, ME 14, Hand Wash, 3rd High Level
AEA09-FF-14-FW-C1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Control
AEA09-FF-14-FW-C2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Control
AEA09-FF-14-FW-L1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Low Level
AEA09-FF-14-FW-L2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Low Level
AEA09-FF-14-FW-L3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd Low Level
AEA09-FF-14-FW-H1	Fortification Sample, ME 14, Face and Neck Wipe, 1st High Level
AEA09-FF-14-FW-H2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd High Level
AEA09-FF-14-FW-H3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd High Level
AEA09-FF-14-ID-C1	Fortification Sample, ME 14, Inner Dosimeter, 1st Control
AEA09-FF-14-ID-C2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Control
AEA09-FF-14-ID-L1	Fortification Sample, ME 14, Inner Dosimeter, 1st Low Level
AEA09-FF-14-ID-L2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Low Level
AEA09-FF-14-ID-L3	Fortification Sample, ME 14, Inner Dosimeter, 3rd Low Level
AEA09-FF-14-ID-H1	Fortification Sample, ME 14, Inner Dosimeter, 1st High Level
AEA09-FF-14-ID-H2	Fortification Sample, ME 14, Inner Dosimeter, 2nd High Level
AEA09-FF-14-ID-H3	Fortification Sample, ME 14, Inner Dosimeter, 3rd High Level
AEA09-FF-14-OD-C1	Fortification Sample, ME 14, Outer Dosimeter, 1st Control
AEA09-FF-14-OD-C2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Control
AEA09-FF-14-OD-L1	Fortification Sample, ME 14, Outer Dosimeter, 1st Low Level
AEA09-FF-14-OD-L2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Low Level
AEA09-FF-14-OD-L3	Fortification Sample, ME 14, Outer Dosimeter, 3rd Low Level
AEA09-FF-14-OD-H1	Fortification Sample, ME 14, Outer Dosimeter, 1st High Level
AEA09-FF-14-OD-H2	Fortification Sample, ME 14, Outer Dosimeter, 2nd High Level
AEA09-FF-14-OD-H3	Fortification Sample, ME 14, Outer Dosimeter, 3rd High Level
AEA09-FF-15-PH-C1	Fortification Sample, ME 15, Painter's Hat, 1st Control
AEA09-FF-15-PH-C2	Fortification Sample, ME 15, Painter's Hat, 2nd Control
AEA09-FF-15-PH-L1	Fortification Sample, ME 15, Painter's Hat, 1st Low Level
AEA09-FF-15-PH-L2	Fortification Sample, ME 15, Painter's Hat, 2nd Low Level
AEA09-FF-15-PH-L3	Fortification Sample, ME 15, Painter's Hat, 3rd Low Level
AEA09-FF-15-PH-H1	Fortification Sample, ME 15, Painter's Hat, 1st High Level
AEA09-FF-15-PH-H2	Fortification Sample, ME 15, Painter's Hat, 2nd High Level
AEA09-FF-15-PH-H3	Fortification Sample, ME 15, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-AR-C1	Fortification Sample, ME 15, Air Sampling Tube, 1st Control
AEA09-FF-15-AR-C2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Control
AEA09-FF-15-AR-L1	Fortification Sample, ME 15, Air Sampling Tube, 1st Low Level
AEA09-FF-15-AR-L2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Low Level
AEA09-FF-15-AR-L3	Fortification Sample, ME 15, Air Sampling Tube, 3rd Low Level
AEA09-FF-15-AR-H1	Fortification Sample, ME 15, Air Sampling Tube, 1st High Level
AEA09-FF-15-AR-H2	Fortification Sample, ME 15, Air Sampling Tube, 2nd High Level
AEA09-FF-15-AR-H3	Fortification Sample, ME 15, Air Sampling Tube, 3rd High Level
AEA09-FF-15-RES-C1	Fortification Sample, ME 15, RespiCon, 1st Control
AEA09-FF-15-RES-C2	Fortification Sample, ME 15, RespiCon, 2nd Control
AEA09-FF-15-RES-L1	Fortification Sample, ME 15, RespiCon, 1st Low Level
AEA09-FF-15-RES-L2	Fortification Sample, ME 15, RespiCon, 2nd Low Level
AEA09-FF-15-RES-L3	Fortification Sample, ME 15, RespiCon, 3rd Low Level
AEA09-FF-15-RES-H1	Fortification Sample, ME 15, RespiCon, 1st High Level
AEA09-FF-15-RES-H2	Fortification Sample, ME 15, RespiCon, 2nd High Level
AEA09-FF-15-RES-H3	Fortification Sample, ME 15, RespiCon, 3rd High Level
AEA09-FF-15-HW-C1	Fortification Sample, ME 15, Hand Wash, 1st Control
AEA09-FF-15-HW-C2	Fortification Sample, ME 15, Hand Wash, 2nd Control
AEA09-FF-15-HW-L1	Fortification Sample, ME 15, Hand Wash, 1st Low Level
AEA09-FF-15-HW-L2	Fortification Sample, ME 15, Hand Wash, 2nd Low Level
AEA09-FF-15-HW-L3	Fortification Sample, ME 15, Hand Wash, 3rd Low Level
AEA09-FF-15-HW-H1	Fortification Sample, ME 15, Hand Wash, 1st High Level
AEA09-FF-15-HW-H2	Fortification Sample, ME 15, Hand Wash, 2nd High Level
AEA09-FF-15-HW-H3	Fortification Sample, ME 15, Hand Wash, 3rd High Level
AEA09-FF-15-FW-C1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Control
AEA09-FF-15-FW-C2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Control
AEA09-FF-15-FW-L1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Low Level
AEA09-FF-15-FW-L2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Low Level
AEA09-FF-15-FW-L3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd Low Level
AEA09-FF-15-FW-H1	Fortification Sample, ME 15, Face and Neck Wipe, 1st High Level
AEA09-FF-15-FW-H2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd High Level
AEA09-FF-15-FW-H3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd High Level
AEA09-FF-15-ID-C1	Fortification Sample, ME 15, Inner Dosimeter, 1st Control
AEA09-FF-15-ID-C2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Control
AEA09-FF-15-ID-L1	Fortification Sample, ME 15, Inner Dosimeter, 1st Low Level
AEA09-FF-15-ID-L2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Low Level
AEA09-FF-15-ID-L3	Fortification Sample, ME 15, Inner Dosimeter, 3rd Low Level
AEA09-FF-15-ID-H1	Fortification Sample, ME 15, Inner Dosimeter, 1st High Level
AEA09-FF-15-ID-H2	Fortification Sample, ME 15, Inner Dosimeter, 2nd High Level
AEA09-FF-15-ID-H3	Fortification Sample, ME 15, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-OD-C1	Fortification Sample, ME 15, Outer Dosimeter, 1st Control
AEA09-FF-15-OD-C2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Control
AEA09-FF-15-OD-L1	Fortification Sample, ME 15, Outer Dosimeter, 1st Low Level
AEA09-FF-15-OD-L2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Low Level
AEA09-FF-15-OD-L3	Fortification Sample, ME 15, Outer Dosimeter, 3rd Low Level
AEA09-FF-15-OD-H1	Fortification Sample, ME 15, Outer Dosimeter, 1st High Level
AEA09-FF-15-OD-H2	Fortification Sample, ME 15, Outer Dosimeter, 2nd High Level
AEA09-FF-15-OD-H3	Fortification Sample, ME 15, Outer Dosimeter, 3rd High Level
AEA09-FF-16-PH-C1	Fortification Sample, ME 16, Painter's Hat, 1st Control
AEA09-FF-16-PH-C2	Fortification Sample, ME 16, Painter's Hat, 2nd Control
AEA09-FF-16-PH-L1	Fortification Sample, ME 16, Painter's Hat, 1st Low Level
AEA09-FF-16-PH-L2	Fortification Sample, ME 16, Painter's Hat, 2nd Low Level
AEA09-FF-16-PH-L3	Fortification Sample, ME 16, Painter's Hat, 3rd Low Level
AEA09-FF-16-PH-H1	Fortification Sample, ME 16, Painter's Hat, 1st High Level
AEA09-FF-16-PH-H2	Fortification Sample, ME 16, Painter's Hat, 2nd High Level
AEA09-FF-16-PH-H3	Fortification Sample, ME 16, Painter's Hat, 3rd High Level
AEA09-FF-16-AR-C1	Fortification Sample, ME 16, Air Sampling Tube, 1st Control
AEA09-FF-16-AR-C2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Control
AEA09-FF-16-AR-L1	Fortification Sample, ME 16, Air Sampling Tube, 1st Low Level
AEA09-FF-16-AR-L2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Low Level
AEA09-FF-16-AR-L3	Fortification Sample, ME 16, Air Sampling Tube, 3rd Low Level
AEA09-FF-16-AR-H1	Fortification Sample, ME 16, Air Sampling Tube, 1st High Level
AEA09-FF-16-AR-H2	Fortification Sample, ME 16, Air Sampling Tube, 2nd High Level
AEA09-FF-16-AR-H3	Fortification Sample, ME 16, Air Sampling Tube, 3rd High Level
AEA09-FF-16-RES-C1	Fortification Sample, ME 16, RespiCon, 1st Control
AEA09-FF-16-RES-C2	Fortification Sample, ME 16, RespiCon, 2nd Control
AEA09-FF-16-RES-L1	Fortification Sample, ME 16, RespiCon, 1st Low Level
AEA09-FF-16-RES-L2	Fortification Sample, ME 16, RespiCon, 2nd Low Level
AEA09-FF-16-RES-L3	Fortification Sample, ME 16, RespiCon, 3rd Low Level
AEA09-FF-16-RES-H1	Fortification Sample, ME 16, RespiCon, 1st High Level
AEA09-FF-16-RES-H2	Fortification Sample, ME 16, RespiCon, 2nd High Level
AEA09-FF-16-RES-H3	Fortification Sample, ME 16, RespiCon, 3rd High Level
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-HW-C2	Fortification Sample, ME 16, Hand Wash, 2nd Control
AEA09-FF-16-HW-L1	Fortification Sample, ME 16, Hand Wash, 1st Low Level
AEA09-FF-16-HW-L2	Fortification Sample, ME 16, Hand Wash, 2nd Low Level
AEA09-FF-16-HW-L3	Fortification Sample, ME 16, Hand Wash, 3rd Low Level
AEA09-FF-16-HW-H1	Fortification Sample, ME 16, Hand Wash, 1st High Level
AEA09-FF-16-HW-H2	Fortification Sample, ME 16, Hand Wash, 2nd High Level
AEA09-FF-16-HW-H3	Fortification Sample, ME 16, Hand Wash, 3rd High Level
AEA09-FF-16-FW-C1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Control
AEA09-FF-16-FW-C2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Control
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-FW-L1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Low Level
AEA09-FF-16-FW-L2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Low Level

Sample ID Number	Description
AEA09-FF-16-FW-L3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd Low Level
AEA09-FF-16-FW-H1	Fortification Sample, ME 16, Face and Neck Wipe, 1st High Level
AEA09-FF-16-FW-H2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd High Level
AEA09-FF-16-FW-H3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd High Level
AEA09-FF-16-ID-C1	Fortification Sample, ME 16, Inner Dosimeter, 1st Control
AEA09-FF-16-ID-C2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Control
AEA09-FF-16-ID-L1	Fortification Sample, ME 16, Inner Dosimeter, 1st Low Level
AEA09-FF-16-ID-L2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Low Level
AEA09-FF-16-ID-L3	Fortification Sample, ME 16, Inner Dosimeter, 3rd Low Level
AEA09-FF-16-ID-H1	Fortification Sample, ME 16, Inner Dosimeter, 1st High Level
AEA09-FF-16-ID-H2	Fortification Sample, ME 16, Inner Dosimeter, 2nd High Level
AEA09-FF-16-ID-H3	Fortification Sample, ME 16, Inner Dosimeter, 3rd High Level
AEA09-FF-16-OD-C1	Fortification Sample, ME 16, Outer Dosimeter, 1st Control
AEA09-FF-16-OD-C2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Control
AEA09-FF-16-OD-L1	Fortification Sample, ME 16, Outer Dosimeter, 1st Low Level
AEA09-FF-16-OD-L2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Low Level
AEA09-FF-16-OD-L3	Fortification Sample, ME 16, Outer Dosimeter, 3rd Low Level
AEA09-FF-16-OD-H1	Fortification Sample, ME 16, Outer Dosimeter, 1st High Level
AEA09-FF-16-OD-H2	Fortification Sample, ME 16, Outer Dosimeter, 2nd High Level
AEA09-FF-16-OD-H3	Fortification Sample, ME 16, Outer Dosimeter, 3rd High Level
AEA09-FF-17-PH-C1	Fortification Sample, ME 17, Painter's Hat, 1st Control
AEA09-FF-17-PH-C2	Fortification Sample, ME 17, Painter's Hat, 2nd Control
AEA09-FF-17-PH-L1	Fortification Sample, ME 17, Painter's Hat, 1st Low Level
AEA09-FF-17-PH-L2	Fortification Sample, ME 17, Painter's Hat, 2nd Low Level
AEA09-FF-17-PH-L3	Fortification Sample, ME 17, Painter's Hat, 3rd Low Level
AEA09-FF-17-PH-H1	Fortification Sample, ME 17, Painter's Hat, 1st High Level
AEA09-FF-17-PH-H2	Fortification Sample, ME 17, Painter's Hat, 2nd High Level
AEA09-FF-17-PH-H3	Fortification Sample, ME 17, Painter's Hat, 3rd High Level
AEA09-FF-17-AR-C1	Fortification Sample, ME 17, Air Sampling Tube, 1st Control
AEA09-FF-17-AR-C2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Control
AEA09-FF-17-AR-L1	Fortification Sample, ME 17, Air Sampling Tube, 1st Low Level
AEA09-FF-17-AR-L2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Low Level
AEA09-FF-17-AR-L3	Fortification Sample, ME 17, Air Sampling Tube, 3rd Low Level
AEA09-FF-17-AR-H1	Fortification Sample, ME 17, Air Sampling Tube, 1st High Level
AEA09-FF-17-AR-H2	Fortification Sample, ME 17, Air Sampling Tube, 2nd High Level
AEA09-FF-17-AR-H3	Fortification Sample, ME 17, Air Sampling Tube, 3rd High Level
AEA09-FF-17-RES-C1	Fortification Sample, ME 17, RespiCon, 1st Control
AEA09-FF-17-RES-C2	Fortification Sample, ME 17, RespiCon, 2nd Control
AEA09-FF-17-RES-L1	Fortification Sample, ME 17, RespiCon, 1st Low Level
AEA09-FF-17-RES-L2	Fortification Sample, ME 17, RespiCon, 2nd Low Level
AEA09-FF-17-RES-L3	Fortification Sample, ME 17, RespiCon, 3rd Low Level

Sample ID Number	Description
AEA09-FF-17-RES-H1	Fortification Sample, ME 17, RespiCon, 1st High Level
AEA09-FF-17-RES-H2	Fortification Sample, ME 17, RespiCon, 2nd High Level
AEA09-FF-17-RES-H3	Fortification Sample, ME 17, RespiCon, 3rd High Level
AEA09-FF-17-HW-C1	Fortification Sample, ME 17, Hand Wash, 1st Control
AEA09-FF-17-HW-C2	Fortification Sample, ME 17, Hand Wash, 2nd Control
AEA09-FF-17-HW-L1	Fortification Sample, ME 17, Hand Wash, 1st Low Level
AEA09-FF-17-HW-L2	Fortification Sample, ME 17, Hand Wash, 2nd Low Level
AEA09-FF-17-HW-L3	Fortification Sample, ME 17, Hand Wash, 3rd Low Level
AEA09-FF-17-HW-H1	Fortification Sample, ME 17, Hand Wash, 1st High Level
AEA09-FF-17-HW-H2	Fortification Sample, ME 17, Hand Wash, 2nd High Level
AEA09-FF-17-HW-H3	Fortification Sample, ME 17, Hand Wash, 3rd High Level
AEA09-FF-17-FW-C1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Control
AEA09-FF-17-FW-C2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Control
AEA09-FF-17-FW-L1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Low Level
AEA09-FF-17-FW-L2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Low Level
AEA09-FF-17-FW-L3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd Low Level
AEA09-FF-17-FW-H1	Fortification Sample, ME 17, Face and Neck Wipe, 1st High Level
AEA09-FF-17-FW-H2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd High Level
AEA09-FF-17-FW-H3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd High Level
AEA09-FF-17-ID-C1	Fortification Sample, ME 17, Inner Dosimeter, 1st Control
AEA09-FF-17-ID-C2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Control
AEA09-FF-17-ID-L1	Fortification Sample, ME 17, Inner Dosimeter, 1st Low Level
AEA09-FF-17-ID-L2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Low Level
AEA09-FF-17-ID-L3	Fortification Sample, ME 17, Inner Dosimeter, 3rd Low Level
AEA09-FF-17-ID-H1	Fortification Sample, ME 17, Inner Dosimeter, 1st High Level
AEA09-FF-17-ID-H2	Fortification Sample, ME 17, Inner Dosimeter, 2nd High Level
AEA09-FF-17-ID-H3	Fortification Sample, ME 17, Inner Dosimeter, 3rd High Level
AEA09-FF-17-OD-C1	Fortification Sample, ME 17, Outer Dosimeter, 1st Control
AEA09-FF-17-OD-C2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Control
AEA09-FF-17-OD-L1	Fortification Sample, ME 17, Outer Dosimeter, 1st Low Level
AEA09-FF-17-OD-L2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Low Level
AEA09-FF-17-OD-L3	Fortification Sample, ME 17, Outer Dosimeter, 3rd Low Level
AEA09-FF-17-OD-H1	Fortification Sample, ME 17, Outer Dosimeter, 1st High Level
AEA09-FF-17-OD-H2	Fortification Sample, ME 17, Outer Dosimeter, 2nd High Level
AEA09-FF-17-OD-H3	Fortification Sample, ME 17, Outer Dosimeter, 3rd High Level
AEA09-FF-18-PH-C1	Fortification Sample, ME 18, Painter's Hat, 1st Control
AEA09-FF-18-PH-C2	Fortification Sample, ME 18, Painter's Hat, 2nd Control
AEA09-FF-18-PH-L1	Fortification Sample, ME 18, Painter's Hat, 1st Low Level
AEA09-FF-18-PH-L2	Fortification Sample, ME 18, Painter's Hat, 2nd Low Level
AEA09-FF-18-PH-L3	Fortification Sample, ME 18, Painter's Hat, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-PH-H1	Fortification Sample, ME 18, Painter's Hat, 1st High Level
AEA09-FF-18-PH-H2	Fortification Sample, ME 18, Painter's Hat, 2nd High Level
AEA09-FF-18-PH-H3	Fortification Sample, ME 18, Painter's Hat, 3rd High Level
AEA09-FF-18-AR-C1	Fortification Sample, ME 18, Air Sampling Tube, 1st Control
AEA09-FF-18-AR-C2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Control
AEA09-FF-18-AR-L1	Fortification Sample, ME 18, Air Sampling Tube, 1st Low Level
AEA09-FF-18-AR-L2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Low Level
AEA09-FF-18-AR-L3	Fortification Sample, ME 18, Air Sampling Tube, 3rd Low Level
AEA09-FF-18-AR-H1	Fortification Sample, ME 18, Air Sampling Tube, 1st High Level
AEA09-FF-18-AR-H2	Fortification Sample, ME 18, Air Sampling Tube, 2nd High Level
AEA09-FF-18-AR-H3	Fortification Sample, ME 18, Air Sampling Tube, 3rd High Level
AEA09-FF-18-RES-C1	Fortification Sample, ME 18, RespiCon, 1st Control
AEA09-FF-18-RES-C2	Fortification Sample, ME 18, RespiCon, 2nd Control
AEA09-FF-18-RES-L1	Fortification Sample, ME 18, RespiCon, 1st Low Level
AEA09-FF-18-RES-L2	Fortification Sample, ME 18, RespiCon, 2nd Low Level
AEA09-FF-18-RES-L3	Fortification Sample, ME 18, RespiCon, 3rd Low Level
AEA09-FF-18-RES-H1	Fortification Sample, ME 18, RespiCon, 1st High Level
AEA09-FF-18-RES-H2	Fortification Sample, ME 18, RespiCon, 2nd High Level
AEA09-FF-18-RES-H3	Fortification Sample, ME 18, RespiCon, 3rd High Level
AEA09-FF-18-HW-C1	Fortification Sample, ME 18, Hand Wash, 1st Control
AEA09-FF-18-HW-C2	Fortification Sample, ME 18, Hand Wash, 2nd Control
AEA09-FF-18-HW-L1	Fortification Sample, ME 18, Hand Wash, 1st Low Level
AEA09-FF-18-HW-L2	Fortification Sample, ME 18, Hand Wash, 2nd Low Level
AEA09-FF-18-HW-L3	Fortification Sample, ME 18, Hand Wash, 3rd Low Level
AEA09-FF-18-HW-H1	Fortification Sample, ME 18, Hand Wash, 1st High Level
AEA09-FF-18-HW-H2	Fortification Sample, ME 18, Hand Wash, 2nd High Level
AEA09-FF-18-HW-H3	Fortification Sample, ME 18, Hand Wash, 3rd High Level
AEA09-FF-18-FW-C1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Control
AEA09-FF-18-FW-C2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Control
AEA09-FF-18-FW-L1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Low Level
AEA09-FF-18-FW-L2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Low Level
AEA09-FF-18-FW-L3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd Low Level
AEA09-FF-18-FW-H1	Fortification Sample, ME 18, Face and Neck Wipe, 1st High Level
AEA09-FF-18-FW-H2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd High Level
AEA09-FF-18-FW-H3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd High Level
AEA09-FF-18-ID-C1	Fortification Sample, ME 18, Inner Dosimeter, 1st Control
AEA09-FF-18-ID-C2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Control
AEA09-FF-18-ID-L1	Fortification Sample, ME 18, Inner Dosimeter, 1st Low Level
AEA09-FF-18-ID-L2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Low Level
AEA09-FF-18-ID-L3	Fortification Sample, ME 18, Inner Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-ID-H1	Fortification Sample, ME 18, Inner Dosimeter, 1st High Level
AEA09-FF-18-ID-H2	Fortification Sample, ME 18, Inner Dosimeter, 2nd High Level
AEA09-FF-18-ID-H3	Fortification Sample, ME 18, Inner Dosimeter, 3rd High Level
AEA09-FF-18-OD-C1	Fortification Sample, ME 18, Outer Dosimeter, 1st Control
AEA09-FF-18-OD-C2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Control
AEA09-FF-18-OD-L1	Fortification Sample, ME 18, Outer Dosimeter, 1st Low Level
AEA09-FF-18-OD-L2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Low Level
AEA09-FF-18-OD-L3	Fortification Sample, ME 18, Outer Dosimeter, 3rd Low Level
AEA09-FF-18-OD-H1	Fortification Sample, ME 18, Outer Dosimeter, 1st High Level
AEA09-FF-18-OD-H2	Fortification Sample, ME 18, Outer Dosimeter, 2nd High Level
AEA09-FF-18-OD-H3	Fortification Sample, ME 18, Outer Dosimeter, 3rd High Level

Megan Boatwright

From: Robert Testman
Sent: Tuesday, March 15, 2016 5:43 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: AEA09 Brush-Roller Study Protocol
Attachments: AEATF Brush Roller Final Protocol 05Jan2016.pdf; AEA09_201307318 _Robert_Testman_Initial_Approval_Letter1.pdf; SAIRB letter 29Feb2016.pdf

Hi Don,

Attached is a copy of the IRB approved final protocol for the brush and roller study. I am also including the IRB approval document, and a copy of a letter to the IRB detailing the changes made as a result of the HSRB/EPA review. The initial CDPR requested changes were incorporated prior to HSRB review, with the exception of the ventilation fan item which was discussed with HSRB (prior email to you). As you will note HSRB agreed with CDPR that the fan should be on the entire time, and this change was incorporated into the protocol. Please let me know if you have any questions or need anything further.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

PROTOCOL

05 January 2016

This Protocol is the Property of the American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II (AEATF II)

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Proposed Experimental Start Date

February 2016

Testing Facility / Analytical Phase Location

Golden Pacific Laboratories (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, California 93722

Field Phase Location

Fresno County

Sponsor Study Identification

AEA09

GPL Study Number

120463

Total Number of Pages: 150

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1. GENERAL INFORMATION

Study Title

A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Sponsor Study No:	AEA09
GPL Study No:	120463

Objective

This study is being conducted to determine potential dermal and inhalation exposures associated with the use of latex paint containing an antimicrobial pesticide.

Proposed Experimental Start Date:	February 2016
Proposed Experimental Termination Date:	July 2016

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal and inhalation exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000 875.1200, 875.1400 and 875.1600) and the OECD guidelines (OECD, 1997). Data development methods will follow the requirements defined in these guidelines.

Applicable Ethical Standards

This is a protocol for third-party research involving what EPA has interpreted to be intentional exposure of human subjects to a pesticide. The study is being conducted with the intention of submitting the resulting data to EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). Thus, the primary ethical standards applicable to this proposal are 40 CFR 26, Subparts K and L. In addition, the requirements of FIFRA §12(a)(2)(P) for fully informed, fully voluntary consent of subjects apply, and since the study will be conducted in California, the provisions of the California Code of Regulations, Title 3, §6710 would apply. The protocol will be reviewed by an Institutional Review Board (IRB).

Good Laboratory Practice

This study will be conducted in compliance with the US EPA FIFRA Good Laboratory Practice (GLP) Standards (40 CFR 160). The study will adhere to applicable SOPs of the Antimicrobial Exposure Assessment Task Force II (AEATF II) as referenced in the table below. The SOPs of the Testing Facility will be followed for procedures not described by the AEATF II SOPs. Not all citations for a particular AEATF II SOP may be listed.

SOP Number	Topic	Section Reference
4A.1	Study Report Preparation	18.0
5A.1 - 5C.1; 5E.1 - 5K.1	Chapter 5: Quality Assurance Unit	16.0
6A.1	Storage of Raw Data	13.0
7A.1	Test, Control, and Reference Substances Receipt and Shipment	7.0
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2. SUMMARY

The Antimicrobial Exposure Assessment Task Force II (AEATF II) was formed to generate generic exposure data on a broad range of use patterns and associated application methods, as well as post application exposures to support registration and re-registration by its member companies of such uses for antimicrobial ingredients. The data will be representative of subject activities and methods used in the handling of antimicrobial products. Determining exposure of consumer painters who occasionally handle antimicrobial pesticides using methods described in this research study will produce reliable data about the dermal and inhalation exposure of consumer painters as well as professional painters performing this task. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

The test substance is Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, at concentrations of approximately 120 ppm, 360 ppm, and 600 ppm. The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve final BIT concentrations of approximately 360 ppm and 600 ppm. The final BIT concentrations in the test substance will be verified analytically by the testing facility prior to its use in the study. The test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans. The test substance will be used in accordance with the product label.

All study participants will be adult subjects capable of and experienced in performing the functions described in the protocol. Subjects will be required to provide their signed Informed Consent using a form approved by an Institutional Review Board (IRB) prior to participation in the study. The total number of subjects monitored will be at least 18 but could be as large as 24 if some of the subjects do not complete their assigned ME. Potential dermal and inhalation exposure of each individual study participant in a ME will be measured during paint application of an amount of product that is estimated to be representative of the use by consumer painters. All participants will be independently monitored while performing the functions described in the protocol.

The study will be conducted using purposely built painting rooms inside a commercial facility (e.g., vacant retail store or warehouse), having adequate

facilities to support the study (working HVAC, working restrooms, changing facilities, etc.). The paint application will be performed in a series of temporary rooms built inside the facility (including walls, ceilings, door with trim, window area with trim, and baseboards). The temporary rooms will be painted with an initial base coat of paint prior to first use for a ME. Painting rooms may be reused no more than every other day to allow sufficient drying time. Background air samples and background wall wipes will be taken prior to each ME. The ambient air temperature and humidity during exposure monitoring will be recorded. The air changes per hour (ACH) in the painting rooms will be measured. A description of the HVAC system in use during each ME will also be documented.

Subjects will apply paint using a specific type of application equipment (brush and roller). Generically speaking the type of equipment used will represent mid-grade "Better" category equipment, the most popular for consumer use. The total amount of test substance (paint) applied during each ME will be approximately 2 gallons. The rationale for the amount of test substance applied is provided in "Interior Latex Paint Application with Brush and Roller Scenario: Rationale for Study Design" (AEATF 2013). Monitoring events are expected to range from 120 to 180 minutes, allowing time for moving between surfaces and rooms, and intermittent breaks desired by the subject. The amount of time spent actually applying the test substance may be less, as would be typical of the painting activity. The approximate time spent applying the test substance, the approximate amount of surface area covered, and the total duration of each subject's ME will be recorded in the raw data. The amount of test substance handled will be determined from the change in weight of the paint containers used by each subject. Subjects will be given and required to wear all personal protective equipment (PPE, i.e., protective eyewear) as needed to comply with the product label or protocol throughout the ME.

Potential dermal exposure to the test substance will be measured externally using whole body inner and outer dosimeters, painter's hats, hand wipes/washes, and face/neck wipes. All monitored subjects will wear the outer dosimeter (representative outer clothing consisting of cotton long pants and cotton long sleeve shirts) directly over the inner dosimeter (consisting of 100% cotton long underwear). Painter's hats will be worn by all subjects. Inner and outer dosimeters, and painter's hats will be provided by AEATF. Subjects will wear their own socks and shoes. Hand exposure will be measured by scrubbing the hands with gauze pads soaked with a solution of 50% isopropyl alcohol/ 50% distilled water followed by rinsing with the same solvent. Face and neck exposure will be measured by wiping the face and neck with gauze pads moistened with 50% isopropyl alcohol / 50% distilled water.

The potential total inhalation exposure for each subject will be measured with an OSHA Versatile Sampler (OVS) tube attached to a personal air sampling pump set at a typical sampling rate (2 L/minute). Potential exposure to respirable, thoracic and inhalable particles (100, 10 and 2.5 µm, respectively) will be characterized

with a three stage RespiCon™ Particle Sampler (Model 8522, TSI Inc.) attached to a personal air sampling pump operating at ~3.1 L/min.

The inner and outer dosimeters, painter's hats, OVS tubes, filters from the RespiCon™ Particle Sampler, hand wipe/wash solutions, and face/neck wipes will be analyzed for residues of BIT using validated analytical methods.

3. RATIONALE AND OBJECTIVE OF THE STUDY

Currently, US EPA relies upon the results from a single study listed in the Pesticide Handler's Exposure Database (PHED) to characterize exposure from the brush and roller application of a paint product (EPA, 1998). That study has a total of 15 MEs where paint was applied with a paintbrush only, and with no variation in amount of active ingredient applied. In addition the analytical quality of dermal and inhalation measurements in the PHED study are given a grade of C. This low quality grade limits the study's reliability for regulatory exposure assessment. Increased sensitivity of the analytical methods, exposure dosimetry methods and regulatory needs have changed significantly since the time of the PHED study. EPA has requested confirmatory exposure monitoring data for a number of antimicrobial use scenarios in Registration Eligibility Decision (RED) documents. A study performed for the European risk assessment database, RISKODERM, (Gijsbers et al., 2004) evaluated painter exposure to DEGBE, a non-solvent component of latex paint. However, this study was found to be lacking in several key areas including: no evaluation of potential inhalation exposure, collection of non-hand dermal samples from only 12 MEs, use of same subject for up to four MEs, unacceptable recoveries for many field fortification samples due to contamination, and no description of regulatory standards followed. There appears to be no other publicly available data with which to make a credible estimate of exposure for persons applying paint with a brush and roller. Thus, the rationale for conducting this study is to measure dermal and inhalation exposure in a large enough group of typical users to reasonably characterize central tendency and variability for this use (scenario) of antimicrobial pesticides. Based upon the existing data, it appears that an outer dosimeter consisting of normal work clothing is necessary to capture measurable exposure over the entire body even using an extremely sensitive analytical method, although dosimeters under the outer clothing will also be used. However, the primary interest is estimating dermal exposure (the amount of antimicrobial that gets through or around the work clothing), since that represents actual dermal exposure for most workers and typically is the route of primary exposure.

A recent summary of available passive dosimetry and biomonitoring studies conducted in the same individuals indicates that the passive dosimetry methods proposed by AEATF will neither over- nor under-estimate actual dosage (Ross et al., 2008). However, under certain circumstances, it is possible that there will be some over-estimation bias in the study design proposed in this protocol as outlined in section 4 of the scenario design document. Generally, from a regulatory

perspective a slight overestimation bias in estimating human exposure is preferable to underestimation.

The primary objective of this study is to use synthetic application-days called monitoring events (MEs) to monitor exposure to consumer painters who apply latex paint containing antimicrobial pesticide products with brush and roller painting equipment.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the test substance when performing painting activities with a brush and roller. There are no acceptable methods or models that could be used to extrapolate subjects' exposure while painting. One subject is needed for each synthetic monitoring event (ME). In this study, at least 18 MEs will be monitored in order to capture the expected variation in brush and roller application conditions using the product. The low toxicity of the test materials and very low expected exposure of subjects wearing extra dosimetry clothing should mean that there is limited incremental risk associated with performing this task, compared to their personal use of paint products.

AEATF may consider tracers in lieu of antimicrobials if they offer an advantage in detection limit. Most tracer substances that AEATF is aware of are not as well-tested toxicologically as the antimicrobial that will be used in this study. Given that the antimicrobial used in this study is commonly available and in wide use, there is minimal risk from its use in the study, and thus no reason to exchange that risk for exposure to a less well characterized chemical at much higher concentration than a person would normally encounter it.

5. OVERSIGHT OF ETHICAL CONDUCT

To comply with regulations regarding studies involving human subjects, written approval from Schulman Associates IRB Incorporated (SAIRB) located in Sunrise, Florida [phone number: (*954) 327-0778*] will be obtained prior to study initiation.

The submission package to SAIRB includes the Study Protocol, justification for amount of product applied and area treated (Interior Latex Paint Application With Brush and Roller Scenario: Rationale for Study Design; AEATF, 2013), a copy of the test substance / paint label (Appendix A), a copy of the label of Mergal® BIT20, a BIT additive product (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the test substance MSDS (Appendix E), as well as all recruiting materials, such as advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's Reregistration Eligibility Document (RED) (EPA, 2006a) for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices A, C, D, E, F, G) will be available in English and Spanish.

Following approval by SAIRB, the Study Protocol, approved ICF and supporting information will be submitted to the EPA, California Department of Pesticide Review (DPR) and HSRB for review. Recruitment of subjects into the study will not be initiated until all reviews (EPA, HSRB, and California DPR) have been completed, and SAIRB approval of the final protocol has been granted.

All protocol changes (amendments and deviations) shall be reported to SAIRB in writing by letter, fax or email. Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior SAIRB approval. All other amendments relating to the human subjects must be reviewed and approved by SAIRB prior to implementation, or as specifically instructed by SAIRB policy in this regard. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email, letter) in the final study report and associated documentation as specified in 40 CFR 26.1303. The SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

The Principal Investigator shall follow written instructions provided by the SAIRB for prompt reporting to SAIRB, appropriate institutional officials, and the EPA of unanticipated problems involving risks to human subjects or others.

The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies (e.g., California DPR) whose notification and prior approval of the study was required.

6. BALANCE OF RISKS AND BENEFITS

A. Risks to the Subjects

Risks to the subjects including those resulting from both chemical and physical hazards are discussed in this section.

The antimicrobial active ingredient BIT has been extensively tested in animals. It was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. The toxicity profile of BIT has been reviewed in the US by the EPA and California DPR. Based on its safety profile, BIT has been approved for use in many formulations,

and is extensively used in many household products such as laundry detergents, household cleaners, inks, adhesives, caulking and paints without undue safety concern. Using the best existing data available to EPA from the PHED, the Agency estimated risk to individuals applying BIT in paint in the RED document. EPA assumed a residential handler would use two gallons of latex paint containing 500 ppm of BIT in a painting event. EPA estimated risk by dermal and inhalation routes, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The calculated inhalation MOE was much greater than the dermal MOE. The maximal AEATF II exposure scenarios in this study will require use of approximately 1.2x the amount of active ingredient assumed by EPA. Thus, the workers involved in this study will have an expected MOE 3.1x the EPA's target MOE. Subjects' exposure will be further reduced not only by long sleeve shirt and long pants, but also by a second layer of dosimetry clothing (long underwear).

The product will be used according to its label. The subjects selected to participate in the study will have at least some experience in painting with a brush and roller. Any subject with a known sensitivity to latex paint or isopropyl alcohol (IPA) will be excluded from participating. At high concentration BIT can produce dermal irritation, but this is not commonly seen at the concentration in the test substance. Significant risks associated with paint ingestion by subjects are very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study would likely be lower than when conducting painting activities at home, due to wearing of inner dosimeter clothing. Risk from irritation due to rubbing alcohol used on the hands and face/neck can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, e.g., eczema or psoriasis. The risk from rubbing alcohol will be reduced by informing the subjects, and screening subject's hands prior to their participation in the study. Subjects' actual duration of exposure during product application (painting) will be limited, and the time involved in performing the described activity will not exceed the maximum normal daily activity.

There could be some discomfort and possibly the risk of heat-related illness associated with wearing two layers of clothing, although the duration, break opportunities, close observation, and controlled temperature in the facility should mitigate against that possibility. There is a small risk of discomfort or inconvenience from wearing the air sampling devices. There could also be some risk of embarrassment from disrobing to the subject's underwear in the presence of a researcher of the subject's own gender. Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The subjects will be painting using equipment such as extension poles and ladders. There is a risk of injury from dropped equipment or falling. These risks will be reduced by continuous observation from the research team and assistance with supporting ladders.

Combined, these factors indicate that subjects will not be at any significant health or safety risk during study conduct or after the study is completed. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

B. Benefits and to Whom Benefits Accrue

While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Paint products containing antimicrobial chemicals are used extensively in homes, schools, businesses, etc. to control mold and other microbes with potential to produce illness in humans, domestic animals and pets. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring exposure of subjects in this research study will produce reliable data about the dermal and inhalation exposure of workers and the general population performing these tasks. The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. The ability to accurately predict risk may allow other chemical classes of antimicrobials to also be registered based on exposure estimates generated from the data to be produced by this study. Results from the study may benefit EPA and painters by reducing uncertainty about the range of exposure experienced by consumers and workers handling paint containing antimicrobials. Registrants of antimicrobials will benefit because they will provide EPA with data on exposure that has been made a condition of re-registration for a number of antimicrobials, and they may be aided in registering new antimicrobials using the data generated from this study.

C. Balance of Risk and Benefit

The benefit of maintaining and potentially adding new antimicrobials that protect both the subjects involved in this research as well as society (including subjects' families) in general from microbial related illness far outweighs any incremental risks to subjects. Numerous health effects from exposure to mold and other microbial environmental pathogens are well-documented. The very slight risks from participation in this study are far lower than the risk of not being able to use effective antimicrobials for lack of information on the exposure to users.

D. Community Involvement

While the latex paint application with brush and roller study is not a community-based participatory research program, there are multiple communities that may be affected by conduct of the study as well as by the data generated from the study. The community of individuals that apply paint is enormous and includes thousands of workers and millions of residents in the U.S. alone.

E. Alternative Data Sources

Biological monitoring is not reasonable with BIT, because the primate metabolism of BIT (if any) is not known. The best exposure monitoring data currently available comes from PHED (EPA, 1998), and is inadequate for use with many antimicrobials as described in the Scenario Design document. This is critical information for appropriate risk assessment with some antimicrobials.

7. TEST SUBSTANCE

The test substance for these studies is the formulated product, Sherwin-Williams latex paint, containing 1,2-benzisothiazoline-3-one (BIT). The EPA does not require registration of paint containing BIT making no claims of antimicrobial activity, therefore no EPA registration number is available for the paint. A reference EPA registration for Mergal® BIT20, a BIT additive product is 5383-121. The product label for Mergal® BIT20 is included in Appendix B. BIT is the active ingredient selected for measurement, based on its stability, abundance in the formulation, and sensitivity of its analytical method.

A. Test Substance Identification

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredients Name:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm, 360 ppm, and 600 ppm (mg/Kg) BIT fortified in latex paint
Lot No.:	to be recorded in the raw data
Stability:	The stability of the active ingredient(s) in the test substance under recommended storage conditions will be documented before the start of the study. An expiration date and recommended storage conditions will be based on the stability data to ensure the test substance strength does not change appreciably during use in the study.

The concentration of BIT in the test substance as manufactured is expected to be approximately 120 ppm. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve additional BIT concentrations of approximately 360 ppm and 600 ppm.
A minimal volume of paint colorant will be added to approximately half the test substance to allow visual confirmation of paint coverage and thickness when applied over the opposite color. The color additive will be one routinely used by the manufacturer or paint supply store for this paint. The source, lot number, and other pertinent information of the color additive will be documented in the raw data. The test substance colors will be used in an alternating manner when rooms are re-used for painting.

GLP purity analysis (content of active ingredient in the test substance) will be performed by the testing facility prior to its use in the study for each preparation of the test substance including colorant.

Test substance received for, but not used in the study will be retained in its original container under monitored storage conditions until the release from the study is authorized by the Study Director. Retained samples of at least 50 mL from each lot of test substance used in the study will be archived at GPL.

B. Justification for Use of Test Substance

Sherwin-Williams Latex Paint is an end use product used for painting surfaces for protective and beautification purposes. Sherwin-Williams Latex Paint contains BIT. BIT in latex paint is added by the paint manufacturer to inhibit the growth of microbes such as bacteria, and may also be present as an anti-microbial additive in various paint components. BIT was selected as the analyte based primarily upon its abundance in paint products, on its stability, and the sensitivity of its analytical method. BIT has a complete toxicology database with low to moderate mammalian toxicity.

The analytical method for the determination of BIT on the proposed monitoring matrices at very low concentrations is being validated (GPL Study 130478). The validation study will also evaluate the freezer storage stability of BIT for the different matrices to be used in this study.

The very sensitive and selective analytical method developed for the analysis of BIT on different study matrices will allow for the detection and quantitation of extremely low levels of active ingredient in the collected samples. This will allow for shorter exposure time, thus minimizing the risk to research study subjects. Additionally, BIT in latex paint has been deemed suitable by the Sponsor and EPA as a surrogate compound for generating exposure data for other antimicrobial pesticides and paint types.

The table below lists the proposed limit of quantitation (LOQ) for BIT in the different matrices.

Matrix	LOQ
Air Sampling Tubes	10 ng/tube
Hand Wipes/Washes	1.0 ng/mL
Face/Neck Wipes	100 ng/sample
Painter's Hats	3.0 µg/sample
Inner Dosimeter Section	3.0 µg/sample
Outer Dosimeter Section	3.0 µg/sample
RespiCon Fiberglass Filters	10 ng/filter

C. Safety Precautions

A copy of the Materials Safety Data Sheet (MSDS) and the product label (English and Spanish versions) will be included in the study file, and provided to the study team (professional observers and researchers). A copy of the product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and a copy in their preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study. The label does not specify any PPE requirement for painting activities. For this study PPE (protective eyewear) will be provided and use directions will be followed by the subjects and ensured by the study research personnel. If a subject does not use required PPE or does not follow use directions within reason, or does so in a manner that presents safety issues in the judgment of the study research personnel, the study research personnel may terminate the subject's participation. The study samples will not be collected or analyzed. The final study report will not include data from the subject.

Heat stress signs and symptoms will be explained to the subjects. A copy of the poster entitled "Controlling Heat Stress Made Simple" in English and Spanish will be posted in the dressing area at the site.

Test substance which may get on the skin will be removed through one or more hand wipes/washes and the face/neck wipe procedure (sample collection events) during the ME. Following completion of each ME, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or on-site health professional will examine their hands and note any irritation to the skin at termination of each participant's monitoring. Section 9D includes additional details regarding stop criteria and medical management.

D. Calibration of Application Equipment

The application equipment (paint brushes and rollers) to be used in this study cannot be calibrated (i.e., the rate of discharge cannot be adjusted).

E. Application Parameters and Amount Applied

Each subject will apply the test substance to walls, ceilings, baseboards, window trim, and door trim in purpose-built temporary rooms inside an unoccupied commercial property. All interior surfaces of the room will be painted with the test substance, except those designated by the Study Director as non-painting surfaces (e.g. doors and fixtures). One gallon of paint is expected to cover the paintable surfaces in approximately one room; however, each participant will be encouraged to apply the paint as they would in normal practice.

In order to assure uniform starting homogeneity, study researchers will shake or stir the bulk paint container, and transfer a weighed amount to a secondary paint container (one gallon can) immediately prior to beginning each application cycle. Study researchers will affix a standard lid to the secondary paint container which subjects will remove and replace. An "application cycle" is defined as the process of applying all test substance poured from the bulk paint container into the secondary paint container.

The test substance will be applied by subjects according to typical painting practices. The subject will remove the lid from the secondary paint container. Application with the brush will involve dipping the brush into the paint in the secondary paint container, wiping off excess paint on the edges of the secondary paint container, and applying to surfaces. Subjects will be provided a smaller container (paint cup) and edger to use at their preference for brush painting. If subjects use the paint cup they will transfer paint from the secondary container to the paint cup. Application with the roller will involve transferring paint from the secondary paint container to a roller pan, pushing the roller through the paint, removing excess paint by rolling on the flat surface of the roller pan, and applying to surfaces. Subjects will be instructed before beginning that the painting goal is to cover the surfaces with an even coat of the minimal thickness that covers the surface completely and does not leave drips or bare spots. Once the subject begins painting they will be allowed to paint using their own techniques and judgment. The subject will be provided an extension pole, step stool and ladder to use as they choose for painting the upper walls and ceiling. If the subject chooses to use a step stool or ladder research staff will remain in close proximity and provide assistance if needed to prevent accidents or spills. If the Principal Investigator determines that a subject's painting technique is outside reasonable consumer practice (e.g. gross over application, under application, or sloppiness) the subject will be re-instructed and then allowed to continue. Subjects will be provided dry

cotton rags ("painter's rags") to use in wiping up paint spills on themselves, the equipment, and the floor. The use of painter's rags is considered normal painting practice. These rags will be weighed before use, and collected and weighed after use to determine the approximate paint content. Used rags will be disposed after weighing. A study researcher will take observational notes on each monitoring event.

When the subject has applied all the usable paint in the secondary paint container they will close the lid, return the secondary container to researchers, and be provided an additional secondary paint container if needed. To determine when a particular subject has applied the amount of test substance in the assigned ME, field personnel will weigh the paint transferred to the secondary paint containers, and maintain a running total of the amount transferred. Unless the subject voluntarily stops painting short of the target amount, the ME will end following completion of the application cycle in which the amount applied is first confirmed to fall within the assigned strata.

Cleaning of the painting equipment and rooms is not part of the latex paint application with brush and roller scenario, and will therefore not be performed by monitored subjects. If any cleaning is necessary following an ME, field research personnel will conduct these activities after the subjects have completed their tasks and have left the treated area.

F. Rationale for the Method and Procedure of Application

The procedures described represent typical consumer and professional worker methods of applying the test substance to indoor surfaces with a brush and roller.

G. Test Substance Storage

The test substance will be stored at ambient room temperature. Storage will be at Golden Pacific Laboratories or at the field site. A location and temperature log will be maintained.

8. STUDY DESIGN

A. Overview

The target study design involves construction of 18-24 synthetic antimicrobial paint application with brush and roller days, called monitoring events (or MEs). Application equipment designed to represent the mid-grade or "better" category of equipment will be used. All MEs will be conducted at a single monitoring site and will apply 1.75 to 2.25 gallons of test substance (based on weight). The monitoring site is to be an unoccupied commercial building housing a series of purpose built painting

rooms. Each of the MEs will be randomly assigned to one of three concentrations of BIT in the test substance in order to vary the amount of active ingredient handled (AaiH). Only 18 MEs are needed in the study. However, extra subjects are allocated to permit a maximum of six additional MEs in the event some subjects are unable to apply the full assigned amount of test substance. Thus, the study might contain as many as 24 valid MEs. (The additional subjects might also substitute for MEs for which a subject withdraws for any reason.) Each of the 18-24 MEs will be performed by a different subject painter. Each ME subject will be monitored for dermal and inhalation exposure. The scenario design document provides a detailed discussion of the rationale for each component of this design (AEATF, 2013).

Procedures for the selection and preparation of the monitoring site, the application equipment and the assignment of amounts of active ingredient and subjects to MEs are described in the following sections (8.B, 8.C, and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9. Exposure monitoring procedures for MEs are described in Section 10.

B. Monitoring Site

The study will be conducted at a commercial facility in Fresno County, California. The facility must have electricity, water, and a functioning HVAC system. The facility will provide a climate controlled open area sufficient in size to allow the construction of a series of at least 6 painting rooms. In addition the facility will include a subject waiting area, restrooms, changing room, and area for preparation of field fortification samples.

Each painting room will measure 10 feet by 12 feet with an 8 foot ceiling height. Each room will contain finished drywall walls and ceiling, an entry door with paintable trim, a simulated window area with paintable trim, baseboards, and a ceiling exhaust fan. The ceiling exhaust fan will be operated continuously during each ME. Room airflow (ACH) will be measured and included in the final study report. Photographs of the painting rooms will be maintained in the raw data. Newly constructed rooms will have an initial coat of primer or paint applied prior to the study. Rooms may be re-painted no more than every other day to allow sufficient drying time. Rooms will be inspected and approved by the Study Director or Field Coordinator prior to each day's use. Background air and wall wipe samples will be taken in each room prior to use and analyzed at the discretion of the Study Director.

C. Application Equipment

Monitoring events will be conducted using a specific type of application equipment (brush and roller). Generically speaking the type of equipment

used will represent mid-grade or "Better" category equipment. The equipment category is defined by materials and techniques used in the construction of the roller and brush. All equipment chosen will be recommended by the manufacturer for use with indoor latex paint. The following set of painting equipment will be used. If the specified equipment is no longer available the Study Director may choose an equivalent replacement with Sponsor approval.

Source	Brush Selection	Roller Selection
Home Depot	Linzer "Better" 3" polyester brush. Home Depot part 1170-3	Linzer "Better" 9" roller cover with 3/8" high density polyester. Home Depot part RS1433

D. Assignment of Amount of Active Ingredient Handled to MEs

In this study all subjects will apply the same substance, i.e., Sherwin-Williams latex paint. As described in section 7.A above, this substance contains the active ingredient BIT at one of three concentrations.

Each ME will apply the same amount of formulated product. The total amount of product applied, will range between 1.75 and 2.25 gallons (i.e., 8636 to 11104 grams of formulated product). The AiAH will be dependent upon the exact amount of test substance applied and the active ingredient concentration assigned to that ME.

As long as the subject is within the correct AaiH interval, it is unnecessary to control the exact amount of product precisely. However, the actual amount of product handled by each subject will be recorded.

E. Random Selection and Assignment of Subject Painters to MEs

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at AE-01 based on the order of their enrollment. The numbers will then be randomized using a research randomizer program accessible at the following internet website: http://randomizer.org. The first 24 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as replacements, their order for potential entry into the study being determined by the randomization process.

The first 18 subjects in the generated randomized list will be assigned to ME01 to ME18. The remaining 6 subjects will be assigned as alternates.

At least 2 alternates will be scheduled to be on hand each study day in case any subject is unable, chooses not to participate, or chooses to stop painting before reaching the necessary volume of paint applied. If the scheduled subjects complete their MEs, the alternates are paid and will not participate that day. Alternates who do not participate will be eligible to participate on another study day. If additional subjects above the 24 initially selected are required, randomized subject 25 will be contacted followed by randomized subject 26 and so on, until all MEs are completed for the study.

ME01 to ME18 will be randomly assigned using the research randomizer program to one of the three test substance concentrations. Each test substance concentration will be assigned to 6 total MEs.

Once the subjects have been randomized they will be scheduled into the study. No more than two subjects will be monitored in one day. It is conceivable that, due to fatigue, irritation or other difficulty, a subject might not complete the painting task for the assigned amount of product applied. If this should occur, the data from this ME can still be used provided the subject applies at least 0.5 gallons. If the subject failed to apply 0.5 gallons, however, the data from this ME will not be used and the monitoring media will not be analyzed. Regardless, an alternate subject in the (randomized) sequence will be assigned to complete the ME. This process will be continued until there are at least six completed MEs for each test substance concentration or until the pool of subjects has been depleted, whichever occurs first. A consistent failure to complete the full amount of painting for reasons such as fatigue would be an indication that such amounts are inappropriate and/or unlikely to occur in practice.

9. SUBJECT RECRUITMENT, SELECTION, COMPENSATION, AND WITHDRAWAL PROCEDURES

Twenty-four subjects are required for this study to serve as surrogate painters (or 'workers') for the MEs. This includes the planned 18 surrogate painters needed for the target design (i.e., six workers for each of three test substance concentrations). As described above, an additional six subjects are included as insurance against subject withdrawal or other failure to complete the assigned painting tasks (see 8.E).

A. Subject Recruitment

i. Population Base

Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area. The most-recent US Census indicates that 40% of the population in Fresno, CA metropolitan area is Hispanic. Therefore to adequately capture the ethnic diversity in the Fresno area, recruitment

materials and all communications with potential subjects will be available in English or Spanish, as preferred by the subject.

ii. Recruitment of Surrogate Workers

IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle. The Fresno Bee is a large, general circulation daily paper in Fresno County. The California Advocate is the dominant African American community weekly paper in Fresno County, and Vida en el Valle is a weekly Spanish language paper targeting the San Joaquin Valley, with separate editions for Fresno and other central valley municipalities. The recruiting advertisements will include a brief description of the study and include telephone numbers for English and Spanish speakers to call for more information. The recruitment period will be opened for 4 weeks following the first publication.

Individuals contacting research personnel and expressing an interest in participating in the study will be informed of the study according to the IRB approved script (Appendix F). The script allows callers to be informed of a general description of the study and key inclusion/exclusion criteria.

Callers responding to the recruitment advertisements placed in the newspapers and interested in participating in the study may be scheduled for Informed Consent meetings at the volunteer's convenience. It is not necessary to wait until the recruiting period is closed before enrollments begin.

During the scheduled meeting, the subjects will first be asked to fill out Part I (the Health Questionnaire) of the Subject Self-Reporting Demographic Form (Appendix D). The investigator will ask the subject the health questions in the Subject-Self-Reporting Demographic Form and inquire about the health of the subject. The investigator will answer any questions the subject may have. If none of the answers disqualifies the subject from participating, and if after all his or her questions have been answered and the potential subject is interested in participating in this research study, the Principal Investigator or designee will share information on the study design with interested participants, and provide them with copies of the IRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their additional questions. The Principal Investigator or designee

will describe the study to the individual in great detail and encourage each potential subject to ask questions and request clarification at any time during this process as well as in all activities that follow. The Principal Investigator or designee will provide each potential subject a copy of the product label (Appendix A), make available the MSDS (Appendix E) and answer any questions regarding the product to be tested. The Principal Investigator or designee will go over the Inclusion and Exclusion Criteria (see 9.A.iii. below) for the study and answer any questions that the potential subjects have. Potential subjects will be asked to complete the rest of the Subject Self-Reporting Demographic Form (Appendix D) and sign the form. Potential subjects will be asked if they would like to take any of the materials home to discuss with family and friends before deciding whether to enroll in the study. If the potential subject wishes to continue with the enrollment process at that time, the Principal Investigator or designee will explain to potential subjects they may withdraw from the research study at any time without penalty to their compensation. The amount and form of compensation, the potential risks and discomforts and treatment and compensation for injury will be more fully explained and potential subjects will be encouraged to ask questions.

The Principal Investigator or designee will check the potential subject's driver license or government-issued identification card to verify age for inclusion in the study, and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken. The subject will be asked to sign the Inform Consent including the Subject's Bill of Rights Form and the Subject Self-Reporting Demographic Form.

When at least three attempts have been made to reach and schedule Informed Consent meetings for every caller on the primary call-in list, and all scheduled Informed Consent meetings have been held, the pool of enrolled volunteers will be tallied.

The recruitment process will terminate at the end of the 4 week recruitment time period if a minimum of 24 subjects have been recruited for the study, i.e., have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 24 subjects have

been recruited during the 4 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 24 subjects have been enrolled into the study, terminating at the end of the 7 day extension. Termination will be done at the end of a specific time window to minimize the potential for an "early responder" bias.

A Spanish-speaking member of the research team will be available at recruitment meetings to assist and ensure communication with anyone preferring Spanish over English. The subjects will be asked if they would like to have the meeting conducted in English or Spanish.

The Principal Investigator will retain the final right to refuse participation to any potential subject; however, all potential subjects who attend the screening interview will be compensated $20 for their inconvenience, and all enrolled subjects who report to their assigned study site will receive $100. See Section 9.C for additional information.

For female potential subjects, final eligibility for participation in the study will be determined on each study day following a pregnancy test.

iii. Inclusion/Exclusion Criteria

Not all volunteers are eligible for participation in this study. The subjects will be asked to fill out a demographic questionnaire the results of which will be used to determine eligibility. While this study may require physically strenuous activities, no upper age limit has been imposed, given that an inclusion criterion is that the volunteer represents that their health is acceptable to conduct the described activities, and they are free from the medical conditions listed under exclusion criteria. In addition, the actual participation of female subjects will be conditional on the results of a pregnancy test taken on the day of scheduled monitoring.

Inclusion Criteria

- Males or females, at least 18 years of age and able to show a government issued identification
- Consider their own health sufficient to conduct the described activities
- Willingness to sign the Informed Consent including the Experimental Subject's Bill of Rights Form and

Subject Self-Reporting Demographic Form

- Speak and read English or Spanish
- Resident of Fresno County
- At least one brush and roller painting experience in the past 5 years

Exclusion Criteria

- Skin conditions on the surface of the hands, face, or neck (e.g., psoriasis, eczema, cuts or abrasions)
- Pregnancy, as shown by a urine pregnancy test
- Lactation
- Allergies or sensitivities to latex paint, soaps, BIT, isopropyl alcohol or other chemical products.
- Severe respiratory disorders (e.g., moderate or severe asthma, emphysema)
- Cardiovascular disease (e.g., history of myocardial infarcts, stroke, congestive heart failure or uncontrolled high blood pressure)
- Other health conditions that make participation difficult or unsafe (e.g. broken bone)
- Has worked as a professional painter in the past 10 years
- Is an employee or spouse of an employee of any company represented by AEATF, GPL, other contract organization involved with the study, paint manufacturer, or the American Chemistry Council.

iv. Community Involvement

There is no single group identifiable that would represent the community of potential appliers of paint with brush and roller.

B. Subject Sequence Number

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and identification code, example AE-01 for subject 1, etc. After this list has been randomized, each individual is assigned a unique study sequence number, numbered from 1 to the total number of subjects randomized, that indicates his/her position in the random order. Because all processing of individuals is in order of study

sequence number, the final list of enrolled subjects comprises a random sample and their study sequence numbers preserve the random order. The first eighteen study sequence numbers will be assigned to ME01 to ME18, the second sequential group of six will be assigned as primary alternates, and the remaining subjects will be extras and may participate if the first 24 subjects do not complete all assigned MEs. Thus, allocation of subjects to each testing slot is also random.

Individual data, excluding the subject's name and address, will be entered in Golden Pacific Laboratories' computer data base by the assigned AE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their AE number will be retained separately from the study file in an area clearly marked "CONFIDENTIAL". Golden Pacific Laboratories will retain subject's records indefinitely. Subjects may obtain copies of their own records from the Principal Investigator on request.

C. Compensation

If with help from the interviewer, a subject fills out Part I of the demographic form (the Health Questionnaire), information that disqualifies them from participation may become evident. If this occurs, the disqualified subject will be paid $20 for their time and inconvenience. All individuals that show up for the informed consent interview will be compensated $20 in cash at completion of the interview for their time and inconvenience. All individuals who are qualified, sign the informed consent form, and report to their assigned study site, will receive $100 in cash for their time and inconvenience when they leave the study site, whether they are monitored or not.

The value for compensation is based roughly on a day's wage of $100 and represents potential lost time from secondary sources of employment, travel time and incidental expenses incurred in study participation. Compensation will be provided to individuals who complete their assigned participation or who need to withdraw for whatever reason.

D. Stop Criteria and Medical Management

It is not expected that test subjects will experience any adverse effects from participation in this study. In the unlikely event adverse effects are experienced, they will likely be related to skin reactions during or following the study, or heat stress or odor aversion during the study. The Principal Investigator or on-site health professional will discuss the symptoms of heat stress, odor aversion and eye and skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal

Investigator or research staff (or personnel) immediately if they feel ill, suffer an eye or skin reaction or experience any other unanticipated adverse effects they feel may be related to the study during or following conduct of the study. The Principal Investigator or on-site health professional will also examine the hands immediately prior to the monitoring period to ensure there are no existing abrasions, cuts or skin conditions that increase the risk of skin problems during the monitoring period. A Spanish-speaking member of the research team will be present during monitoring events involving subjects whose preferred language is Spanish.

If a subject reports an adverse eye or skin reaction during the work period, they will be asked to immediately stop working. Research staff will notify the on-site health professional and follow instructions from that health professional. If instructed, research staff will assist the subject in gently washing exposed skin with clean water and mild soap. After drying the area with a clean towel, the Principal Investigator will be contacted for further instructions.

The extra layer of clothing worn by subjects may increase the risk of heat-related illness. To minimize the possibility of heat stress, the study will be conducted indoors in an environment where the heat index (HI) is expected to be less than 85. If the temperature at the study site exceeds 82 degrees Fahrenheit research personnel shall monitor the heat index, and stop subjects' work if the heat index exceeds 95. The SOP AEATF II-11B.1 describes the procedure for identification and control of heat stress. The poster "Controlling Heat Stress Made Simple" will be posted in the subject dressing area, and the information contained on the poster available to subjects and research personnel at the field site.

In brief, researchers will observe subjects for possible signs of early heat illness such as fatigue, dizziness, irritability, or decreased concentration, especially if the worker has been working for a while. If these symptoms are observed, the subjects will be asked whether they would like to rest for a moment. If they answer affirmatively, they will stop working, be given their choice of water or a sports drink, and the on-site health professional will be immediately contacted for further medical management instructions. If they answer negatively, they will be permitted to continue working, and frequently thereafter asked whether they would like to rest for a moment. Any affirmative answer will be handled as described above.

If subjects develop visible signs or report symptoms of distress such as pronounced fatigue, headache, cramps, feeling faint, increased pulse, muscle spasms, heavy sweating (or dry skin if previously sweating), extreme thirst, or rapid breathing, the subjects will be required to stop working immediately, and given their choice of water or a sports drink. The on-site health professional will immediately be contacted for further medical

management instructions. If the worker's condition appears to be serious, a member of the study team will call 911 and allow emergency medical personnel to respond and treat the subject. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by the subject's own insurance or the insurance of a third party under which the subject is covered.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, heat stress, or other unanticipated adverse effects observed or reported during conduct of the study. The medical management procedures set forth in SOP AEATF II-11C.1 will be implemented for any instance where the subject's work is halted for medical reasons (other than solely because of a heat stress index above 95), and for any post-study reports of illness, skin reactions or other unanticipated adverse effects. If two or more subjects withdraw or are withdrawn from the study for the same medical reasons, the study will be suspended until the cause of the withdrawal is fully investigated and determined. If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Principal Investigator to determine whether further medical management is appropriate.

The Principal Investigator will maintain a record of adverse health observations and reports, and follow Sponsor, SAIRB, Inc., EPA and California DPR policies for medical event reporting per SOP AEATF II-11F.0. Sufficient personnel will be present at the study site to maintain an appropriate level of technical support, scientific supervision and observations relevant to the safety of test subjects.

10. MONITORING EVENT PROCEDURES

Monitoring of each ME is expected to take a maximum of 3 to 4 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures. During that time subjects will change into inner and outer dosimetry clothing and get fitted with two air sampling pumps and sampling trains. Subjects will then be asked to apply the test substance using brush and roller until they have completed applying their assigned amount of test substance or are told to stop by the research team. Finally subjects will remove the dosimetry clothing with aid of the research team and change back into subjects' own clothes.

A. Sampling for Ambient Pre-Existing BIT

Duplicate air samples using personal air sampling pumps and OVS tubes described for worker samples will be collected in the subject dressing area for a fifteen minute period within two hours prior to the start of exposure monitoring on each day of the study. Similarly, duplicate air samples will be collected from each painting room intended for exposure monitoring that day. Duplicate dry gauze wipe samples will be taken by rubbing an

approximately 1 foot square area of wall for at least 15 seconds. Air and wall wipe samples will be collected at heights of approximately three and five feet, and analyzed at the discretion of the Study Director.

B. Subject Preparation

1. On the day of the study, each subject will go to the study location at the designated time, and meet the researchers.

2. The Principal Investigator and the research team will review with the subject their role in the study, and the subject will have a chance to ask additional questions. Subjects will be reminded that they may withdraw at any time before or after the study begins, and that there will be no penalty of any kind to subjects if they decide to withdraw from the study.

3. If a subject is female, she will be taken to a private area and asked to take a urine pregnancy test using an over-the-counter pregnancy test kit. After the subject has taken the pregnancy test she will be asked if she still wants to participate in the study. If she declines, she will be paid $100 for her inconvenience and will be free to go. If she wants to continue, a female member of the research team familiar with interpretation of the test will confirm the results of the pregnancy test. Results of the pregnancy test will be kept in confidence, they will not be recorded, and they will be discussed only with the subject that provided the urine sample. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data.

4. Subjects will wash their hands and face with Ivory soap and water, and dry them thoroughly using paper towels.

5. When an individual subject is ready, the subject will be accompanied to a private dressing area by a researcher of the same gender. Subjects will be asked to remove their street clothes down to their underwear, and put on the inner dosimeter (cotton long underwear), followed by the outer dosimeter (long sleeved cotton shirt and long cotton pants) provided by the AEATF. Care will be taken to provide clothing of adequate fit. The inner dosimeter arm and pant cuffs should not extend beyond the outer dosimeter cuffs (wrists and ankles). If necessary, the excess may be cut from inner dosimeter pant legs and arms at the wrists so the inner dosimeter will not come out from underneath the outer dosimeter during the ME. The outer dosimeter pant cuffs may be cut for proper fit, at a length where the cuffs do not drag on the floor or expose the worker's socks or inner dosimeter. The outer dosimeter pants will not be tucked into boots/shoes. The outer dosimeter shirt will be tucked into the pants.

A secured locker or similar storage area will be provided for the subjects' personal belongings during study participation, and the subject will retain the key during their ME.

6. A low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to an OVS tube with glass filter and XAD2 sorbent will be attached to the subject's belt (or a belt provided by the AEATF). The OVS tube will be placed in the subject's breathing zone with the inlet facing downward, similar to the nasal passage of the subject. A second low-volume personal air-sampling pump with Tygon® tubing (or equivalent) attached to a three stage RespiCon™ Particle Sampler with 2.5 micron inlet module will also be used. The RespiCon™ will be placed in the subject's breathing zone using a chest harness. Airflow of pumps attached to the OVS tube and RespiCon™ sampler will be calibrated to a nominal flow rate of approximately 2 and 3.1 L/min respectively using SOPs of field study procedures. The beginning flow rate of each pump will be checked and documented just before being fitted to the subject.

7. Subjects will be given safety glasses that provide front, and supplemental brow and temple protection, and a painter's hat. A piece of inner dosimeter cloth will be placed underneath the painter's hat. The subjects must wear the safety glasses and hat while applying the test substance to surfaces. If subjects remove their safety glasses or hat while painting, study research personnel will ask them to place them back on and ensure proper placement.

8. Photos of each subject will then be taken. If facial features or other identifiable features (e.g. unique tattoos) are shown, the photos shall be treated as confidential subject information and maintained in a separate, secure raw data file.

C. ME Activities

1. The air pumps will be turned on, and subjects will put on their safety glasses. Subjects will be provided a pail containing the test substance paint, directed to the appropriate ME application area, and asked to select an appropriate starting point and apply the paint to the surfaces the way they normally would do at home. Subjects will be shown the paint brush, roller assembled on roller frame, roller pan, and painting rags which will be present in the first application room. Subjects will be asked to alternate use of the brush and roller by painting room trim and flat areas in sections. Ceiling ventilation fans will remain on while the ME is conducted in a room. A researcher will observe each subject as they work, recording information necessary to characterize each ME. Following each application cycle, the subject will be provided additional test substance until they

have completed their application strata. When painting is complete in each room the subject will be directed by research personnel to the next application area.

2. Periodically throughout the monitoring period, the pumps will be checked to ensure they are still running and the tubing checked to ensure that there are no kinks. Subjects will be instructed to inform a study team member if the pump fails to operate or the tubing becomes kinked. Pumps and/or pump batteries which fail during the work activity will be replaced with another calibrated pump or a replacement battery, as appropriate. The sample train (OVS tube or RespiCon™, with connective tubing) will be retained and moved to the second pump if a replacement pump is necessary. In the event of pump failure or a kink in the tubing, a note will be added to the file documenting what happened and how it was resolved. Air pumps will not be turned off during breaks, and will remain operating until the subjects' work duration is complete.

3. Each subject is assigned to a particular stratum and will be asked to move from room to room (or area to area) applying the test substance as they typically would until they are asked to stop by the observer or decide they wish to withdraw from the study. Subjects will be allowed to position and move paint and painting equipment as they prefer within rooms. When moving between rooms subjects will be asked to place paint and painting equipment on a cart which will be moved to the next room by research staff. Subjects will be provided with additional test substance (paint) as necessary, instructed to take breaks at their discretion, and be provided a drink during breaks as requested. Hand wipe/wash samples (Section 10.D.4 below) will be collected if a subject elects to use the toilet during a break. The duration of a completed ME will depend on the individual painter, but is not anticipated to exceed 180 minutes.

4. The ME will be terminated by the observer when the total test substance applied by the subject falls within the target stratum. The cumulative weight of the test substance provided will be determined for each application cycle by researchers to provide a means of determining when the ME has been completed.

D. Sample Collection

1. At conclusion of the monitoring period, the subject will return to the private area with a researcher of the same gender. Exposure monitoring samples will be collected as described in SOP AEATF II-8A.2 to minimize cross contamination. The sequence of sample collection is outlined below. A more complete description of each sample collected follows.

a. The researcher will help subjects take off the painter's hat plus underlying dosimeter and save them for analysis.

b. The air sampling tube and RespiCon filters will be removed and saved for analysis.

c. The subject will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges (J&J Mirasorb 4-ply each) stacked together. The gauze sponges will be soaked with 50% IPA / 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse by pouring the same solvent while the subject rubs their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponges will be added to the hand wash solution containers and saved with the rinse solution for analysis.

d. The researcher will wipe the subject's face and neck with 2 gauze sponges that have each been moistened with 50% IPA / 50% distilled water solution, and save the gauze sponges for analysis.

e. The researcher will remove shoes and socks (if requested), and help subjects take off the outer shirt and pants, and save the outer shirt and pants for analysis.

f. The researcher will help subjects take off the long underwear, and save it for analysis.

g. When all samples have been collected, subjects will dress again in their street clothes and wash their hands with soap and water.

h. The Principal Investigator or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. They will be paid for their time and inconvenience in cash, and be free to go.

2. Painter's Hat Sample. The painter's hat and underlying dosimeter cloth will be removed with the assistance of a researcher (study team member) of the same gender, placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

3. Inhalation Samples. Upon completion of the ME, the inhalation sample will be collected as described in SOP AEATF II-8D.1. The ending flow rate of the pump with OVS tube attached will be measured, the OVS tube will then be disconnected from the tubing,

sealed at both ends, and placed in a pre-labeled "Ziploc®"-style bag. The ending flow rate of the pump with the RespiCon™ attached will be measured. The RespiCon™ filters will be collected in pre-labeled 25-mL culture tubes. Both OVS and RespiCon™ filters samples will be placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

4. Hand Wipe/Wash Samples. Hand exposure will be assessed by wiping and washing the subjects' hands with a 50% IPA / 50% distilled water solution using a washing procedure modified with scrubbing as described in section D.1.c above. The high solubility of BIT in both IPA and water indicates that this combination of solvents will provide excellent recovery of hand residues. The removal efficiency of BIT in paint from hands will be determined in a separate study and a correction factor applied if deemed appropriate by Study Director and Sponsor.

   A hand wipe/wash sample will be collected at the end of each ME. An interim hand wipe/wash sample will be collected each time a subject uses the toilet during an ME. Interim hand wipe/wash samples will be collected as described above and numbered sequentially. All samples will be analyzed separately and the results will be added to generate one hand wipe/wash number. Subjects will not be allowed to use tobacco, or eat, but they may drink without collection of a hand wipe/wash sample.

   All hand wash samples will be placed in pre-labeled containers and placed in temporary frozen storage as soon after collection as possible. Samples will then be maintained in frozen storage until analyzed.

5. Face/Neck Wipe Samples. Face/neck exposure will be measured by wiping the exposed areas with two gauze pads that have each been wetted with a 50% IPA / 50% distilled water solution as described in the SOP AEATF II-8C.2. After the specified task is completed, a dermal face/neck wipe sample will be collected from each subject after the hand wipe/wash sample is collected and before removal of the whole body dosimeters. Face/neck wipe samples will be placed directly into pre-labeled glass jars. All glass jars will be placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Due to the possibility of sweating during an ME, the observer may need to wipe the subject's face with a dry gauze pad to alleviate the discomfort of the subject. All wipes generated during the ME will be

collected in a glass jar and the samples will be numbered sequentially. All samples will be analyzed separately and the results will be added to generate one face/neck wipe number.

6. Outer and Inner Dosimeter Samples. The outer and inner layer of clothing (outer and inner dosimeter) will be removed with the assistance of a researcher (study team member) of the same gender and sectioned into upper and lower arms, front and back torso, and upper and lower legs per SOP AEATF II-8A.2. The sections will be individually placed in pre-labeled glass jars and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples will then be maintained in frozen storage until analyzed.

   Research personnel will wear disposable gloves when handling personal protective equipment (PPE) and exposure samples. Gloves will be changed after handling PPE, and between collections of each sample type. Plastic or paper sheeting will be used on seating, counter and floor surfaces at conclusion of each monitoring period to minimize transfer of any residues to clean surfaces. The dressing area will be cleaned with cleaning agents appropriate for the study between subjects.

E. Exposure Observations

Subjects will be observed throughout the exposure monitoring period in accordance with SOP AEATF II-10C.1. All activities during the monitoring period, especially specific occurrences that may affect exposure will be documented. While research staff (or personnel) will be instructed by the Study Director to be minimally intrusive with subjects (participants) and to avoid interfering with or influencing their work activities, documenting behavior that may be relevant to the magnitude of potential exposure requires observation of the subjects. For example, activities such as brushing against previously painted surfaces, paint drips and spills landing on subject, excessive splattering of paint from roller use, and cleanup of paint spills all constitute examples of increased exposure potential that require careful observation.

The study director may remove a subject from the study if they fail to follow the instructions of the researchers resulting in “gross violation” or if their behavior poses a threat of harm to them or others. Subjects will be compensated for their efforts and disqualified from the study.

The time spent actually applying (painting) the test substance will be documented for each ME. The observer will identify and describe the surfaces painted, and estimate the surface area painted using each type of application equipment (brush and roller). Surface area estimates may be

based on inspection/measurement following the ME, or estimates of anticipated ME application areas prepared prior to exposure monitoring.

Observations will include detailed time logs adequate to allow the exposure period to be calculated as either the total time or the time actually spent applying (painting) the test substance (e.g., excluding time between painting rooms).

Work activities will be appropriately documented in the observation notes and a detailed time log maintained for all activities. A photographic record (digital photography and videography) will be taken of representative study-related activities during exposure monitoring, with care taken by research personnel to avoid interfering with or influencing subjects work activities. The study subjects will not be photographed at any time while changing into or out of the dosimetry clothing. Photos in the final report will not show faces or identifying marks such as tattoos to preserve anonymity of participants.

F. Environmental Monitoring

Air temperature and relative humidity of the work area for the duration of exposure monitoring will be documented with automated instrumentation logging and recording at intervals appropriate for the duration of the work period per SOP AEATF II-10C.1. Environmental monitoring equipment will be calibrated or standardized according to SOPs. HVAC and room volume will be described in detail and documented in study field notes. Air changes per hour will be experimentally measured for one of the painting rooms.

G. Field Study Personnel

One researcher will be assigned to each subject, and will remain in contact with that subject throughout the study. Study research personnel will attempt to minimize any unnecessary interaction with and intrusion on the study subjects. The study team will be comprised of a sufficient number of people to conduct the following activities:

1. Assist with the donning and collection of all dosimeters in a time-efficient manner to minimize the time from completion of the work cycle to sampling.
2. Calibrate air-sampling pumps and record the beginning and ending flow rates.
3. Observe and record all work practices and record site and treatment details.
4. Take a photographic record of representative study-related activities that may be useful in study interpretation.

5. Prepare field fortification samples.
6. Monitor temperature and humidity, ensure room vent fans are on during ME, document any other environmental conditions that may impact the study.
7. Determine total weight of test substance applied and the estimated surface area covered.

H. Field Recovery Evaluation

Full details regarding field recovery evaluation procedures for all sampling media are given in the most recent version of SOP AEATF II-8E.1. The SOP instructions for "spiking" will be followed.

Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (inner and outer dosimeters, hand wipe/wash solutions, face/neck wipes, painter's hats, and air sampling matrices) will take place on each day of the study. Field fortification solutions of test substance (diluted with water as needed) or BIT in solvent (air tubes only) will be prepared at the appropriate concentrations. The fortification solutions will be taken to the field site and used by the study team for field recovery evaluation on all matrices, including the OVS tubes and RespiCon filters. If necessary the Study Director may authorize field fortification samples to be prepared at the analytical laboratory and transported to the field site (e.g., if a more precise balance is needed than is available at the field site).

Storage conditions of the solutions used for fortifications will be specified by the analytical laboratory and the actual storage details will be recorded in the study file.

A predetermined amount of the fortification solution will be applied to the different matrices using pipettes or syringes to deliver the correct fortification levels listed in the table below. Field fortifications will be conducted at the following levels during the study.

Matrix	Fortification Level
Air Sampling Tubes	100 ng/tube and 2.0 µg/tube
Hand Wipes/Washes	4.0 ng/mL and 400 ng/mL
Face/Neck Wipes	400 ng/sample and 10 µg/sample
Painter's Hats	12 µg/sample and 1.0 mg/sample
Inner Dosimeter Section	12 µg/sample and 1.0 mg/sample
Outer Dosimeter Section	12 µg/sample and 1.0 mg/sample
RespiCon Fiberglass Filters	100 ng/filter and 2.0 µg/filter

On each study day when field fortifications are conducted, samples of each matrix will be fortified at the two levels shown above. The low fortification represents 4 x LOQ. The high fortification levels are based on expected exposure levels for the painting tasks being monitored on that day.

For each matrix/level combination used during the study, three samples (i.e., triplicates) of that matrix will be fortified and analyzed.

After fortification, the inner and outer dosimeters, painter's hats, and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. The weathered samples are typically put out before the worker exposure monitoring commences, and are gathered after the monitoring interval stops, and the time is always recorded. Outer and inner dosimeters and painter's hats will be left uncovered per EPA suggestion. An air sampling system will be set up in the same manner as that of the workers, attached to the fortified OVS tubes in the field, and the pumps will be run during weathering.

Hand wipe/wash, RespiCon™ filters and face/neck wipe samples will be fortified and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Samples will then be maintained in frozen storage until analyzed.

In addition, duplicate samples of the inner and outer dosimeters, painter's hats, and duplicate OVS tubes fortified at the highest fortification level, will be processed and placed in temporary frozen storage as soon after collection as possible without exposure to ambient conditions. Segments of dosimeter representing any body area may be used for fortification samples. These spikes will be analyzed only if deemed necessary by the Principal Investigator, for example to help determine the cause of unusually low field fortification recovery results.

Finally, two untreated control samples of each matrix will be processed similarly to the field fortification samples (i.e., some are weathered).

Packaging, storage and shipment of the field fortification samples will be the same as for the experimental exposure samples.

11. SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

A. Sample Identification

Samples will be identified and tracked by unique sample numbers assigned by GPL consistent with SOP AEATF II-8F.1. For example for the identification number AEA09-BRS-01-ID-LA:

AEA09 = Task Force Study Number
BRS = Brush & Roller Worker Sample
01 = Subject/ME 01
ID = Inner Dosimeter
LA = Lower Arm
Additional designations are as follows:
OD = Outer Dosimeter
PH = Painter's Hats
AR = Air Sampling Tube
RES-01 = RespiCon™ Filter 100 µm
RES-02 = RespiCon™ Filter 10 µm
RES-03 = RespiCon™ Filter 2.5 µm
FW = Face and Neck Wipe
HW = Hand Wash

Sample identification numbers are appended to this protocol (Appendix I). During the analytical phase of the study, the laboratory may assign its own sample numbers as long as the initially assigned number is cross-referenced and included in the documentation of the sample.

B. Transportation

Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain-of-custody record will be available for each sample.

C. Storage

All samples will be placed into frozen storage within 4 hours of collection. The samples will be stored at the analytical facility in a freezer maintained at ≤ -10° C until analyzed.

12. ANALYTICAL PROCEDURES

Experimental exposure and laboratory recovery samples will be analyzed according to the analytical methods specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrices.

A. Reference Substance and Internal Standard

i. Reference Substance

The reference substance for this study is 1,2-Benzisothiazol-3(2H)-one (BIT). The reference substance will be used by the analytical laboratory to prepare calibration standards (HPLC/MS/MS) and fortification solutions used to fortify laboratory QC samples.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be added to the raw data
Purity:	to be added to the raw data
Date Received:	to be added to the raw data
Expiration Date:	to be added to the raw data

The reference substance will be obtained from the sponsor. Receipt of the reference substance will be documented, including label identification, date of receipt, person receiving the standard, and the amount received. Preparation of all stock and serially diluted solutions will be documented.

An expiration date and recommended storage conditions will be obtained from the sponsor to ensure the reference substance strength does not change appreciably during conduct of the study.

Purity analysis (content of active ingredient in the reference substance) will be provided by the Sponsor for each lot of reference substance used in the study. Documentation of purity will be retained in the study raw data file. The reference substance will be stored under the recommended conditions.

ii. Internal Standard

The internal standard, isotopically labeled BIT was supplied by Toronto Research Chemicals (Ontario, Canada).

Name:	Benzoisothiazol-3-one-13C6
CAS Number:	Not Applicable
Active Ingredient:	BIT

Lot No.:	3-MGG-87-2
Purity:	98%
Date Received:	9/27/12
Expiration Date:	NA

The above substance will be used for the preparation of the internal standard solution. A copy of the Certificate of Analysis of the internal standard will be kept in the archives at GPL. The internal standard will be stored frozen (≤-10°C).

B. Analytical Method

The analysis of BIT in all matrices will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The limit of quantitation (LOQ) for air sampling tubes and RespiCon filters, hand washes, and face/neck wipes are 10 ng/sample, 1.0 ng/mL and 100 ng/sample, respectively. The LOQ for inner and outer dosimeters and painter's hats are 3.0 µg/sample. The method (GPL-MTH-079) includes the use of isotopically labeled BIT internal standard to increase accuracy and minimize potential matrix interference or suppression. The validated methods will be followed as rigidly as possible. No changes are permitted without prior approval of the Study Director. All data will be measured against a standard curve (five point minimum, one of which will be at 50-70% of the LOQ concentration) that brackets the levels of the remaining samples. Any sample not bracketed by the standard curve concentrations will be re-diluted and re-analyzed unless it is below the LOQ when at the minimum method dilution.

Each analytical set will include two laboratory fortified matrix samples, a solvent blank and an unfortified matrix control. The fortification levels will bracket the expected levels in the field sample.

The following GPL validated analytical method will be used:

GPL Analytical Method GPL-MTH-079 entitled, "Analytical Method for the Determination of 1,2-Benzisothiazol-3(2H)-one (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Painter's Hats, Air Sampling Tubes and Fiberglass Filters" (GPL, 2013) will be used.

Test substance (paint) aliquots will be measured, diluted with 10% methanol: 90% water, shaken, then centrifuged. The supernatant will be filtered, diluted into range, and analyzed using HPLC/MS/MS.

All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal

standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, to quantitate.

The RespiCon™ will be disassembled and the three filters (2.5, 10, and 100 µm cuts) will be separated and transferred to separate vials for extraction and analysis.

The inner dosimeter sections will be analyzed in accordance with SOP AEATF II-8A.2, which states that when the outer dosimeter section is below the limit of quantification (<LOQ) the corresponding inner dosimeter section will not be analyzed.

Equivalent instrumentation, apparatus, and reagents may be substituted for those specified in the method. All substitutions must be clearly documented in the raw data.

C. Storage Stability

A 6 month storage stability study to determine the stability of BIT on the various matrices under freezer storage conditions will be performed as part of a separate validation study.

D. Sample Quantitation

Chromatographic quantitation (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas of injections of several concentrations of standards. The standard curve will be a 1/X weighted least square fit unless otherwise approved by the AEATF II. Means and standard deviations (arithmetic or geometric), and coefficients of variation may be calculated on the data generated.

E. Data Analysis

The AEATF II will not statistically analyze the monitoring data in order to investigate the relationship between exposure and other factors (e.g., environmental conditions including temperature, humidity, air turnover rate, etc.) However, regulators and other users of the constructed database (BHED) may choose to conduct such analyses. The extent of AEATF II's data analyses will be limited to the statistical characterization of data adequacy for inclusion in BHED scenario monographs. Two specific types of analyses will be performed (these analyses are discussed in more detail in the AEATF II's Governing Document (AEATF II, 2008)).

A confidence interval based approach will be used to determine the realized relative accuracy for the arithmetic mean and 95th percentile of exposure normalized by amount of ai handled.

If the benchmark accuracy goal (i.e., k=3) is not met once the data are collected and analyzed, the AEATF II will, in consultation with regulatory agencies, determine the best course of action to take. This may mean the development of guidance for the use of these data that takes the increased imprecision of the estimates into account. It is possible that collection of additional monitoring events might be considered.

13. STUDY RECORDS

A. Field Records

Raw data will be obtained to cover all aspects of the study, including but not limited to the following:

1. Test and reference substance lot numbers, receipt and storage location(s), use records;
2. Application equipment details;
3. Environmental conditions during each monitoring event;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, and photos or video showing facial features or distinguishing marks on the body maintained apart from other raw data in a secure archive marked confidential;
5. Site location map, including building floor plan or sketches and plans or sketches of the treatment rooms or areas with approximate dimensions. The location of the dressing area and sample collection areas in relation to treatment areas will be noted;
6. The duration of each ME, total amount of test substance applied, and estimates of the surface area treated in each ME for both brush and roller;
7. Dermal exposure sampling information;
8. Inhalation exposure sampling information, including pump identification, calibration, flow rates and times of sampling;
9. Test substance temperature records;
10. Observations on work practices; including photographs and videography (if any of these include faces or other identifiers of subjects, they will be stored separately and securely along with other records identifying subjects);
11. Sample information (including inventory, chain of custody);
12. Resume or curriculum vitae of each study team member participating in the study, including the Spanish-speaking team members.

Field raw data will be recorded directly into a raw data file customized for use in the study. All data generated in this study, except study subject personal information, will be kept in secure files bearing the study number until transferred to a permanent location selected by the Sponsor. Study subject personal information will be maintained in a separate location at GPL and will be marked confidential.

B. Analytical Records

All study-specific original documents and data generated in the course of this study, including but not limited to the following, will be maintained and turned over to the AEATF II when requested, or at the completion of the study:

1. Analytical worksheets, chromatograms, methods, residue calculation sheets and other pertinent analytical data;
2. Laboratory notebooks or bench sheets used to record details of the analyses;
3. Chromatograms and/or machine-generated analysis reports and data.
4. Spreadsheets and other calculated data;
5. Chain of custody records.

In addition to the above study-specific raw data, the following records must also be kept, and true copies submitted with the raw data:

a. Reference substances and samples storage temperature records;
b. Reference substance use log;
c. Communications logs or records.

C. Communication with IRB

Prior to conducting studies involving human subjects, written approval from an IRB will be obtained by the Study Director/Principal Investigator. The package of information that will be submitted to the IRB is composed of the Study Protocol, a copy of the product label (Appendix A), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), test substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix G), interview scripts (Appendix H), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). Justification for Amount of Product Applied and Area Treated will be provided as a stand-alone document (AEATF, 2013). Following submission of the package of information to the IRB for review, all correspondence with the IRB, including any requests for

changes in the protocol, informed consent and recruitment materials will be documented and saved. All correspondence with the IRB, all intermediate drafts as well as the final approved ICF will accompany the study protocol when it is submitted to the EPA for review, before initiation of the study. Following final review of the protocol by the EPA, any additional communication with the IRB will be submitted to the EPA with the final report.

Since this study will be conducted in the state of California, changes requested by California DPR will be implemented and will also be documented. The study will not be initiated prior to receiving review from the EPA and approval from California DPR.

All study-specific documents, including correspondence and changes in the protocol, and Informed Consent Form generated in the course of this study will be maintained in the raw data.

14. STUDY LOCATIONS

The analytical phase location for this study will be at 4720 W. Jennifer Ave., Suite 105, Fresno, CA. The field phase location will be a commercial facility in Fresno County, California. The location of each facility will be recorded in the study files.

15. DATA HANDLING

A. Communication of Results

Results will be communicated from the Principal Investigator to the Sponsor's representative or designated AEATF II Study Monitors on a regular and timely schedule.

Following completion of the study, a simple summary of the study will be made in which the range of exposure (low to high clearly labeled) is shown on a single page. For individual participants requesting their results, an arrow will be drawn on the continuum indicating where the individual result fell compared to the group. A very short narrative will indicate what work task was measured, and clearly indicate that generally less exposure is desirable when handling any chemical.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D. and 12.E.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The field site as well as the analytical facility will be inspected by the quality

assurance unit (QAU). The QAU will report to a member of Golden Pacific Laboratory's Board of Directors. The QAU will review the protocol prior to study initiation. Different phases of the field study and the exposure matrix analyses will be inspected. Field and analytical data generated will be audited as the study progresses. The final report will be audited for completeness and accuracy. Results of the audit will be transmitted to both the Study Director and the Sponsor's Representative. QAU organization and responsibilities are summarized in SOPs AEATF II-5A.1 – 5C.1; 5E.1 – 5K.1.

17. SAMPLE RETENTION

All matrices, sample extracts and reference substances will be retained until the Study Director and Sponsor's Representative determine they are no longer useful. These materials are the property of the AEATF II and will be stored or disposed of in a safe and lawful manner by the appropriate authorized personnel with the approval of AEATF II.

18. FINAL STUDY REPORT

One report will be written summarizing the entire study. A final report formatted per PR 2011-3 will be prepared by the Study Director following procedures in SOP AEATF II-4A.1. The original signed copy of the final study report will be maintained at Golden Pacific Laboratories, LLC until the Sponsor requests that the report be transferred to another facility.

The report must contain, but is not limited to containing the following:

1. Identification of the location of the study, and the general environmental conditions during the exposure monitoring period(s).
2. A record of the application, including a description of the subject's activities.
3. A summary of subject observations identifying any specific occurrences that may contribute to unusual subject exposure.
4. A detailed summary of the amount of test substance applied by each subject.
5. A detailed summary of the length of time each subject was monitored.
6. A complete description of collection, handling and storage of field samples.
7. Results of analysis.
8. A detailed description of the methods.
9. Example calculations.
10. A summary of the recovery data.
11. Representative chromatograms of control, treated, fortified samples and calibration standards.
12. A typical standard curve.

13. Statistical analysis plan for the data generated.
14. The signed protocol, including all amendments and deviations.
15. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
16. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
17. Any adverse findings and the nature and magnitude of every event.
18. All correspondence with California DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the IRB in writing by letter, fax or email. The Principal Investigator shall follow written instructions provided by SAIRB for prompt reporting to the SAIRB, appropriate institutional officials, the EPA and California DPR of unanticipated problems involving risks to human subjects or others. The Principal Investigator shall also follow the protocol change notification and approval policies, if any, of all other agencies or boards whose notification and prior approval of the study was required.

A. Amendments

Proposed changes (amendments) deemed necessary to eliminate apparent immediate hazards to the human subjects may be implemented without prior IRB approval. All other amendments relating to human subjects must be reviewed and approved by the IRB prior to implementation. Approval will be granted in accordance with SAIRB policy and procedures, and may be granted by telephone provided it is documented in writing (e.g., email) in the study raw data. SAIRB may provide expedited review of minor changes as defined by 40 CFR Part 26.1110 at its discretion.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by SAIRB prior to implementation. The Principal Investigator will report any subject protection related protocol deviation or event occurring during field testing to SAIRB by fax or e-mail as soon as possible following the occurrence. Deviations and any response from SAIRB will be included in the final study report and associated documentation as specified in 40 CFR 26.1303.

20. PERSONNEL

A. Study Director/ Principal Investigator

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C. Field Coordinators

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19. PROTOCOL APPROVALS

Has Shah March 15, 2016
Has Shah, Ph.D. Date
Sponsor's Representative

03/15/16
Robert J. Testman, M.B.A. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

03/15/16
Megan T. Boatwright, B.S. Date
Field Coordinator (English)
Golden Pacific Laboratories, LLC

03/15/16
Kimon P. Acedo, B.S. Date
Analytical Coordinator
Golden Pacific Laboratories, LLC

Reviewed By:

03/15/16
Margaret A. Hamelin, B.S., RQAP-GLP Date
Quality Assurance
Golden Pacific Laboratories, LLC

20. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2013. INTERIOR LATEX PAINT APPLICATION WITH BRUSH AND ROLLER SCENARIO: RATIONALE FOR STUDY DESIGN. American Chemistry Council, Arlington, VA.

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2008. Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. January 2008. American Chemistry Council, Arlington, VA.

EPA 1998. Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database. Version 1.1 August 1998

EPA 2005. Reregistration Eligibility Decision (RED) for Benzisothiazoline-3-one. September 29, 2005, US EPA, Office of Pesticide Programs.

Gijsbers, J.H.J, Tielemans, E., Brouwer, D., and Van Hemmen, J.J. *Dermal Exposure During Filling, Loading and Brushing with Products Containing 2-(2-Butoxyethoxy)ethanol*. Ann. Occup. Hyg., Vol. 48, No. 3, pp. 219-227, 2004.

Golden Pacific Laboratories (GPL) 2013 (ongoing). Validation of Method GPL-MTH-079: Analytical Method for the Determination of Benzisothiazolinone (BIT) in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters AND Freezer Storage Stability of BIT in Paint, Dressing Sponges, Hand Washes, Cotton Inner and Outer Dosimeters, Air Sampling Tubes and Fiberglass Filters

OECD 1997. Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application. (1997). OECD Environmental Health and Safety Publications. Series on Testing and Assessment No. 9. OECD/GD(97)148.

Popendorf, W., M. Selim, B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa

Ross, J., Chester, G., Driver, J., Lunchick, C., Holden, L., Rosenheck, L., and Barnekow, D. 2008. Comparative Evaluation of Absorbed Dose Estimates Derived from Passive Dosimetry Measurements with Those Derived From Biological Monitoring: Validation Of Exposure Monitoring Methodologies, J Expos Sci Environ Epidemiol. 18: 211-230.

APPENDIX A: LABEL FOR PRODUCT TO BE USED IN STUDY

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012 Complies with:			
OTC	Yes	LEED®09 CI	Yes
SCAQMD	Yes	LEED®09 NC	Yes
CARB	Yes	LEED®09 CS	Yes
CARB SCM2007	Yes	LEED®09 H	Yes
MPI #	53	NGBS	Yes

CHARACTERISTICS

SuperPaint Interior Latex Flat is for use on previously painted, bare or primed wallboard and wood, and primed plaster, masonry, and metal. SuperPaint provides one coat hiding over any color on smooth surfaces and will provide a durable, scrubbable, and washable finish.

Color: Most colors
To optimize hide and color development, always use the recommended P-Shade primer
Coverage: 350 - 400 sq ft/gal @ 4 mils wet; 1.6 mils dry
Drying Time, @ 77°F, 50% RH:
Touch: 1 hour
Recoat: 4 hours
Drying and recoat times are temperature, humidity, and film thickness dependent
Flash Point: N/A
Finish: 0-5 units @ 85°
Tinting with CCE:

Base	oz/gal	Strength
Extra White	0-6	125%
Deep Base	4-12	100%
Hi Refl White	0-5	125%

Vehicle Type: Vinyl Acrylic
A86W00151
VOC (less exempt solvents): <50 g/L; 0.42 lb/gal
As per 40 CFR 59.406 and SOR/2009-264, s.12
Volume Solids: 43 ± 2%
Weight Solids: 61 ± 2%
Weight per Gallon: 12.1 lb

SPECIFICATIONS

SuperPaint Interior Latex can be used directly over existing coatings, or bare drywall, plaster (cured with a pH of less than 9), masonry (cured with a pH of less than 9) and non-bleeding wood.

Drywall
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Masonry / Block
(can be filled to provide a smooth surface or primed if it is a high pH substrate)
1 ct. Loxon Block Surfacer
or
1 ct. Loxon Concrete & Masonry Primer
2 cts. SuperPaint Interior Latex

Plaster
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex

Wood
Self-prime using 2 cts. of SuperPaint Interior Latex
or
1 ct. Premium Wall & Wood Primer
2 cts. SuperPaint Interior Latex
If the wood has bleeding (such as tannin or knot-holes), prime with Multi-Surface Primer.

Other primers may be appropriate.

When repainting involves a drastic color change, a coat of primer will improve the hiding performance of the topcoat color.

SURFACE PREPARATION

WARNING! Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.

Remove all surface contamination by washing with an appropriate cleaner, rinse thoroughly and allow to dry. Existing peeled or checked paint should be scraped and sanded to a sound surface. Glossy surfaces should be sanded dull. Stains from water, smoke, ink, pencil, grease, etc. should be sealed with the appropriate primer/sealer.

Drywall
Fill cracks and holes with patching paste/spackle and sand smooth. Joint compounds must be cured and sanded smooth. Remove all sanding dust.

Masonry, Concrete, Cement, Block
All new surfaces must be cured according to the supplier's recommendations—usually about 30 days. Remove all form release and curing agents. Rough surfaces can be filled to provide a smooth surface. If painting cannot wait 30 days, allow the surface to cure 7 days and prime the surface with Loxon Concrete & Masonry Primer.

continued on back

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

SURFACE PREPARATION

Plaster
Bare plaster must be cured and hard. Textured, soft, porous, or powdery plaster should be treated with a solution of 1 pint household vinegar to 1 gallon of water. Repeat until the surface is hard, rinse with clear water and allow to dry.

Wood
Sand any exposed wood to a fresh surface. Patch all holes and imperfections with a wood filler or putty and sand smooth.

Mildew
Remove before painting by washing with a solution of 1 part liquid bleach and 3 parts water. Apply the solution and scrub the mildewed area. Allow the solution to remain on the surface for 10 minutes. Rinse thoroughly with water and allow the surface to dry before painting. Wear protective eyewear, waterproof gloves, and protective clothing. Quickly wash off any of the mixture that comes in contact with your skin. Do not add detergents or ammonia to the bleach/water solution.

Caulking
Gaps between walls, ceilings, crown moldings, and other interior trim can be filled with the appropriate caulk after priming the surface.

APPLICATION

Apply at temperatures above 50°F.
No reduction needed.
Brush
Use a nylon/polyester brush.
Roller
Use a 3/8" - 3/4" nap synthetic cover.
Spray—Airless
Pressure..... 2000 psi
Tip..... .017"-.021"

CLEANUP INFORMATION

Clean spills, spatters, hands and tools immediately after use with soap and warm water. After cleaning, flush spray equipment with mineral spirits to prevent rusting of the equipment. Follow manufacturer's safety recommendations when using mineral spirits.

CAUTIONS

For interior use only.
Protect from freezing.
Non-photochemically reactive.

LABEL CAUTIONS
CAUTION contains CRYSTALLINE SILICA. Use only with adequate ventilation. To avoid overexposure, open windows and doors or use other means to ensure fresh air entry during application and drying. If you experience eye watering, headaches, or dizziness, increase fresh air, or wear respiratory protection (NIOSH approved) or leave the area. Adequate ventilation required when sanding or abrading the dried film. If adequate ventilation cannot be provided wear an approved particulate respirator (NIOSH approved). Follow respirator manufacturer's directions for respirator use. Avoid contact with eyes and skin. Wash hands after using. Keep container closed when not in use. Do not transfer contents to other containers for storage. FIRST AID: In case of eye contact, flush thoroughly with large amounts of water. Get medical attention if irritation persists. If swallowed, call Poison Control Center, hospital emergency room, or physician immediately. DELAYED EFFECTS FROM LONG TERM OVEREXPOSURE. Abrading or sanding of the dry film may release crystalline silica which has been shown to cause lung damage and cancer under long term exposure. WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. DO NOT TAKE INTERNALLY. KEEP OUT OF THE REACH OF CHILDREN.
HOTW 03/25/2013 A86W00151 09 47

The information and recommendations set forth in this Product Data Sheet are based upon tests conducted by or on behalf of The Sherwin-Williams Company. Such information and recommendations set forth herein are subject to change and pertain to the product offered at the time of publication. Consult your Sherwin-Williams representative to obtain the most recent Product Data Sheet.

101.02

SHERWIN WILLIAMS.

SUPERPAINT®

Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

Desde el 01/12/2012, cumple con:			
OTC	SI	LEED® 09 CI	SI
SCAQMD	SI	LEED® 09 NC	SI
CARB	SI	LEED® 09 CS	SI
CARB SCM 2007	SI	LEED® 09 H	SI
MPI N.°	53	NGBS	SI

CARACTERÍSTICAS

SuperPaint Interior Latex Flat se utiliza en paneles y maderas vírgenes, imprimados o con pintura previa, así como en revoque imprimado, mampostería y metales. SuperPaint permite cubrir con una capa cualquier color en superficies lisas y ofrece un acabado duradero que se puede lavar y fregar.

Color: Disponible en la mayoría de los colores

Para optimizar la cobertura y la coloración, utilice siempre el imprimador P-Shade recomendado.

Rendimiento: 350-40 ft²/gal (7,2-8,1 m²/L) a 4 mils húmedo; 1,6 mils seco

Tiempo de secado a 77 °F (25 °C) y 50 % RH:

Tacto: 1 hora
Repintado: 4 horas

Los plazos de secado y repintado dependen de la temperatura, la humedad y el espesor de la capa.

Punto de inflamación: N/C

Acabado: 0-5 unidades a 85°

Tinturas con CCE:

Base	oz/gal	Fuerte
Extrablanco	0-6	125 %
Base profunda	4-12	100 %
Blanco de alta reflectividad	0-5	125 %

Tipo de vehículo: Acrílico vinilo

A86W00151

COV (salvo solventes exentos): <50 g/L; 0,42 lb/gal

Conforme al Código de Reglamentos Federales [CFR], Título 40, Artículo 59.406, y a las Regulaciones de Productos Orgánicos [SOR] 2009-264, art. 12

Sólidos por volumen: 43 ± 2 %

Sólidos por peso: 61 ± 2 %

Peso por galón: 12,1 lb (5,4 kg)

ESPECIFICACIONES

SuperPaint Interior Latex se puede aplicar directamente sobre revestimientos previos o sobre paneles de yeso sin pintar, revoque (curado con un pH menor a 9), mampostería (curada con un pH menor a 9), madera sin sangrado.

Panel de yeso
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Mampostería/bloques
(se pueden rellenar para obtener una superficie lisa o imprimar si se trata de un sustrato con un pH alto)
1 capa Loxon Block Surfacer
o
1 capa Loxon Concrete & Masonry Primer
2 capas SuperPaint Interior Latex

Revoque
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex

Madera
Autoimprimación con 2 capas de SuperPaint Látex para interiores
o
1 capa Premium Wall & Wood Primer
2 capas SuperPaint Interior Latex
Si la madera presenta sangrados (como taninos u orificios de nudos), aplique una capa de imprimador con Multi-Surface Primer.

Otros imprimadores podrían ser adecuados.

Cuando volver a pintar implique un cambio de color drástico, la presencia de una capa de imprimador mejorará el poder cubritivo del revestimiento de color definitivo.

PREPARACIÓN DE LA SUPERFICIE

¡ADVERTENCIA! La eliminación de la pintura vieja mediante lija, raspaje u otro medio podría generar polvo o vapores que contengan plomo. La exposición al polvo y vapores con plomo podría causar un daño cerebral u otros problemas de salud, especialmente en el caso de niños y embarazadas. Para controlar la exposición al plomo y otras sustancias peligrosas se necesita utilizar equipos de protección adecuados, como un respirador bien ajustado (aprobado por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) y una contención y limpieza correctos. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-LEAD (en los EE. UU.) o comuníquese con la autoridad sanitaria local.

Elimine de las superficies cualquier tipo de contaminación lavándolas con un limpiador adecuado, enjuague minuciosamente y deje que se sequen. La pintura descascarada o marcada se debería rasquetear y lijar hasta lograr una superficie sólida. Las superficies brillantes se deberían lijar hasta quitarles el brillo. Las manchas causadas por agua, humo, tinta, lápiz, grasa, etc. se deberían sellar utilizando el imprimador/sellador adecuado.

Panel de yeso
Llene las grietas y perforaciones con enduido/masilla y lije hasta que la superficie quede lisa. Los compuestos para juntas se deben curar y lijar hasta que la superficie quede lisa. Elimine todo el polvo producido al lijar.

Mampostería, concreto, cemento, bloques
Todas las superficies nuevas se deben curar según las recomendaciones del proveedor (normalmente, durante unos 30 días). Elimine todo tipo de agente desmoldante y de curado. Las superficies ásperas se deben empastar para obtener una superficie lisa. Si no pudiera esperar 30 días para comenzar a pintar, deje que la superficie se cure durante 7 días y luego imprima la superficie con Loxon Concrete & Masonry Primer.

SHERWIN WILLIAMS.

101.02

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PREPARACIÓN DE LA SUPERFICIE

Revoque
El revoque sin pintar se debe curar y dejar endurecer. El revoque texturado, blando, poroso o granulado debería tratarse con una solución de 1 pinta (473 cm^3) de vinagre de uso doméstico y 1 galón (3,79 L) de agua. Repita hasta que la superficie esté dura, luego enjuague con agua limpia y deje que se seque.

Madera
Lije la madera expuesta para lograr una superficie indemne. Emparche todos los orificios e imperfecciones con masilla o enduido para madera y lije hasta que la superficie quede lisa.

Moho
Antes de pintar, elimine el moho con una solución de 1 parte de blanqueador líquido y 3 partes de agua. Aplique la solución y friegue el área mohosa. Deje trabajar la solución sobre la superficie durante 10 minutos. Enjuague minuciosamente con agua y deje secar la superficie antes de pintarla. Utilice gafas protectoras, guantes impermeables y vestimenta de protección. Enjuague sin demora cualquier resto de la mezcla que tenga contacto con su piel. No agregue detergentes ni amoníaco a la solución de blanqueador y agua.

Enmasillado
Los espacios en las paredes, cielorrasos, molduras de comisas y otros contramarcos internos se pueden rellenar con la masilla adecuada después de imprimar la superficie.

APLICACIÓN

Aplicar a temperaturas superiores a 50 °F (10 °C).
No es necesario diluir.
Brocha
Utilice brochas de nailon/poliéster.
Rodillo
Utilice rodillos de felpa sintética de 3/8" a 3/4" (0,95 a 1,90 cm).
Pistola de pulverización sin aire
Presión ..... 2000 psi
Boquilla..... .017"-.021"

INFORMACIÓN SOBRE LIMPIEZA

Use jabón y agua tibia para limpiar derrames, salpicaduras, manos y herramientas inmediatamente después de utilizar el producto. Después de limpiar, haga correr alcohol mineral por el equipo de la pistola para evitar que se oxide. Siga las recomendaciones de seguridad del fabricante siempre que utilice alcoholes minerales.

PRECAUCIONES

Únicamente para uso en interiores.
Proteja contra el frío.
Sin reacción fotoquímica.

ETIQUETA DE PRECAUCIÓN
PRECAUCIÓN: contiene SÍLICE CRISTALINA. Utilice únicamente con una ventilación adecuada. Para evitar una exposición excesiva, abra las puertas y ventanas o utilice otros medios para garantizar la circulación de aire fresco durante la aplicación y el secado. Si le llora la vista, le duele la cabeza o sufre mareos, aumente la circulación de aire fresco, utilice protección respiratoria (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH) o abandone el lugar. Deberá haber una ventilación adecuada cuando se lije o desgaste la película seca. Si no pudiera proporcionarse una ventilación adecuada, utilice una máscara antipartículas (aprobada por el Instituto Nacional de Salud y Seguridad Ocupacional, NIOSH). Siga las instrucciones del fabricante de la máscara. Evite el contacto con ojos y la piel. Lávese las manos después de usar el producto. Mantenga el recipiente cerrado cuando no lo esté utilizando. No transfiera el contenido a otros recipientes para almacenarlo. PRIMEROS AUXILIOS: En caso de contacto ocular, enjuáguese minuciosamente con una gran cantidad de agua. Consulte a su médico si la irritación persiste. En caso de ingerir el producto, llame de inmediato al Centro de Toxicología, una sala de emergencias hospitalaria o a un médico. EFECTOS RETARDADOS CAUSADOS POR UNA EXPOSICIÓN EXCESIVA PROLONGADA El desgaste o lijado de la película seca podría liberar sílice cristalino que, según se ha comprobado, puede provocar daños pulmonares y cáncer en caso de exposición prolongada. ADVERTENCIA: Este producto contiene sustancias químicas que, según el Estado de California, provocan cáncer y defectos congénitos u otros daños reproductivos. NO INGERIR. MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.
HOTW 03/25/2013 A86W00151 09 47

La información y recomendaciones en la Hoja de Datos del Producto se basan en las pruebas realizadas por The Sherwin-Williams Company o en representación de ella. La información y recomendaciones mencionadas están sujetas a cambios y corresponden al producto ofrecido al momento de su publicación. Consulte a un representante de Sherwin-Williams para obtener la Hoja de Datos del Producto más reciente.

APPENDIX B: LABEL FOR MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Harmful if swallowed, inhaled, or absorbed through skin. Avoid breathing vapor or spray mist. Wear goggles or chemical resistant gloves (such as Barrier laminate, Butyl, Nitrile, or Neoprene Rubber, Polyvinyl Chloride).

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should:
- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID	
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call a Poison Control Center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED:	• Move person to fresh air. • If person is not breathing call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Emergency Phone Number: 800-424-9300

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage following ingestion. Monitor cardiac and circulatory shock, respiratory depression, and convulsion may be needed.

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latices, Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Solutions, Cationic Emulsions, Household Cleaning Products Including Car Washes, Car Waxes, And Silicone Emulsions, Home Care Products Including Liquid Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaners, Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	5383-121
EPA Establishment Number	5383-NJ-1

ACTIVE INGREDIENT:	% Weight
1,2-Benzisothiazolin-3(2H)-One	19.18%
INERT INGREDIENTS	80.82%
TOTAL	100.0%

DANGER

KEEP OUT OF REACH OF CHILDREN

IN CASE OF EMERGENCY:
CALL 1-800-424-9300
Net Weight:

[Produced for/Manufactured for]

Troy Chemical Corporation
One Avenue L, Newark, N.J. 07105

®MERGAL AND POLYPHASE are registered trademarks

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

PHYSICAL OR CHEMICAL HAZARDS

This product is incompatible with other chemicals (oxidizing agents)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

APPLICATION RATE: Mergal® BIT 20 is an effective preservative for most aqueous applications. Mergal® BIT 20 is suggested for use in aqueous or water-containing products and systems, including metalworking fluids, to control the growth of bacteria and fungi. Suggested rate is 0.02-0.25% w/w of Mergal® BIT 20 in the finished product. For example, use 0.5-4.5 lbs. of Mergal® BIT 20 per 1000 lbs. of finished product.

ADHESIVES USED IN FOOD PACKAGING: Follow the FDA clearances cited below. Use of Mergal® BIT 20 must not exceed 0.21 mg/in² (0.0326 mg/cm²) of finished paper and paperboard intended for contact with dry foods and 0.11 mg/in² (0.0168 mg/cm²) of finished paper and paperboard intended for contact with aqueous and fatty foods. Mergal® BIT 20 components are cleared for use by the FDA in accordance with the following conditions, as set forth under Title 21 of the Code of Federal Regulations (CFR):

21 CFR 175.105 – Components for Adhesives
21 CFR 176.170 – Components of Paper and Paperboard in contact with aqueous and fatty foods
21 CFR 176.180 – Components of Paper and Paperboard in contact with dry food
21 CFR 176.300 – Slimicides (in the manufacture of Paper and Paperboard that contact food)
21 CFR 177.2600 – Rubber articles intended for repeated use: follow instructions in paragraph (c)(4)(1)(x).

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum-0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polymer and micellar/polymer waterfloods: Thickeners such as xanthan gum and polysaccharides-0.015-0.15% on solution weight.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Protect from frost. If frozen, allow to thaw and stir well before use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER HANDLING: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

INFORMED CONSENT FORM

Study Title: (Protocol AEA09) A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Principal Investigator: Robert J. Testman, M.B.A.
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Coordinators:

Megan T. Boatwright (English)
Field Coordinator
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Natan R. Chavez (English and Spanish)
Field Research Associate
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Thomas F. Moate, M.S. (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Phone: 559-275-9091

Field Locations: (Subject Informed Consent Interview Location)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Study Procedure Location)
An unoccupied commercial building in Fresno County, CA

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 949-939-3585 (Robert Testman)

We're asking you to think about being in a research study because you have experience doing painting with a brush and roller. Your participation is voluntary. This Informed Consent Form explains the study.

You may take a copy of this form home to think about and discuss with friends or family before you decide whether you want to be in the study. If you have any questions, or if you do not understand anything in this form, please ask one of us to explain. If you would prefer to talk in Spanish, please ask. We can explain the study to you in English or Spanish.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

Purpose of this Study

Golden Pacific Laboratories is doing this research. We would like to know how much chemical may reach your skin when you paint with interior latex paint using a brush and roller. We will measure how much chemical gets on the clothing you wear and on your hands, face and neck. We will ask you to paint indoor surfaces like walls, ceilings, and trim. We also would like to know how much of the chemical is in the air you breathe during the study. This information will be provided to the U.S. Environmental Protection Agency or EPA. The EPA will use this information to evaluate the levels of exposure to chemicals in the paint product in this study and other paint products that are similar to it.

A group of companies that make products to reduce microbes is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Robert Testman, Thomas Moate, Megan Boatwright and Natan Chavez are with Golden Pacific Laboratories. Robert Testman is in charge of the study. Thomas Moate, Megan Boatwright and Natan Chavez are also trained to explain the study and answer any questions you may have. Natan Chavez speaks Spanish. He will be the main Spanish-speaking researcher.

Test Product

The test product is Sherwin-Williams Interior Latex Paint. This is a commonly used paint product. This product is used to paint walls and trim in homes and businesses. The test product contains a chemical known as BIT which helps keep bacteria from growing. We have added some extra BIT to the paint for this study, but not more than necessary to evaluate your exposure to this product. You will be given a copy of the product label. We will also give you the Material Safety Data Sheet or "MSDS" for this product, if you want it.

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Subject Selection
To be in this study you must be healthy and 18 years or older. You must be able to read and speak English or Spanish. You will need to prove your age with a Government-issued photo identification, such as a driver's license or passport. You must have experience painting with a brush and roller, but not be a professional painter. You must want to be in this study. You must be willing to sign this Consent including Experimental Subject's Bill of Rights Form, and a Qualification Worksheet. We will ask you to provide some additional personal information, and to follow the directions of the investigators.

You will not be able to participate in this research if you are employed by or a spouse of an employee of Golden Pacific Laboratories, any of the companies paying for this research, the American Chemistry Council, or a paint manufacturer; if you are pregnant or breast-feeding; if you've had allergic reactions to soap, rubbing alcohol, paint products, or chemical products (including BIT); if you have psoriasis, eczema, sores or open cuts on your skin; if you have heart or breathing problems; or if you have other health problems that would make participation difficult.

Eighteen to twenty-four people will be in this study. We will sign up a few more people than we need, in case anyone can't participate on the day of the test.

We will do the study in an unoccupied building here in Fresno County. You can participate in the study only once. If you are the alternate on one day and are not selected, you may be able to be in the study on another day.

Study Enrollment
Today you are meeting with the Principal Investigator, Robert Testman, the Field Coordinators, Megan Boatwright or Thomas Moate; or if you prefer, with a researcher who speaks Spanish. They will tell you more about what to expect during the study and what will be expected of you. They will also answer any questions you have about the study. You can decide today if you want to be in the study, or you can take this form home to discuss it with your family and friends before making your decision.

We will ask you about your painting experience and about your general health. We will ask for your name and age, and about whether you have any skin conditions on your hands. If we decide you are eligible, and if you decide you want to be in the study, we will ask you to sign this Informed Consent including Experimental Subject's Bill of Rights Form. We will then ask you for your height and weight, and we will ask you for your clothing sizes.

If we enroll you in the study we will ask you to come to the study site on a certain day and time. We will call you the day before to remind you and to make sure you still want to be in the study. We will also ask you to be sure to take a shower or a bath before coming to the study site.

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Study Procedure

If you are selected you will do the testing in small rooms built inside an unoccupied building in Fresno County. The testing will take 3 or 4 hours on one day. After you arrive you will change into special clothing for the test and get fitted with two small pumps to sample the air you breathe. Then we will ask you to paint walls, ceilings, baseboards, window trim, and door trim using both a brush and a paint roller. We will provide all the equipment you will use such as a brush, roller, roller pan, painting rags, etc. You will paint as you normally would when painting a room in your own home. You will be asked to use about two gallons of paint using multiple rooms. You can take breaks if you need to in between the rooms. This may take several hours of actual painting time. After that we will take the special clothing back, you can change back into your own clothes, get paid, and go your way.

Here's exactly what will happen.

1. On the day of the study you will go to the study location at the time you've been told, and meet the research team.

2. Robert Testman and the research team will review with you and the other participants what will happen and you will have another chance to ask questions. We will remind you that you may change your mind about being in the study at any time before or after the study begins. All you need to do is tell us you have changed your mind. There will be no penalty of any kind to you if you decide to withdraw from the study.

3. Because it is important that you NOT be in this study if you are pregnant, on the day of the test each female volunteer will go to a private area and will be given a pregnancy test kit like the ones you can buy at the drug store. A female researcher will be able to explain how to use it and answer questions. After you give yourself the test we will ask you if you want to stay in the study. If you decide not to, you won't be asked why, and the results of the test will not be recorded. You will be paid $100 for coming to the test site, and then you will be free to go. If you want to stay in the study, a trained female researcher will double-check the results with you. No-one but you and she will see the results, but we will make a note that the test was performed.

4. Before the test begins you will wash your hands and face with Ivory soap and water, and dry them with paper towels. We will check your hands to make sure you don't have cuts, scrapes, or any conditions that might increase the risk of skin problems during testing.

5. Someone of your own gender will show you to a clean, private changing area and help you get ready for the study. We will ask you to take off your street clothes down to your underwear. Then you will put on long cotton underwear (long johns), a long sleeved cotton shirt, and long cotton pants. We will provide all these clothes to you. We may need to trim the arms or legs of the long underwear so it doesn't stick out. You will put your street clothes and valuables in a locked storage area, and keep the key with you. You will wear your own shoes, but we will give you shoe covers if you want to keep paint off your shoes.

6. We will give you a painter's hat and safety glasses to wear while you are painting. You must wear the safety glasses and hat while painting with brush or roller.

7. We will attach two small air sampling pumps to a belt around your waist. If you don't have a belt, we will provide one for you to use. We will attach a small tube to your shirt collar and connect it to one of the pumps. We will attach a small air sampler to the other pump and position it in front of you with a small strap around your chest. Both of these pumps will sample the air you breathe while you are painting. Each pump is about the size of a portable radio. The tube is about the size of a pen, and the air sampler is about the size of a tennis ball.

8. We will show you the equipment that you will use to paint, including the small pail which contains the paint, the brush, the roller, the roller pan, the extension handle, and the paint rags. We will also have a paint edger and small paint cup if you want to use them. We will ask if you have any questions.

9. We will take you to one of the small rooms where you will begin your work. We will turn on your air pumps and ask you to put on your hat and safety glasses. We will give you a closed paint can which contains paint. You will open the lid of the paint can using an opening tool. You will use a brush with the paint can to paint the trim pieces on one or more of the walls. You will pour some of the paint from the paint can into the roller pan and paint the ceiling and walls with a roller. When the paint in the paint can is gone we will give you a new one until you have used up the assigned amount. One of us will watch you as you work; keeping track of how long you work and how much surface you paint. We may also take pictures or video to show what happened in the study, but those pictures will not show faces, tattoos, or other identifying features in the final report. **If you do not want to have your picture taken, you should not participate in this study.**

10. We will ask you to apply about two gallons of paint. You will work in as many rooms as it takes to use up the assigned amount of paint. You may take a short break at any time you want, just like you would do at work. You won't be able to smoke or eat during the test, but you can have a cold drink during the break. If you need to use the toilet, one of the researchers will clean your hands before you go to collect any paint that may be on them.

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11. When you finish painting, a researcher of your own gender will take you back to the changing area and collect samples:

    a. The researcher will remove the painter's hat, air sampling pumps and equipment from you;

    b. The researcher will scrub your hands with cotton pad wet with a rubbing alcohol and water mixture, rinse them with the same solution, and save the rinse solution;

    c. The researcher will wipe your face and neck with a cotton pad wet with a rubbing alcohol and water mixture to collect any of the paint that might be on your skin;

    d. The researcher will help you remove your shoes (and socks if you wish);

    e. The researcher will help you take off your outer shirt and pants and will save them for analysis;

    f. The researcher will help you take off the long underwear, and will save it for analysis.

    When we have collected all these samples, you will dress again in your street clothes. We will check your hands before you leave for redness or other signs of irritation. We will pay you $100 in cash and you will be free to go.

Risks

If you are in this study you would be exposed to several kinds of risks:

1. Risk of a reaction to the latex paint or the pesticide ingredient (BIT) contained in it. Direct contact with the paint can cause temporary eye redness, pain and swelling or skin irritation, and breathing the vapor can cause coughing and irritate your throat. You will wear safety glasses to keep the paint out of your eyes, and long sleeves and pants to keep it off your skin. You might also have an allergic reaction to the paint. You might feel dizzy or have a headache. If you have had a reaction to a paint product before be sure to tell us. If you notice any redness or itching, feel dizzy or if you think you may have gotten any of the paint in your eye, stop painting right away and tell a researcher.

2. Risk of discomfort. The air pumps on your belt and the air hoses used to sample the air you breathe may be uncomfortable. Wearing two layers of clothing may also be uncomfortable.

3. Risk of injury. You will be asked to use painting equipment and a ladder to paint rooms. If you were to lose your balance and fall you might be injured. If you feel you need help to avoid injury, or might have been injured, tell a member of the research team.

4. Risk of stinging from alcohol wash and wipes. The diluted rubbing alcohol used to scrub and rinse your hands and wipe your face and neck may sting, if you have any cuts or abrasions on your hands or face.

5. Risk from heat. Because you'll be wearing an extra layer of clothing you might get too hot. We will monitor the temperature and humidity during the test, and will stop the study if it gets too hot to be safe. If you feel faint or too hot, or are sweating a lot, stop painting right away and tell a member of the research team.

6. Risk of embarrassment. You may find it embarrassing to have a researcher with you while you change clothes. This is necessary to make sure the special clothing fits properly, and that it does not get dirty when the test is over. The researcher who helps you will be of your own gender, and will be the only other person with you. You will wear your own underwear all the time.

7. If you are female, you might be surprised to learn on the day of the research that you are pregnant. No-one but you will know if the test shows that you're pregnant, and the results will not be recorded.

Unknown/Unforeseeable Risks
Participating in this study may pose other risks to you that we don't know about or can't predict. If we learn anything new that might influence your decision to participate, we will share it with you right away.

Research-Related Injuries
If you are hurt or sick while you are participating in this study, a nearby medical facility will provide care. If necessary, we will take you there. The AEATF will pay for reasonable and appropriate medical treatment for a study-related injury or illness that is not paid for by your own insurance or the insurance of a third party under which you are covered. The Principal Investigator in consultation with the on-site medical professional will decide if you have an injury or illness that is due to your participation in the study. If within 24 hours of your participation in the study you experience a skin reaction or other adverse effect that you believe is related to your participation in the study you should seek medical treatment and call the Principal Investigator, Robert Testman, at Golden Pacific Laboratories (559 275-9091) as soon as possible. Any medical records will not be a part of the study.

You do not waive (give up) any of your legal rights by signing this form.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

Alternatives to Participation
If you decide to be in this study it will be because you want to. There will be no direct benefit to you if you do decide to participate and no harm to you if you decide not to. The choice is up to you.

Benefits
You will not benefit directly from being in this study. What we learn from this study will help make sure that paint products like Sherwin-Williams Latex Paint can be used safely. You may benefit if you ask for your own results from this study, so you can learn how much paint got on you compared to other workers doing the same task. The people who are paying for the study will also benefit from it, since they need to do this study to keep their anti-bacterial products for paint on the market.

Questions about this Study
If you have questions, you can ask them at any time; before, during, or after the study. Just ask Robert Testman or any other member of the research team.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time. Schulman IRB is in charge of protecting your rights. You can also find out more about your rights and role of research at the Schulman IRB website - www.sairb.com.

Costs and Payment
It will cost you nothing to participate in this study. At the end of the informed consent interview you will be paid $20 in cash for your time and trouble coming to our office. If you are selected for the study and come to the assigned study site, you will be paid $100 in cash when you are finished for the day, whether or not you are actually take part.

Confidentiality
We will give you a special ID number for this study, and we will record and report all data under that number. We will keep only one record linking your name to this ID number, and we will store it apart from other data, in a locked cabinet. We will not identify you by name or in any other way in study reports. Any pictures of you in a report of this study will not show your face or other identifying features (such as tattoos).

We will restrict access to records of this study to only a few people. But the people who are paying for it, the government agencies who will review the reports, and the SAIRB, Inc., that looks out for your safety may all review study records. Because of this we can't completely guarantee confidentiality. You may obtain a copy of your own records from the Principal Investigator upon request.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

Right to Withdraw
You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team. If you decide not to participate in this study or to withdraw from it, you will not be penalized in any way or lose any benefits.

Removal from Study
Robert Testman, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. He might remove you if, for example:

- He thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped because it gets too hot to continue safely, or for other reasons.

If you are removed from the study, or if the entire study is stopped, you will still be paid for your time and trouble.

SCHULMAN APPROVED
IRB#201307318
DATE: March 4, 2016

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS FORM

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told the purpose of the study;
2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice;
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me during the study;
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
5. To be told the alternatives to participating in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my status with my employer;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether I wish to participate in the study.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman IRB, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST or from 5 am to 3 pm Pacific Time,

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Robert Testman (559) 275-9091 or (949) 939-3585

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

Consent and Signature

I have read this Informed Consent Form and Subject's Bill of Rights, and all my questions have been answered in a language I understand well. I voluntarily consent to take part in this study as a research subject. I do not waive any legal rights by signing this form. I will get my own copy of this form with all signatures.

Date/Time: _____ _____
Subject's Signature

_____
Subject's Name (Print)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA09) Estudio para medir la potencial exposición dérmica y por inhalación durante la aplicación con brocha y rodillo de una pintura de látex que contiene un producto pesticida antimicrobiano en superficies interiores

Investigador principal:
Robert J. Testman, M.B.A.
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4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Coordinadores de campo:

Megan T. Boatwright (inglés)
Coordinadora de campo
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Natan R. Chavez (inglés y español)
Asociado de investigaciones en el campo
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
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Thomas F. Moate, M.S. (inglés)
Asociado de investigaciones en el campo
Gerente general
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Instalaciones en el campo:
(Lugar de la entrevista para el consentimiento informado del sujeto)
Golden Pacific Laboratories, LLC.
4720 W. Jennifer Avenue Suite 105
Fresno, CA 93722
(Lugar de los procedimientos del estudio)
Un edificio comercial vacante en Fresno County, CA

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono las 24 horas: 949-939-3585 (Robert Testman)

Le estamos pidiendo que considere participar en un estudio de investigación porque tiene experiencia pintando con brocha y rodillo. Su participación es voluntaria. Este formulario de consentimiento informado explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar y comentarlo con sus amigos o familia antes de decidir si desea participar en el estudio. Si tiene alguna pregunta o si no entiende algo de este formulario, pida a uno de nosotros que se lo expliquemos. Si prefiere hablar en español, por favor indíquelo así. Le podemos explicar el estudio en inglés o en español.

Schulman Institutional Review Board, Inc. (Schulman), un comité institucional de revisión, ha aprobado la información que contiene este documento de consentimiento y ha autorizado al médico del estudio para que efectúe el estudio. Un comité institucional de revisión (Institutional Review Board o IRB, por sus siglas en inglés) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado que usted participe en el estudio. Es a usted a quien corresponde examinar la información de este documento de consentimiento y, seguidamente, decidir si desea participar en el estudio.

Finalidad de este estudio

Golden Pacific Laboratories está llevando a cabo esta investigación. Nos gustaría saber cuánta sustancia química puede caer en su piel cuando aplica una pintura de látex para interiores con una brocha y un rodillo. Mediremos la cantidad de la sustancia química que le cae en la ropa que usa y en sus manos, cara y cuello. Le pediremos que pinte superficies interiores como paredes, cielorraso y molduras. También nos gustaría saber la cantidad de la sustancia química que se encuentra en el aire que usted respira durante el estudio. Esta información se proporcionará a la Agencia de Protección Ambiental de EE. UU. o EPA por sus siglas en inglés. La EPA usará esta información para evaluar los niveles de exposición a las sustancias químicas de la pintura de este estudio y de otras pinturas similares a ella.

Un grupo de compañías que fabrica productos para reducir la cantidad de microorganismos paga este estudio. Este grupo de compañías se llama Grupo Operativo de Evaluación de la Exposición a Agentes Antimicrobianos II (Antimicrobial Exposure Assessment Task Force II). La EPA ha registrado estos productos como pesticidas.

Robert Testman, Thomas Moate, Megan Boatwright y Natan Chavez trabajan en Golden Pacific Laboratories. Robert Testman está a cargo del estudio. Thomas Moate, Megan Boatwright y Natan Chavez también están capacitados para explicar el estudio y contestar cualquier pregunta que pudiera tener. Natan Chavez habla español. Él será el principal investigador de habla hispana.

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

Producto de prueba
El producto de prueba es una pintura de látex para interiores de Sherwin-Williams. Esta es una pintura de uso común. Este producto se usa para pintar paredes y molduras en casas y empresas. El producto de prueba contiene una sustancia química conocida como BIT que ayuda a evitar el crecimiento bacteriano. Hemos añadido una cantidad adicional de BIT a la pintura para este estudio, pero no más que la necesaria para evaluar su exposición a este producto. Se le entregará una copia de la etiqueta del producto. También le daremos la hoja de datos de seguridad del material, o "MSDS" por sus siglas en inglés, de este producto, si lo desea.

Selección de sujetos
Para participar en el estudio debe estar sano y tener 18 años de edad o más. Debe poder leer y hablar inglés o español. Necesitará comprobar su edad con un documento de identidad con fotografía expedido por el gobierno, como una licencia para conducir o un pasaporte. Debe tener experiencia pintando con brocha y rodillo, pero no ser pintor profesional. Debe querer participar en este estudio. Debe estar dispuesto a firmar este consentimiento, el formulario Declaración de derechos de los sujetos participantes en experimentos y una ficha de calificación. Le pediremos que proporcione cierta información personal adicional y que siga las instrucciones de los investigadores.

No podrá participar en esta investigación si es empleado o cónyuge de un empleado de Golden Pacific Laboratories, de cualquiera de las compañías que pagan esta investigación, del Consejo Americano de Química (American Chemistry Council) o de un fabricante de pinturas; si está embarazada o lactando; si ha tenido reacciones alérgicas al jabón, alcohol isopropílico, productos de pintura o productos químicos (incluido el BIT); si tiene psoriasis, eccema, llagas o cortaduras abiertas en la piel; si tiene problemas cardiacos o respiratorios; o si tiene otros problemas médicos que dificultaran su participación.

En este estudio participarán entre dieciocho y veinticuatro personas. Inscribiremos a unas pocas personas más que las que necesitamos en caso de que alguien no pueda participar el día de la prueba.

Haremos el estudio en un edificio vacante aquí en Fresno County. Puede participar en el estudio solamente una vez. Si en un día usted es el suplente y no se lo selecciona, es posible que pueda participar en el estudio otro día.

Inscripción en el estudio
Hoy se va a reunir con el investigador principal, Robert Testman, con los coordinadores de campo, Megan Boatwright o Thomas Moate; o si lo prefiere, con un investigador que habla español. Ellos le darán más información sobre lo que debe esperar durante el estudio y lo que se espera de usted. También contestarán cualquier pregunta que tenga sobre el estudio. Usted puede decidir hoy si desea participar en el estudio o puede llevarse a casa este formulario para conversarlo con su familia y amigos antes de tomar su decisión.

Le preguntaremos sobre su experiencia como pintor y sobre su salud general. Le preguntaremos su nombre y edad, y si tiene alguna afección en la piel de sus manos. Si decidimos que es apto, y si usted decide que quiere participar en el estudio, le pediremos que firme este consentimiento informado y el formulario Declaración de derechos de los sujetos participantes en experimentos. Luego le preguntaremos su estatura y peso y la talla de su ropa.

Si lo inscribimos en el estudio, le pediremos que venga al sitio del estudio cierto día y a cierta hora. Lo llamaremos un día antes para recordarle y asegurarnos de que aún desea participar en el estudio. También le pediremos que se asegure de tomar una ducha o darse un baño antes de ir al sitio del estudio.

Procedimiento del estudio
Si se lo selecciona, hará la prueba en cuartos pequeños construidos dentro de un edificio vacante ubicado en Fresno County. La prueba durará 3 o 4 horas en un día. Después de que llegue se pondrá ropa especial para la prueba y se le colocarán dos bombas pequeñas para tomar muestras del aire que respira. Luego le pediremos que pinte las paredes, los cielorrasos, los zócalos, la moldura de la ventana y la moldura de la puerta con una brocha y un rodillo de pintura. Le proporcionaremos todo el equipo que usará, como una brocha, un rodillo, una bandeja para el rodillo, trapos para pintura, etc. Usted pintará como lo hace normalmente cuando pinta una habitación en su propia casa. Se le pedirá que use aproximadamente dos galones de pintura en varios cuartos. Puede descansar entre cuartos si lo necesita. El tiempo real que pasará pintando puede ser de varias horas. Después recogeremos la ropa especial que usó, usted se pondrá su propia ropa, recibirá su pago y se irá.

Esto es exactamente lo que sucederá.

1. El día del estudio usted irá al sitio del estudio a la hora que se le dijo, y se reunirá con el equipo de estudio.

2. Robert Testman y el equipo de investigación revisarán con usted y con los otros participantes lo que sucederá, y usted tendrá otra oportunidad de hacer preguntas. Le recordaremos que en cualquier momento, antes o después de que comience el estudio, puede cambiar de parecer con respecto a su participación en el estudio. Todo lo que necesita hacer es decirnos que cambió de parecer. No sufrirá sanciones de ningún tipo si decide abandonar el estudio.

3. Dado que es importante que usted NO participe en este estudio si está embarazada, el día de la prueba cada voluntaria pasará a un área privada y recibirá un kit de prueba de embarazo como los que puede comprar en la farmacia. Una investigadora le explicará cómo usarlo y contestará sus preguntas. Después de hacerse la prueba le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no se le preguntará la razón y no se registrarán los resultados de la prueba. Se le pagarán $100 por venir al sitio de la prueba y entonces podrá irse. Si desea permanecer en el estudio, una investigadora capacitada verificará los resultados con usted. Nadie aparte de usted verá los resultados pero nosotros haremos una nota indicando que la prueba se hizo.

4. Antes de que comience la prueba se lavará las manos y la cara con jabón Ivory y agua, y se las secará con toallas de papel. Revisaremos sus manos para asegurarnos de que no tiene cortaduras, raspaduras ni ninguna afección que pudiera aumentar el riesgo de que sufra problemas en la piel durante la prueba.

5. Una persona de su mismo sexo lo llevará a un área limpia y privada para que se cambie y se prepare para el estudio. Le pediremos que se quite su ropa excepto la ropa interior. Luego se pondrá calzoncillos largos de algodón (*long johns*), una camiseta de algodón de mangas largas y pantalones largos de algodón. Nosotros le proporcionaremos toda esta ropa. Es posible que tengamos que recortar el reborde de las mangas o de las piernas de los calzoncillos largos para que no sobresalgan. Colocará su propia ropa y sus objetos de valor en un área de almacenamiento bajo llave, y usted conservará la llave. Usará su propio calzado, pero si quiere le daremos cubiertas para evitar que le caiga pintura en los zapatos.

6. Le daremos una gorra de pintor y gafas de seguridad para que las use mientras pinta. Debe usar estos artículos mientras pinta con la brocha o el rodillo.

7. Le instalaremos en el cinturón, alrededor de su cintura, dos pequeñas bombas para muestreo de aire. Si no lleva cinturón le proporcionaremos uno para que lo use. Le colocaremos un pequeño tubo en el cuello de la camisa y lo conectaremos en una de las bombas. Instalaremos un pequeño tomador de muestras de aire en la otra bomba y lo colocaremos frente a usted con una pequeña correa alrededor de su pecho. Ambas bombas tomarán muestras del aire que respira mientras pinta. Cada bomba es del tamaño aproximado de un radio portátil. El tubo es del tamaño de un lápiz, y el tomador de muestras de aire es aproximadamente del tamaño de una bola de tenis.

8. Le mostraremos el equipo que usará para pintar, incluido el pequeño cubo que contiene la pintura, la brocha, el rodillo, la bandeja para el rodillo, el mango de extensión y los trapos para pintura. También contaremos con ribeteadores de pintura y pequeños vasos de pintura por si desea usarlos. Le preguntaremos si tiene alguna pregunta.

9. Lo llevaremos a uno de los cuartos pequeños en donde comenzará a trabajar. Encenderemos las bombas de aire que le colocamos y le pediremos que se ponga la gorra y las gafas de seguridad. Le entregaremos una lata de pintura cerrada que contiene pintura. Quitará la tapa de la lata de pintura con un abridor. Usará una brocha con la lata de pintura para pintar las molduras de una o más paredes. Verterá algo de pintura de la lata en la bandeja para el rodillo y pintará con el rodillo el cielorraso y las paredes. Cuando se termine la pintura de la lata, le daremos una lata nueva hasta que haya usado la cantidad asignada. Uno de nosotros lo observará mientras trabaja, anotando el tiempo que trabaja y la cantidad de superficie que pinta. También podemos tomar fotografías o grabar videos para mostrar lo que sucedió en el estudio, pero en el informe final, tales fotografías no mostrarán rostros, tatuajes ni otras características identificadoras. **Si no desea que se le tomen fotografías, no debe participar en este estudio.**

10. Le pediremos que aplique aproximadamente dos galones de pintura. Trabajará en tantos cuartos como sea necesario para usar la cantidad asignada de pintura. Puede tomar un breve descanso en cualquier momento que desee, tal como lo haría en el trabajo. No podrá fumar ni comer durante la prueba, pero puede consumir una bebida fría durante su descanso. Si necesita usar el baño, uno de los investigadores le limpiará sus manos antes de que vaya, para recoger cualquier pintura que pueda tener en ellas.

11. Cuando termine de pintar, un investigador de su mismo sexo lo llevará al área donde se cambia la ropa y le tomará muestras:

    a. El investigador le quitará la gorra de pintor, las bombas tomadoras de muestras de aire y el equipo.

    b. El investigador frotará sus manos con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua, se las enjuagará con la misma solución y guardará la solución del enjuague.

    c. El investigador le limpiará la cara y el cuello con una almohadilla de algodón humedecida con una mezcla de alcohol isopropílico y agua para recoger cualquier pintura que pudiera tener en la piel.

    d. El investigador lo ayudará a quitarse los zapatos (y los calcetines si lo desea).

    e. El investigador lo ayudará a quitarse la camiseta y los pantalones y los guardará para analizarlos.

    f. El investigador lo ayudará a quitarse los calzoncillos largos y los guardará para analizarlos.

Cuando hayamos tomado todas estas muestras, se vestirá otra vez con su propia ropa. Revisaremos sus manos antes de que se vaya para ver si las tiene enrojecidas o muestra otros signos de irritación. Le pagaremos $100 en efectivo y podrá irse.

Riesgos
Si participa el este estudio estaría expuesto a varias clases de riesgos:

1. El riesgo de una reacción a la pintura de látex o al ingrediente de pesticida (BIT) de la pintura. El contacto directo con la pintura puede causar enrojecimiento de los ojos, dolor e inflamación o irritación de la piel, de manera temporal, y la respiración del vapor puede causar tos e irritar su garganta. Usará gafas de seguridad para evitar que le caiga pintura en los ojos, y camiseta de manga larga y pantalones para evitar que le caiga pintura en la piel. También podría tener una reacción alérgica a la pintura. Pudiera sentirse mareado o tener dolor de cabeza. Si anteriormente ha tenido una reacción a un producto de pintura, asegúrese de decírnoslo. Si nota enrojecimiento o comezón, se siente mareado o piensa que le cayó pintura en los ojos, deje de pintar inmediatamente y dígaselo al investigador.

2. Riesgo de molestia Las bombas de aire instaladas en su cinturón y las mangueras de aire usadas para muestrear el aire que respira pueden causarle incomodidad. También pudiera resultarle incómodo usar dos capas de ropa.

3. Riesgo de lesiones Se le pedirá que use equipo para pintura y unas escaleras para pintar los cuartos. Si perdiera el equilibrio y cayera pudiera resultar herido. Si piensa que necesita ayuda para evitar lesionarse, o pudiera haberse lesionado, dígaselo a un miembro del equipo de investigación.

4. Riesgo de escozor causado por el lavado con alcohol y las toallitas El alcohol isopropílico diluido usado para frotar y enjuagar sus manos y limpiar su cara y cuello puede causarle escozor si tiene alguna cortadura o abrasiones en las manos o en la cara.

5. Riesgo de calor Como usará una capa adicional de ropa, pudiera tener demasiado calor. Supervisaremos la temperatura y la humedad durante la prueba, y detendremos el estudio si aumenta demasiado la temperatura para su seguridad. Si siente desvanecerse o demasiado calor, o está sudando mucho, deje de pintar inmediatamente y notifíquelo a un miembro del equipo de investigación.

6. Riesgo de sentir vergüenza Es posible que sienta vergüenza que un investigador esté presente mientras se cambia de ropa. Esto es necesario para asegurarnos de que la ropa le queda adecuadamente y que no se ensucie cuando termine la prueba. El investigador que lo ayudará será de su mismo sexo y será la única persona presente con usted. Usted usará su propia ropa interior en todo momento.

7. Si es mujer, le podría sorprender enterarse el día de la investigación que está embarazada. Solamente usted sabrá si los resultados de la prueba muestran que está embarazada, y no se registrarán estos resultados.

Riesgos desconocidos o imprevisibles
La participación en este estudio pudiera conllevar otros riesgos que desconocemos o que no podemos predecir. Si nos enteramos de algo nuevo que pudiera influenciar su decisión de participar, se lo notificaremos inmediatamente.

Lesiones relacionadas con la investigación
Si se lesiona o enferma mientras participa en el estudio, se le proporcionará atención en una instalación médica cercana. Si es necesario lo llevaremos ahí. AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no pague su propio seguro o el seguro de un tercero en el cual tenga cobertura. El investigador principal, en consulta con el profesional médico del sitio, decidirán si usted sufre una lesión o enfermedad que se debe a su participación en el estudio. Si dentro del período de 24 horas de su participación en el estudio experimenta una reacción en la piel u otro efecto adverso que usted cree que se relaciona con su participación en el estudio, debe buscar tratamiento médico y llamar al investigador principal, Robert Testman, a Golden Pacific Laboratories (559 275-9091) tan pronto como sea posible. Ningún expediente médico formará parte del estudio.

Al firmar este formulario no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio será porque usted quiere hacerlo. No recibirá un beneficio directo si decide participar y no sufrirá daños si decide no participar. Es su decisión.

Beneficios
Su participación en este estudio no le producirá beneficios directos. Lo que aprendamos de este estudio nos ayudará a asegurarnos de que los productos de pintura como la pintura de látex de Sherwin-Williams se puede usar con seguridad. Usted se pudiera beneficiar si pide sus resultados de este estudio, pues se puede enterar de cuánta pintura le cayó en el cuerpo en comparación con otros trabajadores que hicieron la misma tarea. Las personas que pagan el estudio también se beneficiarán del mismo, ya que ellos necesitan hacer este estudio para mantener en el mercado sus productos antibacterianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede formularlas en cualquier momento, antes durante o después del estudio. Simplemente hágalas a Robert Testman o a cualquier otro miembro del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico. Schulman IRB está a cargo de proteger sus derechos. Puede encontrar más información sobre sus derechos y el papel de los investigadores en el sitio web de Schulman IRB, www.sairb.com.

Costos y pagos
No le costará nada participar en este estudio. Al final de la entrevista para el consentimiento informado se le pagarán $20 en efectivo por su tiempo y las inconveniencias de venir a nuestra oficina. Si se lo selecciona para el estudio y va al sitio del estudio asignado, se le pagarán $100 en efectivo cuando termine el día, independientemente de si participa o no.

Confidencialidad
Le daremos un número de ID especial para este estudio y registraremos e informaremos todos los datos usando este número. Solo conservaremos un registro que relacione su nombre con este número de ID, y lo guardaremos separado de otros datos, en un gabinete bajo llave. No lo identificaremos por su nombre ni de ninguna otra manera en los informes del estudio. Ninguna fotografía suya que se use en un informe de este estudio mostrará su cara ni ninguna otra característica que lo identifique (como tatuajes).

Restringiremos el acceso a los expedientes de este estudio a solo unas pocas personas. Pero las personas que pagan el estudio, las agencias gubernamentales que revisarán los informes, y SAIRB, Inc., que vigila su seguridad, pueden revisar los expedientes del estudio. Debido a esto no podemos garantizar completamente la confidencialidad. Puede obtener una copia de sus propios expedientes con el investigador principal si la solicita.

Derecho a retirarse del estudio
Puede retirarse de este estudio en cualquier momento, por cualquier motivo. Simplemente notifíquelo a cualquier miembro del equipo de investigación. Si decide no participar en este estudio o retirarse del mismo, no se lo penalizará de ninguna manera ni perderá ningún beneficio.

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

Retiro del estudio
Robert Testman, el investigador principal a cargo de este estudio, puede retirarlo del estudio aunque usted desee permanecer en él. Lo pudiera retirar si, por ejemplo:

- Piensa que si usted permanece en el estudio correría riesgos.
- Usted no sigue las indicaciones de los investigadores.
- El estudio se detiene porque aumenta mucho la temperatura para continuar de forma segura, o por otra razón.

Si se lo retira del estudio o si se detiene todo el estudio, se le pagará de todas maneras por su tiempo e inconveniencias.

FORMULARIO DECLARACIÓN DE DERECHOS DE LOS SUJETOS PARTICIPANTES EN EXPERIMENTOS

Los siguientes son los derechos de cualquier persona a la que se pide que participe en un estudio de investigación. Como sujeto de un experimento, tengo los siguientes derechos:

1. Que se me diga el propósito del estudio.
2. Que se me diga lo que me sucederá y si cualquiera de los procedimientos, pesticidas o dispositivos es diferente del que se utilizaría en la práctica normal.
3. Que se me informe acerca de los riesgos, efectos secundarios o malestares frecuentes e/o importantes, o de las cosas que me sucederán durante el estudio.
4. Que se me informe si puedo esperar algún beneficio de mi participación y, de ser así, cuál podría ser el beneficio.
5. Que se me digan las alternativas a participar en el estudio.
6. Que se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el curso del estudio.
7. Que se me diga qué tipo de tratamiento médico está disponible en caso de que surjan complicaciones.
8. Rehusarme absolutamente a participar o cambiar de parecer acerca de mi participación después de que el estudio haya comenzado. Esta decisión no afectará mi estado con mi empleador.
9. Recibir una copia del formulario de consentimiento firmado y fechado; y
10. No ser presionado cuando esté considerando si deseo participar en el estudio;

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación, y/o inquietudes o quejas con respecto a este estudio de investigación, escriba a Schulman IRB, Inc., 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, o llame al número gratuito 1-888-557-2472 en horas de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p.m., hora del este o de 5 a. m. a 3 p. m. hora del Pacífico.

Si tiene otras preguntas, debe formularlas al investigador principal o a los investigadores del estudio.

Contactos telefónicos:

Investigador principal: Robert Testman (559) 275-9091 o (949) 939-3585

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de Derechos de los Sujetos, y todas mis preguntas han sido contestadas en un idioma que entiendo bien. Acepto voluntariamente participar en este estudio como sujeto de investigación. Al firmar este formulario no renuncio a ninguno de mis derechos legales. Recibiré mi propia copia de este formulario con todas las firmas.

Fecha y hora: _____ _____
Firma del sujeto

_____
Nombre del sujeto (en letra de imprenta)

[*For Spanish language version of the IC document only, but in English*]
This Informed Consent Form has been explained to the volunteer named above in Spanish. I have faithfully responded to all questions from the volunteer. I believe the volunteer understands the information and has freely and voluntarily agreed to participate in the research.

Date/Time: _____ _____
Spanish Speaking Researcher's Signature

_____
Spanish Speaker's Name (Print)

I have reviewed this Informed Consent Form with the volunteer named above, and answered all his/her questions. I have made every effort to ensure the volunteer understands the purpose, risks and benefits of the research, what will happen on the day of the test, and his/her freedom to withdraw at any time and for any reason. I have done this in circumstances that minimize the possibility of coercion or undue influence, and I believe the volunteer has made an informed and free choice to participate.

Date/Time: _____ _____
Robert J. Testman
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

APROBADO POR SCHULMAN
IRB N.° 201307318
FECHA: 4 de marzo de 2016

SchulmanIRB

CERTIFICATION OF TRANSLATION

Protocol Number: AEA09
IRB Number: 201307318
PI: Robert J. Testman, M.B.A.
Material Type (if applicable): Informed Consent
Description (if applicable):
This is to certify that this Spanish translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Diane Barrett

Translated from English source document approved 03/04/2016

Diane Barrett 03/10/2016

ata A Corporate Member of the American Translators Association
Schulman Associates, IRB, Inc. (ATA Member No. 252187)

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA09: Interior Latex Paint Application with Brush and Roller Scenario

Part I: *Interview questions*		**Q/NQ**
1. Do you have any skin conditions on your hands (psoriasis, eczema, etc.)?	☐Yes ☐ No	
2. Do you have difficulty breathing? Moderate or severe asthma or emphysema?	☐Yes ☐ No	
3. Do you have Cardiovascular disease? Have you ever had a myocardial infarct, stroke, or congestive heart failure? Do you have uncontrolled high blood pressure?	☐Yes ☐ No	
4. Do you have other health problems that might make it difficult to participate in this study as described? ☐ No	☐Yes	
5. Are you employed by or married to an employee of an AEATF company, GPL, a paint manufacturer or the ACC (interviewer to explain initials of various entities)?	☐Yes ☐ No	

Part II: *To be filled out by candidate*				
6. Name			9. Weight: lbs	
7. Address			10. Height: ft in	
			11. Shirt size: ☐ **S** ☐ **M** ☐ **L** ☐ **XL** ☐ **XXL** ☐ **XXXL**	
8. City, ST, Zip			12. Waist: ☐ 24-28 in ☐ 28-32 in ☐ 32-36 in	
13. Telephone(s)			☐ 36-40 in ☐ 40-44 in ☐ 44-50 in	
14. Age in years =	15. DOB:	16. Sex ☐ M ☐ F		
17. Resident in Fresno County? ☐ Yes ☐ No		18. Have you painted with a brush and roller in the past 5 years? ☐Yes ☐ No		
		19. Have you worked as a professional painter in the past 10 years? ☐Yes ☐ No		
20. Preferred Language: ☐ English ☐ Spanish		21. Reads: ☐ English ☐ Spanish		
22. Are you pregnant? ☐ NA ☐Yes ☐ No		23. Are you nursing a baby? ☐ NA ☐Yes ☐ No		
24. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No				
25. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐ No				
26. Are you bothered by rubbing alcohol or soap on your skin more than family or friends? ☐Yes ☐ No				
Interviewer ID age verification: ☐Yes ☐ No _____ _____ Subject Signature Date				
Language of interview: : ☐ English ☐ Spanish	Interviewer Name:			
Interview date:	Interviewer Signature:			

Hoja de trabajo para calificación

Estudio sobre la exposición en trabajadores AEA09 de la AEATF (*Antimicrobial Exposure Assessment Task Force*, Grupo de trabajo de evaluación de la exposición antimicrobiana): Situación de aplicación de pintura de látex para interiores con brocha y rodillo

Parte I: *Preguntas de la entrevista*	*C/NC*
1. ¿Tiene algún problema de la piel en las manos (por ejemplo, psoriasis, eczema, etc.)? ☐ Sí ☐ No	
2.¿Tiene dificultad para respirar? ¿Enfisema o asma moderada o grave? ☐ Sí ☐ No	
3. ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio, derrame cerebral o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta no controlada? ☐ Sí ☐ No	
4. ¿Tiene algún otro problema de salud que pueda dificultar su participación en este estudio tal como se describió? ☐ Sí ☐ No	
5. ¿Es empleado o está casado con un empleado de una compañía de AEATF, GPL, un fabricante de pinturas o el ACC? (el entrevistador explicará las iniciales de las distintas entidades) ☐ Sí ☐ No	

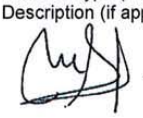
Parte II: *Para que la llene el candidato*			
6. Nombre		9. Peso: libras	
7. Dirección		10. Estatura: pies pulgadas	
		11. Talla de camisa: ☐ **P** ☐ **M** ☐ **G** ☐ **XG** ☐ **XXG** ☐ **XXXG**	
8. Ciudad, estado, código postal		12. Cintura: ☐ 24-28 pulgadas ☐ 28-32 pulgadas ☐ 32-36 pulgadas ☐ 36-40 pulgadas ☐ 40-44 pulgadas ☐ 44-50 pulgadas	
13. Teléfono(s)			
14. Edad en años =	15. Fecha de nacimiento:	16. Sexo ☐ M ☐ F	
17. ¿Es residente del condado de Fresno? ☐ Sí ☐ No		18. ¿Pintó con brocha y rodillo los últimos 5 años? ☐ Sí ☐ No	
		19. ¿Trabajó como pintor profesional los últimos 10 años? ☐ Sí ☐ No	
20. Idioma de preferencia: ☐ Inglés ☐ Español		21. Lee: ☐ Inglés ☐ Español	
22. ¿Está embarazada? ☐ NC ☐ Sí ☐ No		23. ¿Está amamantando? ☐ NC ☐ Sí ☐ No	
24. ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio tal como se describió? ☐ Sí ☐ No			
25. ¿El olor de la pintura para interiores o la sensación en la piel de la pintura para interiores le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
26. ¿Frotarse la piel con alcohol o jabón le molesta más que a sus familiares o amigos? ☐ Sí ☐ No			
Verificación de la edad mediante documento de identificación realizada por el entrevistador: ☐ Sí ☐ No _____ _____ Firma del sujeto Fecha			

Idioma de la entrevista: ☐ Inglés ☐ Español	Nombre del entrevistador:
Fecha de la entrevista:	Firma del entrevistador:

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Subject Information Sheet – MA1601860-0
Description (if applicable): Subject Self-Reporting Demographic Form



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT

MATERIAL SAFETY DATA SHEET

A87W151
14 00

DATE OF PREPARATION
May 2, 2013

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A87W151
PRODUCT NAME
SUPERPAINT® Interior Satin Latex Wall Paint, Extra White
MANUFACTURER'S NAME
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

Telephone Numbers and Websites

Product Information	www.sherwin-williams.com
Regulatory Information	(216) 566-2902 www.paintdocs.com
Medical Emergency	(216) 566-2917
Transportation Emergency*	(800) 424-9300
*for Chemical Emergency ONLY (spill, leak, fire, exposure, or accident)	

SECTION 2 — COMPOSITION/INFORMATION ON INGREDIENTS

% by Weight	CAS Number	Ingredient	Units	Vapor Pressure
0.8	14464-46-1	Cristobalite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
4	471-34-1	Calcium Carbonate		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
21	13463-67-7	Titanium Dioxide		
		ACGIH TLV	10 mg/m3 as Dust	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECTION 3 — HAZARDS IDENTIFICATION

ROUTES OF EXPOSURE
INHALATION of vapor or spray mist.
EYE or SKIN contact with the product, vapor or spray mist.
EFFECTS OF OVEREXPOSURE
EYES: Irritation.
SKIN: Prolonged or repeated exposure may cause irritation.
INHALATION: Irritation of the upper respiratory system.

In a confined area vapors in high concentration may cause headache, nausea or dizziness.
SIGNS AND SYMPTOMS OF OVEREXPOSURE
Redness and itching or burning sensation may indicate eye or excessive skin exposure.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE
None generally recognized.
CANCER INFORMATION
For complete discussion of toxicology data refer to Section 11.

HMIS Codes

Health	1*
Flammability	0
Reactivity	0

page 1 of 4

A87W151

SECTION 4 — FIRST AID MEASURES

EYES: Flush eyes with large amounts of water for 15 minutes. Get medical attention.
SKIN: Wash affected area thoroughly with soap and water.
Remove contaminated clothing and launder before re-use.
INHALATION: If affected, remove from exposure. Restore breathing. Keep warm and quiet.
INGESTION: Do not induce vomiting. Get medical attention immediately.

SECTION 5 — FIRE FIGHTING MEASURES

FLASH POINT	LEL	UEL	FLAMMABILITY CLASSIFICATION
Not Applicable	Not Applicable	Not Applicable	Not Applicable

EXTINGUISHING MEDIA
Carbon Dioxide, Dry Chemical, Alcohol Foam
UNUSUAL FIRE AND EXPLOSION HAZARDS
Closed containers may explode (due to the build-up of pressure) when exposed to extreme heat.
During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent. Obtain medical attention.
SPECIAL FIRE FIGHTING PROCEDURES
Full protective equipment including self-contained breathing apparatus should be used.
Water spray may be ineffective. If water is used, fog nozzles are preferable. Water may be used to cool closed containers to prevent pressure build-up and possible autoignition or explosion when exposed to extreme heat.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Remove all sources of ignition. Ventilate the area.
Remove with inert absorbent.

SECTION 7 — HANDLING AND STORAGE

STORAGE CATEGORY
Not Applicable
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Keep container closed when not in use. Transfer only to approved containers with complete and appropriate labeling. Do not take internally. Keep out of the reach of children.

SECTION 8 — EXPOSURE CONTROLS/PERSONAL PROTECTION

PRECAUTIONS TO BE TAKEN IN USE
Use only with adequate ventilation.
Avoid contact with skin and eyes. Avoid breathing vapor and spray mist.
Wash hands after using.
This coating may contain materials classified as nuisance particulates (listed "as Dust" in Section 2) which may be present at hazardous levels only during sanding or abrading of the dried film. If no specific dusts are listed in Section 2, the applicable limits for nuisance dusts are ACGIH TLV 10 mg/m3 (total dust), 3 mg/m3 (respirable fraction), OSHA PEL 15 mg/m3 (total dust), 5 mg/m3 (respirable fraction).
Removal of old paint by sanding, scraping or other means may generate dust or fumes that contain lead. Exposure to lead dust or fumes may cause brain damage or other adverse health effects, especially in children or pregnant women. Controlling exposure to lead or other hazardous substances requires the use of proper protective equipment, such as a properly fitted respirator (NIOSH approved) and proper containment and cleanup. For more information, call the National Lead Information Center at 1-800-424-LEAD (in US) or contact your local health authority.
VENTILATION
Local exhaust preferable. General exhaust acceptable if the exposure to materials in Section 2 is maintained below applicable exposure limits. Refer to OSHA Standards 1910.94, 1910.107, 1910.108.
RESPIRATORY PROTECTION
If personal exposure cannot be controlled below applicable limits by ventilation, wear a properly fitted organic vapor/particulate respirator approved by NIOSH/MSHA for protection against materials in Section 2.
When sanding or abrading the dried film, wear a dust/mist respirator approved by NIOSH/MSHA for dust which may be generated from this product, underlying paint, or the abrasive.
PROTECTIVE GLOVES
Wear gloves which are recommended by glove supplier for protection against materials in Section 2.
EYE PROTECTION
Wear safety spectacles with unperforated sideshields.

A87W151

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	10.91 lb/gal	1307 g/l
SPECIFIC GRAVITY	1.31	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	61%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.0	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.34 lb/gal	41 g/l	Less Water and Federally Exempt Solvents
0.14 lb/gal	16 g/l	Emitted VOC

SECTION 10 — STABILITY AND REACTIVITY

STABILITY — Stable
CONDITIONS TO AVOID
None known.
INCOMPATIBILITY
None known.
HAZARDOUS DECOMPOSITION PRODUCTS
By fire: Carbon Dioxide, Carbon Monoxide
HAZARDOUS POLYMERIZATION
Will not occur

SECTION 11 — TOXICOLOGICAL INFORMATION

CHRONIC HEALTH HAZARDS
Crystalline Silica (Quartz, Cristobalite) is listed by IARC and NTP. Long term exposure to high levels of silica dust, which can occur only when sanding or abrading the dry film, may cause lung damage (silicosis) and possibly cancer.
IARC's Monograph No. 93 reports there is sufficient evidence of carcinogenicity in experimental rats exposed to titanium dioxide but inadequate evidence for carcinogenicity in humans and has assigned a Group 2B rating. In addition, the IARC summary concludes, "No significant exposure to titanium dioxide is thought to occur during the use of products in which titanium is bound to other materials, such as paint."

TOXICOLOGY DATA

CAS No.	Ingredient Name			
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
471-34-1	Calcium Carbonate			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
13463-67-7	Titanium Dioxide			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available

SECTION 12 — ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION
No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD
Waste from this product is not hazardous as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.
Incinerate in approved facility. Do not incinerate closed container. Dispose of in accordance with Federal, State/Provincial, and Local regulations regarding pollution.

A87W151

SECTION 14 — TRANSPORT INFORMATION

Multi-modal shipping descriptions are provided for informational purposes and do not consider container sizes. The presence of a shipping description for a particular mode of transport (ocean, air, etc.), does not indicate that the product is packaged suitably for that mode of transport. All packaging must be reviewed for suitability prior to shipment, and compliance with the applicable regulations is the sole responsibility of the person offering the product for transport.

US Ground (DOT)
Not Regulated for Transportation.

Canada (TDG)
Not Regulated for Transportation.

IMO
Not Regulated for Transportation.

IATA/ICAO
Not Regulated for Transportation.

SECTION 15 — REGULATORY INFORMATION

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICATION

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

No ingredients in this product are subject to SARA 313 (40 CFR 372.65C) Supplier Notification.

CALIFORNIA PROPOSITION 65
WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

TSCA CERTIFICATION
All chemicals in this product are listed, or are exempt from listing, on the TSCA Inventory.

SECTION 16 — OTHER INFORMATION

This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

The above information pertains to this product as currently formulated, and is based on the information available at this time. Addition of reducers or other additives to this product may substantially alter the composition and hazards of the product. Since conditions of use are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information.

HOJA DE DATOS SOBRE LA SEGURIDAD DEL MATERIAL

A86W151
12 00

FECHA DE PREPARACIÓN
30-dic-2014

SECCIÓN 1 — PRODUCTO Y COMPAÑÍA IDENTIFICATIÓN

NÚMERO DEL PRODUCTO
A86W151
NOMBRE DEL PRODUCTO
SUPERPAINT® Interior Flat Latex Wall Paint, Extra White
NOMBRE DEL FABRICANTE
THE SHERWIN-WILLIAMS COMPANY
101 Prospect Avenue N.W.
Cleveland, OH 44115

NÚMEROS DE TELÉFONOS Y SITIOS WEB

Información sobre el producto	www.sherwin-williams.com
Información reguladora	(216) 566-2902 www.paintdocs.com
Emergencia médica	(216) 566-2917
Emergencia de transporte*	(800) 424-9300
*para una emergencia química SOLAMENTE (derrame, fuga, fuego, exposición o accidente)	

SECCIÓN 2 — INGREDIENTES DEL PRODUCTO

% por peso	CAS No.	INGREDIENTE	UNIDADES	PRESIÓN DE VAPOR
15	14808-60-7	Cuarzo		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,1 mg/m3 Resp. de Polvo	
1	14464-46-1	cristobalita		
		ACGIH TLV	0,025 mg/m3 Resp. de Polvo	
		OSHA PEL	0,05 mg/m3 Resp. de Polvo	
2	1332-58-7	Kaolin		
		ACGIH TLV	No Disponible	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	13463-67-7	Dioxido de Titanio		
		ACGIH TLV	10 mg/m3 de Polvo	
		OSHA PEL	10 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	

SECCIÓN 3 — EFECTOS POTENCIALES PARA LA SALUD

VÍAS DE EXPOSICIÓN
INHALACIÓN de vapor o de la niebla para la atomización.
Contacto del producto, del vapor o de la niebla para la atomización con los OJOS o la PIEL.
EFECTOS DE LA SOBREEXPOSICIÓN
OJOS: Irritación.
PIEL: Una exposición prolongada y repetida puede causar irritación.
INHALACIÓN: Irritación del sistema respiratorio superior.

En un recinto cerrado, los vapores en alta concentración pueden causar dolor de cabeza, náusea o mareo.
SEÑALES Y SÍNTOMAS DE LA SOBREEXPOSISCIÓN
La rojez, la picazón o la sensación de ardor indican exposición excesiva de los ojos o la piel.
CONDICIONES MÉDICAS EMPEORADAS POR LA SOBREEXPOSICIÓN
Ninguno generalmente reconocido.
CANCER INFORMATION
Vea la Sección 11.

HMIS Codes

Salud	1*
Inflamabilidad	0
Reactividad	0

A86W151

SECCIÓN 4 — PRIMEROS AUXILIOS

OJOS: Lávese los ojos durante 15 minutos usando mucha agua. Consulte con un médico.
PIEL: Lávese bien la parte afectada con agua y jabón.
Quítese la ropa contaminada y lávela antes de volverla a usar.
INHALACIÓN: Si le afecta, salga del lugar contaminado. Respire. Manténgase abrigado y tranquilo.
INGESTIÓN: No induzca o vomite. Consulte inmediatamente con un médico.

SECCIÓN 5 — PROCEDIMIENTOS DE EXTINCIÓN

PUNTO DE INFLAMACIÓN	LEL	UEL	CLASIFICACIÓN DE INFLAMACIÓN
No corresponde	No corresponde	No corresponde	No corresponde

PRODUCTOS PARA COMBATIR EL FUEGO
Anhídrido carbónico, producto químico seco, espuma de alcohol
PELIGROS DE EXPLOSIÓN E INCENDIO INUSUALES
Los envases cerrados pueden reventar (debido al acumulamiento de presión) cuando expuestos a calor intenso.
En casos de emergencias, la exposición prolongada a productos de su descomposición puede causar un peligro a la salud. Puede ser que los síntomas no se manifiesten de inmediato. Obtenga atención médica.
PROCEDIMIENTOS ESPECIALES PARA COMBATIR EL FUEGO
Debe usarse equipos de protección total, incluyendo aparatos respiratorios autocontenidos.
La atomización de agua puede resultar ineficaz. Si se usa agua, es preferible usar boquillas de neblina. Se puede usar agua para enfriar los envases cerrados a modo de prevenir el aumento de presión y la posible autoignición o explosión cuando expuesto a calor extremado.

SECCIÓN 6 — ACCIÓN EN CASO DE ACCIDENTES

PASOS A SEGUIR EN CASO QUE OCURRA UN DERRAME O FUGA DE MATERIAL
Elimine todas las fuentes de ignición. Ventile el lugar.
Elimine con absorbente inerte.

SECCIÓN 7 — MANEJO SEGURO Y ALMACENAMIENTO

CATEGORÍA DE ALMACENAMIENTO DEPT. TRAVAJO
No corresponde
PRECAUCIONES QUE DEBEN TOMARSE DURANTE EL MANEJO Y ALMACENAMIENTO
Mantenga cerrado el envase cuando no se usa. Transfiéralo únicamente a envases aprobados colocando todas las etiquetas con las indicaciones apropiadas. No es para uso interno. Manténgalo fuera del alcance de los niños.

SECCIÓN 8 — PROTECCIÓN PERSONAL

PRECAUCIONES A TOMARSE DURANTE EL USO
Use solamente con ventilación adecuada.
Evite el contacto con la piel y los ojos. Evite respirar el vapor y la niebla producida por la atomización.
Lávese las manos después de usar.
Este recubrimiento puede contener materiales clasificados como "partículas molestosas" (listadas como "polvo" en la Sección 2) las cuales puede que estén presentes a niveles peligrosos únicamente durante el lijado o el pulido de película seca. Si la Sección 2 no menciona polvos específicos, los límites aplicables para los "polvos molestosos" son ACGIH TLV 10 mg/m3 (total de polvo), 3 mg/m3 (fracción respirable), OSHA PEL 15 mg/m3 (total de polvo), 5 mg/m3 (fracción respirable).
Remover la pintura vieja ya sea lijando, raspando, gastando o de cualquier otra manera creará polvo o gases que pueden contener plomo. La exposición al polvo o a los gases que contengan plomo puede causar daños al cerebro o causar otros efectos adversos a la salud, especialmente en personas menores de edad y mujeres embarazadas. Para controlar la exposición al plomo y a otras substancias peligrodas, será necesario el uso de equipos de protección tales como un respirador apropiado aprobado por NIOSH, como así también el uso de procedimientos correctos de contención y limpieza. Para obtener más información, llame al Centro Nacional de Información sobre el Plomo al 1-800-424-5323 (en los EE.UU.) o consulte con una autoridad competente en temas de salud a nivel local.
VENTILACIÓN
El escape de ventilación local es preferible. El escape general es aceptable si la exposición a los materiales en la Sección 2 se mantiene debajo de los límites de exposición aplicables. Recurra a los Estándares de OSHA 1910.94, 1910.107, 1910.108.
PROTECCIÓN RESPIRATORIA
Si la exposición individual no puede ser controlada debajo de los límites aplicables por medio de la ventilación, use un respirador apropiado para vapor orgánico/partículas aprobado por NIOSH/MSHA para protección contra los materiales mencionados en la Sección 2.
Cuando lije o pula la película seca, use un respirador para polvo/niebla aprobado por NIOSH/MSHA para protección contra el polvo que pueda generarse de este producto, de la capa anterior de pintura o del abrasivo utilizado.
GUANTES DE PROTECCIÓN
Use guantes apropiados para protección contra los materiales de la Sección 2.
PROTECCIÓN DE LOS OJOS
Use anteojos de seguridad con protectores laterales sin perforación.

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SECCIÓN 9 — PROPIEDADES FISICAS Y QUIMICAS

PESO DEL PRODUCTO	12,05 lb/gal	1443 g/l
PESO ESPECÍFICO	1,45	
PUNTOS DE EBULLICIÓN	212 - 213 °F	100 - 100 °C
PUNTO DE FUSIÓN	No disponible	
% VOLÁTIL VOLUMEN	57%	
COEFICIENTE DE EVAPORACIÓN	Más lento que el éter	
DENSIDAD DE VAPOR	Más pesado que el aire	
SOLUBILIDAD EN AGUA	No disponible	
pH	9,3	

COV (Teorético)

0,35 lb/gal	42 g/l	Less Water and Federally Exempt Solventes
0,16 lb/gal	19 g/l	Emitido COV

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0,41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

SECCIÓN 10 — ESTABILIDAD Y REACTIVIDAD

ESTABILIDAD — Estable
CONDICIONES A EVITAR
Ninguno conocido.
INCOMPATIBILIDAD
Ninguno conocido.
PRODUCTOS DE DESCOMPOSICIÓN PELIGROSA
Por el fuego: Dióxido de carbono, monóxido de carbono
POLIMERIZACIÓN PELIGROSA
No ocurrirá.

SECCIÓN 11 — INFORMACIÓN TOXICOLOGICA

PELIGROS CRÓNICOS PARA LA SALUD
La silice cristalina (cuarzo, cristobalita) aparece en la lista IARC y NTP. La exposición por mucho tiempo a altos niveles de polvo de silica, que ocurre solamente cuando se lija o pule la película seca, puede causar daño al pulmón (silicosis) y quizas cáncer.
La Agencia Internacional de Investigación del Cáncer reporta en su Monografía No. 93 que existen evidencias suficientes para afirmar que el dióxido de titanio provoca cáncer en ratas de laboratorio, pero que no hay evidencias de que provoque cáncer en los seres humanos y lo clasifica dentro del Grupo 2B. Además, el resumen de la agencia IARC concluye que "No se cree que exista una exposición significativa al dióxido de titanio durante el uso de productos donde el titanio se junta con otros materiales, como en el caso de la pintura."
INFORMACIÓN TOXICOLOGIA

CAS No.	INGREDIENTE			
14808-60-7	Cuarzo			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
14464-46-1	cristobalita			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
1332-58-7	Kaolin			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible
13463-67-7	Dioxido de Titanio			
		LC50 RAT	4HR	No Disponible
		LD50 RAT		No Disponible

SECCIÓN 12 — INFORMACIÓN ECOLÓGICA

ECOTOXICOLÓGICA INFORMACIÓN
Ningunos datos disponibles.

SECCIÓN 13 — CONSIDERACIONES DE DESECHO

MÉTODO PARA EL DESCARTE DE RESIDUOS
El residuo de este producto no es peligroso tal como lo define la Ley de Conservación y Recuperación de Recursos ("RCRA") 40 CFR 261. Incinérelo en los lugares autorizados. No incinere envases cerrados. Descártelo de acuerdo con las regulaciones locales, estatales y federales concernientes a la polución.

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SECCIÓN 14 — INFORMACIÓN DE TRANSPORTE

Las descripciones de envío multimodal se proporcionan a título informativo, y no tienen en cuenta el tamaño de los recipientes. La presencia de una descripción de envío para un modo de transporte en particular (mar, aire, etc.) no indica que el producto esté envasado de forma adecuada para ese modo de transporte. La idoneidad de todos los envases se debe revisar antes de los envíos y el cumplimiento de todos los reglamentos pertinentes es responsabilidad exclusiva de la persona que ofrece el producto para su transporte. El personal que carga y descarga materiales o sustancias peligrosos debe contar con formación sobre todos los riesgos derivados de dichas sustancias y sobre las medidas necesarias en caso de emergencia.

US Ground (DOT)
No regulado.
Canada (TDG)
No regulado.
IMO
No regulado.
IATA/ICAO
No regulado.

SECCIÓN 15 — INFORMACIÓN REGLAMENTARIA

SARA 313 *(40 CFR 372.65C)* SUPPLIER NOTIFICACIÓN

CAS No.	CHEMICAL/COMPOUND	% by WT	% Element

Ningún ingrediente en este producto está sujeto a la notificación por parte del proveedor bajo la ley SARA 313 (40 CFR 372.65C).

CALIFORNIA PROPOSITION 65
CUIDADO: Este producto contiene químicos que a conocimiento del estado de California puede causar cáncer defectos de nacimiento u otros daños reproductivos.

TSCA INFORMACIÓN
Todos los químicos en este producto estan en la lista o son exhonerado de la lista de inventario de TSCA.

SECCIÓN 16 — INFORMACIÓN MISCELÁNEA

La información anterior se refiere a este producto tal como ha sido recientemente formulado, y está basada en información disponible a la fecha. La adición de reductores u otros aditivos a este producto puede substancialmente alterar la composición y los peligros del producto. Debido a que las condiciones de uso están fuera de nuestro control, no damos ningún tipo de garantía, expresa o implícita, ni asumimos responsabilidad en conexión con el uso de cualquier parte de esta información.

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APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

HOUSEHOLD PAINTERS WANTED

Seeking volunteers for a research study evaluating exposure to paint ingredients while painting indoors with a brush and roller. Volunteers will be compensated a total of up to $120 for their inconvenience. No professional painters please.

Please contact Robert Testman (English), Thomas Moate (English) or Natan Chavez (English/Spanish) at 559-275-9091 For more information.

Study sponsored by the Antimicrobial Exposure Assessment Task Force administered by the American Chemistry Council, and directed by Golden Pacific Laboratories of Fresno, CA. 559-275-9091

Version: 11/04/2013

SE BUSCAN PINTORES AFICIONADOS

Se buscan voluntarios que deseen participar en un estudio de investigación que evalúa la exposición a componentes de la pintura al pintar en el interior con una brocha y un rodillo. Los voluntarios recibirán una compensación de hasta $120 por las molestias de participar. No se aceptan pintores profesionales.

Comuníquese con Robert Testman (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091 para obtener más información.

Estudio patrocinado por *Antimicrobial Exposure Assessment Task Force* (AEATF, Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos); administrado por *American Chemistry Council* (ACC, Consejo Estadounidense de Química) y dirigido por Golden Pacific Laboratories (GPL) de Fresno, CA. 559-275-9091

Versión: 04/11/2013

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Ad-Print - MA1601862-0
Description (if applicable): N/A

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

MMB

3/14/2016 8:00 AM (PST)

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

We want to find out how much chemical is in the air you breathe or may reach your skin when you apply paint products with a brush and roller. We will measure how much of a paint ingredient gets on the clothes you wear and on your hands, face and neck. We will also measure how much is in the air you breathe while you paint rooms.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

You must have painted with a brush and roller in the last five years, but not have been a professional painter for the last ten years.

The study itself will take you about half a day. We will provide you with special clothing to wear during the test. We will fit you with a little air pump to sample the air you breathe. Then you'll be asked to paint the test product on walls, moldings, and baseboards. You will be asked to apply two gallons of paint using both a brush and a roller. When you're done you'll change back into your own clothes and give the special clothing to the research team.

Would you like to find out more about this project?

(If no, thank them for their time.)

(If yes, instruct them as follows)

If you are selected to participate in the study, you will receive $100 in cash at the end of the day of the study. To be qualified for participation, you must show your picture identification to prove your age. You must be over 18 and able to read either English or Spanish. You must be in good health. If you are female, you must not be pregnant or nursing a child.

If you want to be in this project, you would first come to Golden Pacific Laboratories for an interview. The office is at 4720 W. Jennifer Ave., Suite 105, in Fresno. This is just off of Shaw Avenue, behind Costco. Here you would meet with the Principal Investigator, Robert Testman. If you prefer, we can interview you in Spanish. This meeting will be set when it's convenient for you—including on the weekend. We will explain the study in detail, including what you can expect, and what would be expected of you. We will answer all your questions. This first visit will take about an hour. You would need to bring a Government-issued ID with a picture, like a driver's license. We will pay you $20 in cash at the end of this visit.

(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

Guión de invitación a participar para el sujeto

[Identify yourself and company affiliation, ask if they are calling about the brush and roller paint application study. If yes, ask how they found out about the study and document response. Ask the potential subject if he/she would like more information on the study. If yes, continue.]

Queremos determinar la cantidad de productos químicos que se encuentra en el aire que respira o que puede entrar en contacto con la piel cuando aplica productos de pintura con una brocha y un rodillo. Mediremos la cantidad de compuestos de pintura que quede en la ropa que vista y en las manos, cara y cuello. Además, mediremos la cantidad presente en el aire que respira en el momento que pinte habitaciones.

El producto de prueba será la PINTURA DE LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

Debe haber pintado con una brocha y un rodillo en los últimos cinco años, pero no haber trabajado como pintor profesional en los últimos diez años.

Su participación en el estudio durará alrededor de medio día. Le proporcionaremos una ropa especial que deberá usar durante la prueba. Le colocaremos una pequeña bomba de aire para tomar muestras del aire que respira. Luego, se le pedirá que pinte paredes, molduras y zócalos con los productos de prueba. Deberá usar una brocha y un rodillo para aplicar dos galones de pintura. Cuando termine, deberá cambiarse para volver a ponerse su ropa y devolver la ropa especial al equipo de investigación.

¿Le gustaría saber más sobre este proyecto?

(If no, thank them for their time.)

(If yes, instruct them as follows)

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del día del estudio. Para reunir los requisitos para participar, debe mostrar una identificación con foto para comprobar su edad. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni amamantando.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está ubicada en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con el investigador principal, Robert Testman. Si prefiere, podemos realizar la entrevista en español. La entrevista se programará para la fecha y hora que le resulte más conveniente, incluso durante un fin de semana. Le explicaremos el estudio en detalle, entre otras cosas, qué puede esperar y qué se espera de usted. Responderemos todas sus preguntas. La primera visita durará alrededor de una hora. Deberá traer un documento de identificación con foto emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

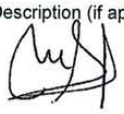
(Time and date of appointment will be documented.)

(Note: if the potential subjects ask questions not addressed in this telephone script, inform them additional questions can be answered by Robert Testman or the Spanish speaking researcher.)

CERTIFICATION

This is to certify that this Spanish (Latin America) Translation was completed and reviewed by persons who read, comprehend and write fluently in both the Spanish (Latin America) and English languages and that this is a complete and true translation to the best of our knowledge and belief, and in accordance with industry standards.

Protocol Number: AEA09
IRB Number: 201307318
PI: Testman
Material Type (if applicable): Phone Screen - MA1601861-0
Description (if applicable): Subject Invitation to Participate Script



MMB 3/14/2016 8:00 AM (PST)

MELISA BERASATEGUI
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX H: EPA EXECUTIVE SUMMARY FROM BIT REGISTRATION ELIGIBILITY DECISION DOCUMENT

EXECUTIVE SUMMARY

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for 1,2-benzisothiazolin-3-one (hereafter referred to as BIT) and is issuing its risk management decision. The Agency has decided BIT is eligible for reregistration provided all measures outlined in this document are implemented. BIT is an antimicrobial that is used as an industrial preservative for the protection of water-based adhesives, caulks, sealants, grouts, spackling, ready-mixed cements, ready-mixed wallboard compounds, aqueous compositions such as emulsion paints, aqueous slurries, home cleaning and car care products, laundry detergents, fabric softeners, stain removers, inks, photographic processing solutions, paints and stains, titanium dioxide slurries, oil in water emulsions, latices, metalworking fluids, casein/rosin dispersions, textile spin-finish solutions, pesticide formulations, tape joint compound, leather processing solutions, preservation of fresh animal hides and skins, and for offshore and terrestrial gas/oil drilling muds and packer fluids preservation. 1,2-Benzisothiazolin-3-one is also used as an inert ingredient in a variety of products as a materials preservative. Exposures and risks from the use of products containing 1,2-benzisothiazolin-3-one as both the active and inert ingredients are assessed in this reregistration eligibility decision (RED). End-use products are formulated as either a soluble, ready-to-use, or flowable concentrates (all of which are considered to be liquids).

Overall Risk Summary

The Agency's human health risk assessment indicates few risks of concern. Acute and chronic dietary exposure is below the agency's level of concern for general U.S. populations and all population subgroups. Likewise, it was concluded that risk from exposure of BIT in drinking water would also not represent a risk of concern because it is not likely to be in drinking water sources at substantial concentrations. This is based on the fact that BIT readily biodegrades, is applied to crops via inert use in small amounts and is only likely to come into contact with soil/surface water via paint uses in small amounts. The acute and chronic aggregate dietary risk assessment estimates associated with the use of BIT as an inert or active ingredient are below the Agency's level of concern.

Short and intermediate term residential post-application and handler exposures (dermal, inhalation or incidental oral) from hard surface residues did not exceed the Agency's level of concern. For residential exposure and risk, the toddler post-application dermal exposure scenario from residues remaining on pets from the inert use, the margin of exposure (MOE) is below the targeted MOE, indicating that this scenario is a risk of concern.

For aggregate exposure, the risk estimates associated with BIT are below the Agency's level of concern. In cases where an aggregate risk index (ARI) was used to assess risk because of the different uncertainty factors for oral, dermal and inhalation exposure scenarios, the risk indices suggested that there is reasonable certainty of no harm from using products containing BIT. Based on the information provided, inhalation exposures were not considered to be of concern with regard to inhalation risk from occupational handler scenarios; however the dermal MOE indicated that the dermal risk for occupational handlers was below the target MOE for one

scenario, handlers of BIT-containing paint using an airless sprayer. While the inhalation risk may be an underestimation based on extrapolation from an oral study, the dermal risk is based on a number of conservative assumptions and are not of concern. Dermal and inhalation exposures to bystanders from the occupational use of BIT are also expected to be minimal.

The indoor uses of BIT make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters.

1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. The ecological risks from the use of BIT suggest that because of the high toxicity of BIT to green algae and invertebrate species, adverse effects to the environment could result from contamination from BIT-treated oil recovery fluids.

Dietary Risk

The Agency has conducted a dietary exposure and risk assessment for use of 1,2-benzisothiazolin-3-one as a pulp and paper mill slimicide, and a preservative in paper coatings and paper adhesives, all of which may end in indirect food contact scenarios. For both the acute and chronic dietary exposure, the risk is highest for children (21.8% of the acute and chronic PAD). For an adult, the acute and chronic dietary exposure is 9.4% of the acute and chronic PAD. All dietary exposures calculated are below the Agency's level of concern (100% of aPAD or cPAD) for non-cancer risk. Furthermore, given the conservative nature of the assumptions used in the inert dietary exposure and risk assessment, risks of concern from food are not likely from the use of 1,2-benzisothiazolin-3-one as inert ingredients in pesticide products. A dietary cancer risk assessment could not be performed as there are no carcinogenicity data for 1,2-benzisothiazolin-3-one.

Drinking Water Risk

Based on environmental fate data, 1,2-benzisothiazolin-3-one binds moderately with soil and may potentially move with the soil during rainfall events and reach surface waters. Although, 1,2-benzisothiazolin-3-one has been shown to be hydrolytically stable with a half life of > 30 days, it breaks down fairly quickly in aerobic soils. Outdoor use patterns of 1,2-benzisothiazolin-3-one which may lead to contact with soil and/or surface water include: 1) the application of agricultural pesticides that contain 1,2-benzisothiazolin-3-one as an inert ingredient, and 2) the application of paints that contain 1,2-benzisothiazolin-3-one. Considering 1,2-benzisothiazolin-3-one readily biodegrades and the small amount (0.02 lbs. per acre) that may be applied to crops via the inert use and the small amount likely to come into contact with soils/surface waters via the paint use, 1,2-benzisothiazolin-3-one is not likely to be present in drinking water sources at substantial concentrations.

v

Residential Risk

To address residential exposure dermal, inhalation and incidental oral risks were assessed for the active and inert ingredient uses of BIT. The residential handler scenarios evaluated are considered to be representative of all possible exposure scenarios. None of the residential handler exposure scenarios or post-application exposure scenarios exceeded the Agency's level of concern.

For the inert uses of BIT, none of the residential handler exposure scenarios exceeded the Agency's level of concern. Although most of the post-application exposures did not exceed the Agency's level of concern, the toddler post-application dermal exposure scenario to residues remaining on pets resulted in a MOE of 33 which is lower than the target MOE of 100 resulting in risks of concern.

Aggregate Risk

The acute and chronic aggregate risk assessments generally include only dietary and drinking water exposures. Since drinking water exposure is not expected from any of the indoor or outdoor uses of 1,2-benzisothiazolin-3-one used as either an inert or active ingredient, the acute and chronic aggregate assessments only included dietary exposures from the active indirect food uses (i.e., use in food-contact packaging) and inert dietary exposures from agricultural pesticide uses. The acute and chronic aggregate risk estimates associated with 1,2-benzisothiazolin-3-one are well below the Agency's level of concern where, the adult's risks were 17.1% of the aPAD and 12.2% of the cPAD, and the children's risks were 44.1% of the aPAD and 31.8% of the cPAD.

The short- and intermediate-term aggregate assessments were conducted for adults and children. Since the toxicity endpoints for all of the routes of exposure (oral, dermal and inhalation) are based on the same study and same toxic effect, all routes are aggregated together. However, the aggregate risk index (ARI) method was utilized in the assessment. This method was used because the oral, dermal and inhalation endpoints have different uncertainty factors that need to be applied. For 1,2-benzisothiazolin-3-one, all endpoints for exposure were derived from a subchronic oral study in dogs however, the uncertainty factors (i.e., target MOEs) for oral, dermal and inhalation routes are 300, 100 and 100, respectively. A risk index $1 indicates no risk of concern. The short-term ARIs for adults and children were 6.8 and 1.9, respectively, while the intermediate-term ARIs for adults and children were 7.5 and 1.9, respectively. Therefore, short- and intermediate-term aggregate calculated risks are below the Agency's level of concern. Please note that the inert use in pet products is considered to result in intermittent exposures and, as such, were not included in the aggregate assessment.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term combined dermal and inhalation risks were assessed. The inhalation exposures are not of concern for the any of the handler scenarios assessed (i.e., MOEs >1,000). However, for handlers using BIT-treated paint via an airless sprayer, the dermal MOE of 90 indicates a risk of concern (i.e., MOEs < 100).

Postapplication exposures may occur in industrial settings around the water systems via inhalation, and dermal exposures may occur while maintaining industrial equipment. However, occupational post-application dermal and inhalation exposures to 1,2-benzisothiazolin-3-one are likely to be minimal when compared to handler exposure because of dilution during processing or when compared to machinists using the metal working fluid. Inhalation exposures are expected to be minimal because aerosol generation is not expected and the vapor pressure of 1,2-benzisothiazolin-3-one is low.

Ecological Risk

Based on acute toxicity information, 1,2-benzisothiazolin-3-one displays low to moderate toxicity to birds and mammals. It is moderately toxic to freshwater fish and invertebrates, slightly toxic to marine/estuarine fish, and highly toxic to marine/estuarine invertebrates.

The indoor uses of BIT considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur. Facilities using BIT for indoor industrial applications are required to have NPDES permits before discharging effluents into receiving waters. The potential exposure to terrestrial and aquatic species from the oil recovery uses of BIT cannot be estimated at this time, as there is currently no validated model available for such a purpose. The high toxicity of BIT to green algae and invertebrate species suggests that potential adverse acute effects could occur to some species if environmental contamination from BIT-treated oil recovery fluids occurs.

1,2-Benzisothiazolin-3-one is used as an inert ingredient in pesticide products but the allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre). Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (halflife < 24 hours in sandy loam soil). 1,2-Benzisothiazolin-3-one's ready biodegradation in soil and small application amount greatly reduce the exposure potential for terrestrial and aquatic organisms. Run-off into surface water from pesticidal uses is likely to be low and it is not likely to be present in water sources at substantial concentrations. Therefore, risk to nontarget organisms is not anticipated from the inert uses of 1,2-benzisothiazolin-3-one.

Listed Species

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a Ano effect@ determination. The active ingredient uses of 1,2-benzisothiazolin-3-one fall into this category.

The inert uses of 1,2-benzisothiazolin-3-one are also considered to fall under a "no effect" determination, for the following reasons:
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1. The allowable amount that can be applied is small (not more than 0.1% formulation and 0.02 lbs. per acre).
2. Data indicate that 1,2-benzisothiazolin-3-one breaks down quickly in aerobic soils (half-life < 24 hours in sandy loam soil).
3. 1,2-Benzisothiazolin-3-one=s ready biodegradation in soil and small application result in minimal to no terrestrial or aquatic organism exposure.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing BIT. The Agency is issuing this RED for BIT, as announced in a Notice of Availability published in the *Federal Register*.

Summary of Mitigation Measures

The Agency has determined that BIT is eligible for reregistration provided the mitigation measures described in this document are implemented.

Residential Risk

The Agency has concluded that to have an acceptable MOE for toddler dermal post-application dermal scenarios, the maximum percent BIT as an inert in flea and tick pet products is 0.033%. The Agency target MOE for this exposure scenario is 100, while the Agency calculated toddler dermal post-application MOE is 33; a value that indicates a risk of concern. All pet products containing BIT as an inert ingredient must contain a maximum of 0.033% BIT in order mitigate the current risk that the flea and tick pet products pose.

Data Requirements

Additional confirmatory data is required to complete the reregistration of BIT. A complete list of data gaps is presented Section V and Appendix B (Table of Generic Data Requirements). In addition, product-specific data is required for all products containing BIT as described in Section V of this document.

APPENDIX I: FIELD SAMPLE IDENTIFICATION CODES

Sample ID Number	Description
AEA09-BRS-01-PH	Brush and Roller Worker Sample, ME 01, Painter's Hat
AEA09-BRS-01-PH-ID	Brush and Roller Worker Sample, ME 01, Painter's Hat Dosimeter
AEA09-BRS-01-AR	Brush and Roller Worker Sample, ME 01, Air Sampling Tube
AEA09-BRS-01-RES-01	Brush and Roller Worker Sample, ME 01, RespiCon™ 100 µm
AEA09-BRS-01-RES-02	Brush and Roller Worker Sample, ME 01, RespiCon™ 10 µm
AEA09-BRS-01-RES-03	Brush and Roller Worker Sample, ME 01, RespiCon™ 2.5 µm
AEA09-BRS-01-HW-01	Brush and Roller Worker Sample, ME 01, Hand Wash
AEA09-BRS-01-FW-01	Brush and Roller Worker Sample, ME 01, Face and Neck Wipe
AEA09-BRS-01-ID-UA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-01-ID-LA	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Arm
AEA09-BRS-01-ID-FT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Front Torso
AEA09-BRS-01-ID-RT	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Rear Torso
AEA09-BRS-01-ID-UL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Upper Leg
AEA09-BRS-01-ID-LL	Brush and Roller Worker Sample, ME 01, Inner DosimeterDosimeter, Lower Leg
AEA09-BRS-01-OD-UA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Arm
AEA09-BRS-01-OD-LA	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-01-OD-FT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Front Torso
AEA09-BRS-01-OD-RT	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Rear Torso
AEA09-BRS-01-OD-UL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Upper Leg
AEA09-BRS-01-OD-LL	Brush and Roller Worker Sample, ME 01, Outer DosimeterDosimeter, Lower Leg
AEA09-BRS-02-PH	Brush and Roller Worker Sample, ME 02, Painter's Hat
AEA09-BRS-02-PH-ID	Brush and Roller Worker Sample, ME 02, Painter's Hat Dosimeter
AEA09-BRS-02-AR	Brush and Roller Worker Sample, ME 02, Air Sampling Tube
AEA09-BRS-02-RES-01	Brush and Roller Worker Sample, ME 02, RespiCon™ 100 µm
AEA09-BRS-02-RES-02	Brush and Roller Worker Sample, ME 02, RespiCon™ 10 µm
AEA09-BRS-02-RES-03	Brush and Roller Worker Sample, ME 02, RespiCon™ 2.5 µm
AEA09-BRS-02-HW-01	Brush and Roller Worker Sample, ME 02, Hand Wash
AEA09-BRS-02-FW-01	Brush and Roller Worker Sample, ME 02, Face and Neck Wipe
AEA09-BRS-02-ID-UA	Brush and Roller Worker Sample, ME 02, Inner DosimeterDosimeter, Upper Arm
AEA09-BRS-02-ID-LA	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Arm
AEA09-BRS-02-ID-FT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-02-ID-RT	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Rear Torso
AEA09-BRS-02-ID-UL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Upper Leg
AEA09-BRS-02-ID-LL	Brush and Roller Worker Sample, ME 02, Inner Dosimeter, Lower Leg
AEA09-BRS-02-OD-UA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Arm
AEA09-BRS-02-OD-LA	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Arm
AEA09-BRS-02-OD-FT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Front Torso
AEA09-BRS-02-OD-RT	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Rear Torso
AEA09-BRS-02-OD-UL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Upper Leg
AEA09-BRS-02-OD-LL	Brush and Roller Worker Sample, ME 02, Outer Dosimeter, Lower Leg
AEA09-BRS-03-PH	Brush and Roller Worker Sample, ME 03, Painter's Hat
AEA09-BRS-03-PH-ID	Brush and Roller Worker Sample, ME 03, Painter's Hat Dosimeter
AEA09-BRS-03-AR	Brush and Roller Worker Sample, ME 03, Air Sampling Tube
AEA09-BRS-03-RES-01	Brush and Roller Worker Sample, ME 03, RespiCon™ 100 µm
AEA09-BRS-03-RES-02	Brush and Roller Worker Sample, ME 03, RespiCon™ 10 µm
AEA09-BRS-03-RES-03	Brush and Roller Worker Sample, ME 03, RespiCon™ 2.5 µm
AEA09-BRS-03-HW-01	Brush and Roller Worker Sample, ME 03, Hand Wash
AEA09-BRS-03-FW-01	Brush and Roller Worker Sample, ME 03, Face and Neck Wipe
AEA09-BRS-03-ID-UA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Arm
AEA09-BRS-03-ID-LA	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Arm
AEA09-BRS-03-ID-FT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Front Torso
AEA09-BRS-03-ID-RT	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Rear Torso
AEA09-BRS-03-ID-UL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Upper Leg
AEA09-BRS-03-ID-LL	Brush and Roller Worker Sample, ME 03, Inner Dosimeter, Lower Leg
AEA09-BRS-03-OD-UA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Arm
AEA09-BRS-03-OD-LA	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Arm
AEA09-BRS-03-OD-FT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Front Torso
AEA09-BRS-03-OD-RT	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-03-OD-UL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Upper Leg
AEA09-BRS-03-OD-LL	Brush and Roller Worker Sample, ME 03, Outer Dosimeter, Lower Leg
AEA09-BRS-04-PH	Brush and Roller Worker Sample, ME 04, Painter's Hat
AEA09-BRS-04-PH-ID	Brush and Roller Worker Sample, ME 04, Painter's Hat Dosimeter
AEA09-BRS-04-AR	Brush and Roller Worker Sample, ME 04, Air Sampling Tube
AEA09-BRS-04-RES-01	Brush and Roller Worker Sample, ME 04, RespiCon™ 100 µm
AEA09-BRS-04-RES-02	Brush and Roller Worker Sample, ME 04, RespiCon™ 10 µm
AEA09-BRS-04-RES-03	Brush and Roller Worker Sample, ME 04, RespiCon™ 2.5 µm
AEA09-BRS-04-HW-01	Brush and Roller Worker Sample, ME 04, Hand Wash
AEA09-BRS-04-FW-01	Brush and Roller Worker Sample, ME 04, Face and Neck Wipe
AEA09-BRS-04-ID-UA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Arm
AEA09-BRS-04-ID-LA	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Arm
AEA09-BRS-04-ID-FT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Front Torso
AEA09-BRS-04-ID-RT	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Rear Torso
AEA09-BRS-04-ID-UL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Upper Leg
AEA09-BRS-04-ID-LL	Brush and Roller Worker Sample, ME 04, Inner Dosimeter, Lower Leg
AEA09-BRS-04-OD-UA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Arm
AEA09-BRS-04-OD-LA	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Arm
AEA09-BRS-04-OD-FT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Front Torso
AEA09-BRS-04-OD-RT	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Rear Torso
AEA09-BRS-04-OD-UL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Upper Leg
AEA09-BRS-04-OD-LL	Brush and Roller Worker Sample, ME 04, Outer Dosimeter, Lower Leg
AEA09-BRS-05-PH	Brush and Roller Worker Sample, ME 05, Painter's Hat
AEA09-BRS-05-PH-ID	Brush and Roller Worker Sample, ME 05, Painter's Hat Dosimeter
AEA09-BRS-05-AR	Brush and Roller Worker Sample, ME 05, Air Sampling Tube
AEA09-BRS-05-RES-01	Brush and Roller Worker Sample, ME 05, RespiCon™ 100 µm
AEA09-BRS-05-RES-02	Brush and Roller Worker Sample, ME 05, RespiCon™ 10 µm
AEA09-BRS-05-RES-03	Brush and Roller Worker Sample, ME 05, RespiCon™ 2.5 µm
AEA09-BRS-05-HW-01	Brush and Roller Worker Sample, ME 05, Hand Wash
AEA09-BRS-05-FW-01	Brush and Roller Worker Sample, ME 05, Face and Neck Wipe
AEA09-BRS-05-ID-UA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Arm

Sample ID Number	Description
AEA09-BRS-05-ID-LA	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Arm
AEA09-BRS-05-ID-FT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Front Torso
AEA09-BRS-05-ID-RT	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Rear Torso
AEA09-BRS-05-ID-UL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Upper Leg
AEA09-BRS-05-ID-LL	Brush and Roller Worker Sample, ME 05, Inner Dosimeter, Lower Leg
AEA09-BRS-05-OD-UA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Arm
AEA09-BRS-05-OD-LA	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Arm
AEA09-BRS-05-OD-FT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Front Torso
AEA09-BRS-05-OD-RT	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Rear Torso
AEA09-BRS-05-OD-UL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Upper Leg
AEA09-BRS-05-OD-LL	Brush and Roller Worker Sample, ME 05, Outer Dosimeter, Lower Leg
AEA09-BRS-06-PH	Brush and Roller Worker Sample, ME 06, Painter's Hat
AEA09-BRS-06-PH-ID	Brush and Roller Worker Sample, ME 06, Painter's Hat Dosimeter
AEA09-BRS-06-AR	Brush and Roller Worker Sample, ME 06, Air Sampling Tube
AEA09-BRS-06-RES-01	Brush and Roller Worker Sample, ME 06, RespiCon™ 100 µm
AEA09-BRS-06-RES-02	Brush and Roller Worker Sample, ME 06, RespiCon™ 10 µm
AEA09-BRS-06-RES-03	Brush and Roller Worker Sample, ME 06, RespiCon™ 2.5 µm
AEA09-BRS-06-HW-01	Brush and Roller Worker Sample, ME 06, Hand Wash
AEA09-BRS-06-FW-01	Brush and Roller Worker Sample, ME 06, Face and Neck Wipe
AEA09-BRS-06-ID-UA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Arm
AEA09-BRS-06-ID-LA	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Arm
AEA09-BRS-06-ID-FT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Front Torso
AEA09-BRS-06-ID-RT	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Rear Torso
AEA09-BRS-06-ID-UL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Upper Leg
AEA09-BRS-06-ID-LL	Brush and Roller Worker Sample, ME 06, Inner Dosimeter, Lower Leg
AEA09-BRS-06-OD-UA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Arm
AEA09-BRS-06-OD-LA	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Arm

Sample ID Number	Description
AEA09-BRS-06-OD-FT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Front Torso
AEA09-BRS-06-OD-RT	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Rear Torso
AEA09-BRS-06-OD-UL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Upper Leg
AEA09-BRS-06-OD-LL	Brush and Roller Worker Sample, ME 06, Outer Dosimeter, Lower Leg
AEA09-BRS-07-PH	Brush and Roller Worker Sample, ME 07, Painter's Hat
AEA09-BRS-07-PH-ID	Brush and Roller Worker Sample, ME 07, Painter's Hat Dosimeter
AEA09-BRS-07-AR	Brush and Roller Worker Sample, ME 07, Air Sampling Tube
AEA09-BRS-07-RES-01	Brush and Roller Worker Sample, ME 07, RespiCon™ 100 µm
AEA09-BRS-07-RES-02	Brush and Roller Worker Sample, ME 07, RespiCon™ 10 µm
AEA09-BRS-07-RES-03	Brush and Roller Worker Sample, ME 07, RespiCon™ 2.5 µm
AEA09-BRS-07-HW-01	Brush and Roller Worker Sample, ME 07, Hand Wash
AEA09-BRS-07-FW-01	Brush and Roller Worker Sample, ME 07, Face and Neck Wipe
AEA09-BRS-07-ID-UA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Arm
AEA09-BRS-07-ID-LA	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Arm
AEA09-BRS-07-ID-FT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Front Torso
AEA09-BRS-07-ID-RT	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Rear Torso
AEA09-BRS-07-ID-UL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Upper Leg
AEA09-BRS-07-ID-LL	Brush and Roller Worker Sample, ME 07, Inner Dosimeter, Lower Leg
AEA09-BRS-07-OD-UA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Arm
AEA09-BRS-07-OD-LA	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Arm
AEA09-BRS-07-OD-FT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Front Torso
AEA09-BRS-07-OD-RT	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Rear Torso
AEA09-BRS-07-OD-UL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Upper Leg
AEA09-BRS-07-OD-LL	Brush and Roller Worker Sample, ME 07, Outer Dosimeter, Lower Leg
AEA09-BRS-08-PH	Brush and Roller Worker Sample, ME 08, Painter's Hat
AEA09-BRS-08-PH-ID	Brush and Roller Worker Sample, ME 08, Painter's Hat Dosimeter
AEA09-BRS-08-AR	Brush and Roller Worker Sample, ME 08, Air Sampling Tube
AEA09-BRS-08-RES-01	Brush and Roller Worker Sample, ME 08, RespiCon™ 100 µm
AEA09-BRS-08-RES-02	Brush and Roller Worker Sample, ME 08, RespiCon™ 10 µm
AEA09-BRS-08-RES-03	Brush and Roller Worker Sample, ME 08, RespiCon™ 2.5 µm

Sample ID Number	Description
AEA09-BRS-08-HW-01	Brush and Roller Worker Sample, ME 08, Hand Wash
AEA09-BRS-08-FW-01	Brush and Roller Worker Sample, ME 08, Face and Neck Wipe
AEA09-BRS-08-ID-UA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Arm
AEA09-BRS-08-ID-LA	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Arm
AEA09-BRS-08-ID-FT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Front Torso
AEA09-BRS-08-ID-RT	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Rear Torso
AEA09-BRS-08-ID-UL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Upper Leg
AEA09-BRS-08-ID-LL	Brush and Roller Worker Sample, ME 08, Inner Dosimeter, Lower Leg
AEA09-BRS-08-OD-UA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Arm
AEA09-BRS-08-OD-LA	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Arm
AEA09-BRS-08-OD-FT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Front Torso
AEA09-BRS-08-OD-RT	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Rear Torso
AEA09-BRS-08-OD-UL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Upper Leg
AEA09-BRS-08-OD-LL	Brush and Roller Worker Sample, ME 08, Outer Dosimeter, Lower Leg
AEA09-BRS-09-PH	Brush and Roller Worker Sample, ME 09, Painter's Hat
AEA09-BRS-09-PH-ID	Brush and Roller Worker Sample, ME 09, Painter's Hat Dosimeter
AEA09-BRS-09-AR	Brush and Roller Worker Sample, ME 09, Air Sampling Tube
AEA09-BRS-09-RES-01	Brush and Roller Worker Sample, ME 09, RespiCon™ 100 µm
AEA09-BRS-09-RES-02	Brush and Roller Worker Sample, ME 09, RespiCon™ 10 µm
AEA09-BRS-09-RES-03	Brush and Roller Worker Sample, ME 09, RespiCon™ 2.5 µm
AEA09-BRS-09-HW-01	Brush and Roller Worker Sample, ME 09, Hand Wash
AEA09-BRS-09-FW-01	Brush and Roller Worker Sample, ME 09, Face and Neck Wipe
AEA09-BRS-09-ID-UA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Arm
AEA09-BRS-09-ID-LA	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Arm
AEA09-BRS-09-ID-FT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Front Torso
AEA09-BRS-09-ID-RT	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Rear Torso
AEA09-BRS-09-ID-UL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Upper Leg
AEA09-BRS-09-ID-LL	Brush and Roller Worker Sample, ME 09, Inner Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-BRS-09-OD-UA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Arm
AEA09-BRS-09-OD-LA	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Arm
AEA09-BRS-09-OD-FT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Front Torso
AEA09-BRS-09-OD-RT	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Rear Torso
AEA09-BRS-09-OD-UL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Upper Leg
AEA09-BRS-09-OD-LL	Brush and Roller Worker Sample, ME 09, Outer Dosimeter, Lower Leg
AEA09-BRS-10-PH	Brush and Roller Worker Sample, ME 10, Painter's Hat
AEA09-BRS-10-PH-ID	Brush and Roller Worker Sample, ME 10, Painter's Hat Dosimeter
AEA09-BRS-10-AR	Brush and Roller Worker Sample, ME 10, Air Sampling Tube
AEA09-BRS-10-RES-01	Brush and Roller Worker Sample, ME 10, RespiCon™ 100 µm
AEA09-BRS-10-RES-02	Brush and Roller Worker Sample, ME 10, RespiCon™ 10 µm
AEA09-BRS-10-RES-03	Brush and Roller Worker Sample, ME 10, RespiCon™ 2.5 µm
AEA09-BRS-10-HW-01	Brush and Roller Worker Sample, ME 10, Hand Wash
AEA09-BRS-10-FW-01	Brush and Roller Worker Sample, ME 10, Face and Neck Wipe
AEA09-BRS-10-ID-UA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Arm
AEA09-BRS-10-ID-LA	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Arm
AEA09-BRS-10-ID-FT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Front Torso
AEA09-BRS-10-ID-RT	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Rear Torso
AEA09-BRS-10-ID-UL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Upper Leg
AEA09-BRS-10-ID-LL	Brush and Roller Worker Sample, ME 10, Inner Dosimeter, Lower Leg
AEA09-BRS-10-OD-UA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Arm
AEA09-BRS-10-OD-LA	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Arm
AEA09-BRS-10-OD-FT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Front Torso
AEA09-BRS-10-OD-RT	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Rear Torso
AEA09-BRS-10-OD-UL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Upper Leg
AEA09-BRS-10-OD-LL	Brush and Roller Worker Sample, ME 10, Outer Dosimeter, Lower Leg
AEA09-BRS-11-PH	Brush and Roller Worker Sample, ME 11, Painter's Hat
AEA09-BRS-11-PH-ID	Brush and Roller Worker Sample, ME 11, Painter's Hat Dosimeter

Sample ID Number	Description
AEA09-BRS-11-AR	Brush and Roller Worker Sample, ME 11, Air Sampling Tube
AEA09-BRS-11-RES-01	Brush and Roller Worker Sample, ME 11, RespiCon™ 100 µm
AEA09-BRS-11-RES-02	Brush and Roller Worker Sample, ME 11, RespiCon™ 10 µm
AEA09-BRS-11-RES-03	Brush and Roller Worker Sample, ME 11, RespiCon™ 2.5 µm
AEA09-BRS-11-HW-01	Brush and Roller Worker Sample, ME 11, Hand Wash
AEA09-BRS-11-FW-01	Brush and Roller Worker Sample, ME 11, Face and Neck Wipe
AEA09-BRS-11-ID-UA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Arm
AEA09-BRS-11-ID-LA	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Arm
AEA09-BRS-11-ID-FT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Front Torso
AEA09-BRS-11-ID-RT	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Rear Torso
AEA09-BRS-11-ID-UL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Upper Leg
AEA09-BRS-11-ID-LL	Brush and Roller Worker Sample, ME 11, Inner Dosimeter, Lower Leg
AEA09-BRS-11-OD-UA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Arm
AEA09-BRS-11-OD-LA	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Arm
AEA09-BRS-11-OD-FT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Front Torso
AEA09-BRS-11-OD-RT	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Rear Torso
AEA09-BRS-11-OD-UL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Upper Leg
AEA09-BRS-11-OD-LL	Brush and Roller Worker Sample, ME 11, Outer Dosimeter, Lower Leg
AEA09-BRS-12-PH	Brush and Roller Worker Sample, ME 12, Painter's Hat
AEA09-BRS-12-PH-ID	Brush and Roller Worker Sample, ME 12, Painter's Hat Dosimeter
AEA09-BRS-12-AR	Brush and Roller Worker Sample, ME 12, Air Sampling Tube
AEA09-BRS-12-RES-01	Brush and Roller Worker Sample, ME 12, RespiCon™ 100 µm
AEA09-BRS-12-RES-02	Brush and Roller Worker Sample, ME 12, RespiCon™ 10 µm
AEA09-BRS-12-RES-03	Brush and Roller Worker Sample, ME 12, RespiCon™ 2.5 µm
AEA09-BRS-12-HW-01	Brush and Roller Worker Sample, ME 12, Hand Wash
AEA09-BRS-12-FW-01	Brush and Roller Worker Sample, ME 12, Face and Neck Wipe
AEA09-BRS-12-ID-UA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Arm
AEA09-BRS-12-ID-LA	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Arm
AEA09-BRS-12-ID-FT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Front Torso
AEA09-BRS-12-ID-RT	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Rear Torso

Sample ID Number	Description
AEA09-BRS-12-ID-UL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Upper Leg
AEA09-BRS-12-ID-LL	Brush and Roller Worker Sample, ME 12, Inner Dosimeter, Lower Leg
AEA09-BRS-12-OD-UA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Arm
AEA09-BRS-12-OD-LA	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Arm
AEA09-BRS-12-OD-FT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Front Torso
AEA09-BRS-12-OD-RT	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Rear Torso
AEA09-BRS-12-OD-UL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Upper Leg
AEA09-BRS-12-OD-LL	Brush and Roller Worker Sample, ME 12, Outer Dosimeter, Lower Leg
AEA09-BRS-13-PH	Brush and Roller Worker Sample, ME 13, Painter's Hat
AEA09-BRS-13-PH-ID	Brush and Roller Worker Sample, ME 13, Painter's Hat Dosimeter
AEA09-BRS-13-AR	Brush and Roller Worker Sample, ME 13, Air Sampling Tube
AEA09-BRS-13-RES-01	Brush and Roller Worker Sample, ME 13, RespiCon™ 100 µm
AEA09-BRS-13-RES-02	Brush and Roller Worker Sample, ME 13, RespiCon™ 10 µm
AEA09-BRS-13-RES-03	Brush and Roller Worker Sample, ME 13, RespiCon™ 2.5 µm
AEA09-BRS-13-HW-01	Brush and Roller Worker Sample, ME 13, Hand Wash
AEA09-BRS-13-FW-01	Brush and Roller Worker Sample, ME 13, Face and Neck Wipe
AEA09-BRS-13-ID-UA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Arm
AEA09-BRS-13-ID-LA	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Arm
AEA09-BRS-13-ID-FT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Front Torso
AEA09-BRS-13-ID-RT	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Rear Torso
AEA09-BRS-13-ID-UL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Upper Leg
AEA09-BRS-13-ID-LL	Brush and Roller Worker Sample, ME 13, Inner Dosimeter, Lower Leg
AEA09-BRS-13-OD-UA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Arm
AEA09-BRS-13-OD-LA	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Arm
AEA09-BRS-13-OD-FT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Front Torso
AEA09-BRS-13-OD-RT	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Rear Torso
AEA09-BRS-13-OD-UL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Upper Leg

Sample ID Number	Description
AEA09-BRS-13-OD-LL	Brush and Roller Worker Sample, ME 13, Outer Dosimeter, Lower Leg
AEA09-BRS-14-PH	Brush and Roller Worker Sample, ME 14, Painter's Hat
AEA09-BRS-14-PH-ID	Brush and Roller Worker Sample, ME 14, Painter's Hat Dosimeter
AEA09-BRS-14-AR	Brush and Roller Worker Sample, ME 14, Air Sampling Tube
AEA09-BRS-14-RES-01	Brush and Roller Worker Sample, ME 14, RespiCon™ 100 µm
AEA09-BRS-14-RES-02	Brush and Roller Worker Sample, ME 14, RespiCon™ 10 µm
AEA09-BRS-14-RES-03	Brush and Roller Worker Sample, ME 14, RespiCon™ 2.5 µm
AEA09-BRS-14-HW-01	Brush and Roller Worker Sample, ME 14, Hand Wash
AEA09-BRS-14-FW-01	Brush and Roller Worker Sample, ME 14, Face and Neck Wipe
AEA09-BRS-14-ID-UA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Arm
AEA09-BRS-14-ID-LA	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Arm
AEA09-BRS-14-ID-FT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Front Torso
AEA09-BRS-14-ID-RT	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Rear Torso
AEA09-BRS-14-ID-UL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Upper Leg
AEA09-BRS-14-ID-LL	Brush and Roller Worker Sample, ME 14, Inner Dosimeter, Lower Leg
AEA09-BRS-14-OD-UA	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Arm
AEA09-BRS-14-OD-LA	Brush and Roller Worker Sample, ME 14, Outer DosimeterDosimeter, Lower Arm
AEA09-BRS-14-OD-FT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Front Torso
AEA09-BRS-14-OD-RT	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Rear Torso
AEA09-BRS-14-OD-UL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Upper Leg
AEA09-BRS-14-OD-LL	Brush and Roller Worker Sample, ME 14, Outer Dosimeter, Lower Leg
AEA09-BRS-15-PH	Brush and Roller Worker Sample, ME 15, Painter's Hat
AEA09-BRS-15-PH-ID	Brush and Roller Worker Sample, ME 15, Painter's Hat Dosimeter
AEA09-BRS-15-AR	Brush and Roller Worker Sample, ME 15, Air Sampling Tube
AEA09-BRS-15-RES-01	Brush and Roller Worker Sample, ME 15, RespiCon™ 100 µm
AEA09-BRS-15-RES-02	Brush and Roller Worker Sample, ME 15, RespiCon™ 10 µm
AEA09-BRS-15-RES-03	Brush and Roller Worker Sample, ME 15, RespiCon™ 2.5 µm
AEA09-BRS-15-HW-01	Brush and Roller Worker Sample, ME 15, Hand Wash
AEA09-BRS-15-FW-01	Brush and Roller Worker Sample, ME 15, Face and Neck Wipe
AEA09-BRS-15-ID-UA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Arm
AEA09-BRS-15-ID-LA	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Arm

Sample ID Number	Description
AEA09-BRS-15-ID-FT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Front Torso
AEA09-BRS-15-ID-RT	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Rear Torso
AEA09-BRS-15-ID-UL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Upper Leg
AEA09-BRS-15-ID-LL	Brush and Roller Worker Sample, ME 15, Inner Dosimeter, Lower Leg
AEA09-BRS-15-OD-UA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Arm
AEA09-BRS-15-OD-LA	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Arm
AEA09-BRS-15-OD-FT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Front Torso
AEA09-BRS-15-OD-RT	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Rear Torso
AEA09-BRS-15-OD-UL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Upper Leg
AEA09-BRS-15-OD-LL	Brush and Roller Worker Sample, ME 15, Outer Dosimeter, Lower Leg
AEA09-BRS-16-PH	Brush and Roller Worker Sample, ME 16, Painter's Hat
AEA09-BRS-16-PH-ID	Brush and Roller Worker Sample, ME 16, Painter's Hat Dosimeter
AEA09-BRS-16-AR	Brush and Roller Worker Sample, ME 16, Air Sampling Tube
AEA09-BRS-16-RES-01	Brush and Roller Worker Sample, ME 16, RespiCon™ 100 µm
AEA09-BRS-16-RES-02	Brush and Roller Worker Sample, ME 16, RespiCon™ 10 µm
AEA09-BRS-16-RES-03	Brush and Roller Worker Sample, ME 16, RespiCon™ 2.5 µm
AEA09-BRS-16-HW-01	Brush and Roller Worker Sample, ME 16, Hand Wash
AEA09-BRS-16-FW-01	Brush and Roller Worker Sample, ME 16, Face and Neck Wipe
AEA09-BRS-16-ID-UA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Arm
AEA09-BRS-16-ID-LA	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Arm
AEA09-BRS-16-ID-FT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Front Torso
AEA09-BRS-16-ID-RT	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Rear Torso
AEA09-BRS-16-ID-UL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Upper Leg
AEA09-BRS-16-ID-LL	Brush and Roller Worker Sample, ME 16, Inner Dosimeter, Lower Leg
AEA09-BRS-16-OD-UA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Arm
AEA09-BRS-16-OD-LA	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Arm
AEA09-BRS-16-OD-FT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Front Torso

Sample ID Number	Description
AEA09-BRS-16-OD-RT	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Rear Torso
AEA09-BRS-16-OD-UL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Upper Leg
AEA09-BRS-16-OD-LL	Brush and Roller Worker Sample, ME 16, Outer Dosimeter, Lower Leg
AEA09-BRS-17-PH	Brush and Roller Worker Sample, ME 17, Painter's Hat
AEA09-BRS-17-PH-ID	Brush and Roller Worker Sample, ME 17, Painter's Hat Dosimeter
AEA09-BRS-17-AR	Brush and Roller Worker Sample, ME 17, Air Sampling Tube
AEA09-BRS-17-RES-01	Brush and Roller Worker Sample, ME 17, RespiCon™ 100 µm
AEA09-BRS-17-RES-02	Brush and Roller Worker Sample, ME 17, RespiCon™ 10 µm
AEA09-BRS-17-RES-03	Brush and Roller Worker Sample, ME 17, RespiCon™ 2.5 µm
AEA09-BRS-17-HW-01	Brush and Roller Worker Sample, ME 17, Hand Wash
AEA09-BRS-17-FW-01	Brush and Roller Worker Sample, ME 17, Face and Neck Wipe
AEA09-BRS-17-ID-UA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Arm
AEA09-BRS-17-ID-LA	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Arm
AEA09-BRS-17-ID-FT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Front Torso
AEA09-BRS-17-ID-RT	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Rear Torso
AEA09-BRS-17-ID-UL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Upper Leg
AEA09-BRS-17-ID-LL	Brush and Roller Worker Sample, ME 17, Inner Dosimeter, Lower Leg
AEA09-BRS-17-OD-UA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Arm
AEA09-BRS-17-OD-LA	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Arm
AEA09-BRS-17-OD-FT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Front Torso
AEA09-BRS-17-OD-RT	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Rear Torso
AEA09-BRS-17-OD-UL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Upper Leg
AEA09-BRS-17-OD-LL	Brush and Roller Worker Sample, ME 17, Outer Dosimeter, Lower Leg
AEA09-BRS-18-PH	Brush and Roller Worker Sample, ME 18, Painter's Hat
AEA09-BRS-18-PH-ID	Brush and Roller Worker Sample, ME 18, Painter's Hat Dosimeter
AEA09-BRS-18-AR	Brush and Roller Worker Sample, ME 18, Air Sampling Tube
AEA09-BRS-18-RES-01	Brush and Roller Worker Sample, ME 18, RespiCon™ 100 µm
AEA09-BRS-18-RES-02	Brush and Roller Worker Sample, ME 18, RespiCon™ 10 µm
AEA09-BRS-18-RES-03	Brush and Roller Worker Sample, ME 18, RespiCon™ 2.5 µm
AEA09-BRS-18-HW-01	Brush and Roller Worker Sample, ME 18, Hand Wash
AEA09-BRS-18-FW-01	Brush and Roller Worker Sample, ME 18, Face and Neck Wipe

Sample ID Number	Description
AEA09-BRS-18-ID-UA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Arm
AEA09-BRS-18-ID-LA	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Arm
AEA09-BRS-18-ID-FT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Front Torso
AEA09-BRS-18-ID-RT	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Rear Torso
AEA09-BRS-18-ID-UL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Upper Leg
AEA09-BRS-18-ID-LL	Brush and Roller Worker Sample, ME 18, Inner Dosimeter, Lower Leg
AEA09-BRS-18-OD-UA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Arm
AEA09-BRS-18-OD-LA	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Arm
AEA09-BRS-18-OD-FT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Front Torso
AEA09-BRS-18-OD-RT	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Rear Torso
AEA09-BRS-18-OD-UL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Upper Leg
AEA09-BRS-18-OD-LL	Brush and Roller Worker Sample, ME 18, Outer Dosimeter, Lower Leg

Sample ID Number	Description
AEA09-FF-01-PH-C1	Fortification Sample, ME 01, Painter's Hat, 1st Control
AEA09-FF-01-PH-C2	Fortification Sample, ME 01, Painter's Hat, 2nd Control
AEA09-FF-01-PH-L1	Fortification Sample, ME 01, Painter's Hat, 1st Low Level
AEA09-FF-01-PH-L2	Fortification Sample, ME 01, Painter's Hat, 2nd Low Level
AEA09-FF-01-PH-L3	Fortification Sample, ME 01, Painter's Hat, 3rd Low Level
AEA09-FF-01-PH-H1	Fortification Sample, ME 01, Painter's Hat, 1st High Level
AEA09-FF-01-PH-H2	Fortification Sample, ME 01, Painter's Hat, 2nd High Level
AEA09-FF-01-PH-H3	Fortification Sample, ME 01, Painter's Hat, 3rd High Level
AEA09-FF-01-AR-C1	Fortification Sample, ME 01, Air Sampling Tube, 1st Control
AEA09-FF-01-AR-C2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Control
AEA09-FF-01-AR-L1	Fortification Sample, ME 01, Air Sampling Tube, 1st Low Level
AEA09-FF-01-AR-L2	Fortification Sample, ME 01, Air Sampling Tube, 2nd Low Level
AEA09-FF-01-AR-L3	Fortification Sample, ME 01, Air Sampling Tube, 3rd Low Level
AEA09-FF-01-AR-H1	Fortification Sample, ME 01, Air Sampling Tube, 1st High Level
AEA09-FF-01-AR-H2	Fortification Sample, ME 01, Air Sampling Tube, 2nd High Level
AEA09-FF-01-AR-H3	Fortification Sample, ME 01, Air Sampling Tube, 3rd High Level
AEA09-FF-01-RES-C1	Fortification Sample, ME 01, RespiCon, 1st Control
AEA09-FF-01-RES-C2	Fortification Sample, ME 01, RespiCon, 2nd Control
AEA09-FF-01-RES-L1	Fortification Sample, ME 01, RespiCon, 1st Low Level
AEA09-FF-01-RES-L2	Fortification Sample, ME 01, RespiCon, 2nd Low Level
AEA09-FF-01-RES-L3	Fortification Sample, ME 01, RespiCon, 3rd Low Level
AEA09-FF-01-RES-H1	Fortification Sample, ME 01, RespiCon, 1st High Level
AEA09-FF-01-RES-H2	Fortification Sample, ME 01, RespiCon, 2nd High Level
AEA09-FF-01-RES-H3	Fortification Sample, ME 01, RespiCon, 3rd High Level
AEA09-FF-01-HW-C1	Fortification Sample, ME 01, Hand Wash, 1st Control
AEA09-FF-01-HW-C2	Fortification Sample, ME 01, Hand Wash, 2nd Control
AEA09-FF-01-HW-L1	Fortification Sample, ME 01, Hand Wash, 1st Low Level
AEA09-FF-01-HW-L2	Fortification Sample, ME 01, Hand Wash, 2nd Low Level
AEA09-FF-01-HW-L3	Fortification Sample, ME 01, Hand Wash, 3rd Low Level
AEA09-FF-01-HW-H1	Fortification Sample, ME 01, Hand Wash, 1st High Level
AEA09-FF-01-HW-H2	Fortification Sample, ME 01, Hand Wash, 2nd High Level
AEA09-FF-01-HW-H3	Fortification Sample, ME 01, Hand Wash, 3rd High Level
AEA09-FF-01-FW-C1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Control
AEA09-FF-01-FW-C2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Control
AEA09-FF-01-FW-L1	Fortification Sample, ME 01, Face and Neck Wipe, 1st Low Level
AEA09-FF-01-FW-L2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd Low Level
AEA09-FF-01-FW-L3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd Low Level
AEA09-FF-01-FW-H1	Fortification Sample, ME 01, Face and Neck Wipe, 1st High Level
AEA09-FF-01-FW-H2	Fortification Sample, ME 01, Face and Neck Wipe, 2nd High Level
AEA09-FF-01-FW-H3	Fortification Sample, ME 01, Face and Neck Wipe, 3rd High Level

Sample ID Number	Description
AEA09-FF-01-ID-C1	Fortification Sample, ME 01, Inner Dosimeter, 1st Control
AEA09-FF-01-ID-C2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Control
AEA09-FF-01-ID-L1	Fortification Sample, ME 01, Inner Dosimeter, 1st Low Level
AEA09-FF-01-ID-L2	Fortification Sample, ME 01, Inner Dosimeter, 2nd Low Level
AEA09-FF-01-ID-L3	Fortification Sample, ME 01, Inner Dosimeter, 3rd Low Level
AEA09-FF-01-ID-H1	Fortification Sample, ME 01, Inner Dosimeter, 1st High Level
AEA09-FF-01-ID-H2	Fortification Sample, ME 01, Inner Dosimeter, 2nd High Level
AEA09-FF-01-ID-H3	Fortification Sample, ME 01, Inner Dosimeter, 3rd High Level
AEA09-FF-01-OD-C1	Fortification Sample, ME 01, Outer Dosimeter, 1st Control
AEA09-FF-01-OD-C2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Control
AEA09-FF-01-OD-L1	Fortification Sample, ME 01, Outer Dosimeter, 1st Low Level
AEA09-FF-01-OD-L2	Fortification Sample, ME 01, Outer Dosimeter, 2nd Low Level
AEA09-FF-01-OD-L3	Fortification Sample, ME 01, Outer Dosimeter, 3rd Low Level
AEA09-FF-01-OD-H1	Fortification Sample, ME 01, Outer Dosimeter, 1st High Level
AEA09-FF-01-OD-H2	Fortification Sample, ME 01, Outer Dosimeter, 2nd High Level
AEA09-FF-01-OD-H3	Fortification Sample, ME 01, Outer Dosimeter, 3rd High Level
AEA09-FF-02-PH-C1	Fortification Sample, ME 02, Painter's Hat, 1st Control
AEA09-FF-02-PH-C2	Fortification Sample, ME 02, Painter's Hat, 2nd Control
AEA09-FF-02-PH-L1	Fortification Sample, ME 02, Painter's Hat, 1st Low Level
AEA09-FF-02-PH-L2	Fortification Sample, ME 02, Painter's Hat, 2nd Low Level
AEA09-FF-02-PH-L3	Fortification Sample, ME 02, Painter's Hat, 3rd Low Level
AEA09-FF-02-PH-H1	Fortification Sample, ME 02, Painter's Hat, 1st High Level
AEA09-FF-02-PH-H2	Fortification Sample, ME 02, Painter's Hat, 2nd High Level
AEA09-FF-02-PH-H3	Fortification Sample, ME 02, Painter's Hat, 3rd High Level
AEA09-FF-02-AR-C1	Fortification Sample, ME 02, Air Sampling Tube, 1st Control
AEA09-FF-02-AR-C2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Control
AEA09-FF-02-AR-L1	Fortification Sample, ME 02, Air Sampling Tube, 1st Low Level
AEA09-FF-02-AR-L2	Fortification Sample, ME 02, Air Sampling Tube, 2nd Low Level
AEA09-FF-02-AR-L3	Fortification Sample, ME 02, Air Sampling Tube, 3rd Low Level
AEA09-FF-02-AR-H1	Fortification Sample, ME 02, Air Sampling Tube, 1st High Level
AEA09-FF-02-AR-H2	Fortification Sample, ME 02, Air Sampling Tube, 2nd High Level
AEA09-FF-02-AR-H3	Fortification Sample, ME 02, Air Sampling Tube, 3rd High Level
AEA09-FF-02-RES-C1	Fortification Sample, ME 02, RespiCon, 1st Control
AEA09-FF-02-RES-C2	Fortification Sample, ME 02, RespiCon, 2nd Control
AEA09-FF-02-RES-L1	Fortification Sample, ME 02, RespiCon, 1st Low Level
AEA09-FF-02-RES-L2	Fortification Sample, ME 02, RespiCon, 2nd Low Level
AEA09-FF-02-RES-L3	Fortification Sample, ME 02, RespiCon, 3rd Low Level
AEA09-FF-02-RES-H1	Fortification Sample, ME 02, RespiCon, 1st High Level
AEA09-FF-02-RES-H2	Fortification Sample, ME 02, RespiCon, 2nd High Level
AEA09-FF-02-RES-H3	Fortification Sample, ME 02, RespiCon, 3rd High Level
AEA09-FF-02-HW-C1	Fortification Sample, ME 02, Hand Wash, 1st Control
AEA09-FF-02-HW-C2	Fortification Sample, ME 02, Hand Wash, 2nd Control
AEA09-FF-02-HW-L1	Fortification Sample, ME 02, Hand Wash, 1st Low Level
AEA09-FF-02-HW-L2	Fortification Sample, ME 02, Hand Wash, 2nd Low Level
AEA09-FF-02-HW-L3	Fortification Sample, ME 02, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-02-HW-H1	Fortification Sample, ME 02, Hand Wash, 1st High Level
AEA09-FF-02-HW-H2	Fortification Sample, ME 02, Hand Wash, 2nd High Level
AEA09-FF-02-HW-H3	Fortification Sample, ME 02, Hand Wash, 3rd High Level
AEA09-FF-02-FW-C1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Control
AEA09-FF-02-FW-C2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Control
AEA09-FF-02-FW-L1	Fortification Sample, ME 02, Face and Neck Wipe, 1st Low Level
AEA09-FF-02-FW-L2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd Low Level
AEA09-FF-02-FW-L3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd Low Level
AEA09-FF-02-FW-H1	Fortification Sample, ME 02, Face and Neck Wipe, 1st High Level
AEA09-FF-02-FW-H2	Fortification Sample, ME 02, Face and Neck Wipe, 2nd High Level
AEA09-FF-02-FW-H3	Fortification Sample, ME 02, Face and Neck Wipe, 3rd High Level
AEA09-FF-02-ID-C1	Fortification Sample, ME 02, Inner Dosimeter, 1st Control
AEA09-FF-02-ID-C2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Control
AEA09-FF-02-ID-L1	Fortification Sample, ME 02, Inner Dosimeter, 1st Low Level
AEA09-FF-02-ID-L2	Fortification Sample, ME 02, Inner Dosimeter, 2nd Low Level
AEA09-FF-02-ID-L3	Fortification Sample, ME 02, Inner Dosimeter, 3rd Low Level
AEA09-FF-02-ID-H1	Fortification Sample, ME 02, Inner Dosimeter, 1st High Level
AEA09-FF-02-ID-H2	Fortification Sample, ME 02, Inner Dosimeter, 2nd High Level
AEA09-FF-02-ID-H3	Fortification Sample, ME 02, Inner Dosimeter, 3rd High Level
AEA09-FF-02-OD-C1	Fortification Sample, ME 02, Outer Dosimeter, 1st Control
AEA09-FF-02-OD-C2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Control
AEA09-FF-02-OD-L1	Fortification Sample, ME 02, Outer Dosimeter, 1st Low Level
AEA09-FF-02-OD-L2	Fortification Sample, ME 02, Outer Dosimeter, 2nd Low Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-02-OD-H1	Fortification Sample, ME 02, Outer Dosimeter, 1st High Level
AEA09-FF-02-OD-H2	Fortification Sample, ME 02, Outer Dosimeter, 2nd High Level
AEA09-FF-02-OD-H3	Fortification Sample, ME 02, Outer Dosimeter, 3rd High Level
AEA09-FF-02-OD-L3	Fortification Sample, ME 02, Outer Dosimeter, 3rd Low Level
AEA09-FF-03-PH-C1	Fortification Sample, ME 03, Painter's Hat, 1st Control
AEA09-FF-03-PH-C2	Fortification Sample, ME 03, Painter's Hat, 2nd Control
AEA09-FF-03-PH-L1	Fortification Sample, ME 03, Painter's Hat, 1st Low Level
AEA09-FF-03-PH-L2	Fortification Sample, ME 03, Painter's Hat, 2nd Low Level
AEA09-FF-03-PH-L3	Fortification Sample, ME 03, Painter's Hat, 3rd Low Level
AEA09-FF-03-PH-H1	Fortification Sample, ME 03, Painter's Hat, 1st High Level
AEA09-FF-03-PH-H2	Fortification Sample, ME 03, Painter's Hat, 2nd High Level
AEA09-FF-03-PH-H3	Fortification Sample, ME 03, Painter's Hat, 3rd High Level
AEA09-FF-03-AR-C1	Fortification Sample, ME 03, Air Sampling Tube, 1st Control
AEA09-FF-03-AR-C2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Control
AEA09-FF-03-AR-L1	Fortification Sample, ME 03, Air Sampling Tube, 1st Low Level
AEA09-FF-03-AR-L2	Fortification Sample, ME 03, Air Sampling Tube, 2nd Low Level
AEA09-FF-03-AR-L3	Fortification Sample, ME 03, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-03-AR-H1	Fortification Sample, ME 03, Air Sampling Tube, 1st High Level
AEA09-FF-03-AR-H2	Fortification Sample, ME 03, Air Sampling Tube, 2nd High Level
AEA09-FF-03-AR-H3	Fortification Sample, ME 03, Air Sampling Tube, 3rd High Level
AEA09-FF-03-RES-C1	Fortification Sample, ME 03, RespiCon, 1st Control
AEA09-FF-03-RES-C2	Fortification Sample, ME 03, RespiCon, 2nd Control
AEA09-FF-03-RES-L1	Fortification Sample, ME 03, RespiCon, 1st Low Level
AEA09-FF-03-RES-L2	Fortification Sample, ME 03, RespiCon, 2nd Low Level
AEA09-FF-03-RES-L3	Fortification Sample, ME 03, RespiCon, 3rd Low Level
AEA09-FF-03-RES-H1	Fortification Sample, ME 03, RespiCon, 1st High Level
AEA09-FF-03-RES-H2	Fortification Sample, ME 03, RespiCon, 2nd High Level
AEA09-FF-03-RES-H3	Fortification Sample, ME 03, RespiCon, 3rd High Level
AEA09-FF-03-HW-C1	Fortification Sample, ME 03, Hand Wash, 1st Control
AEA09-FF-03-HW-C2	Fortification Sample, ME 03, Hand Wash, 2nd Control
AEA09-FF-03-HW-L1	Fortification Sample, ME 03, Hand Wash, 1st Low Level
AEA09-FF-03-HW-L2	Fortification Sample, ME 03, Hand Wash, 2nd Low Level
AEA09-FF-03-HW-L3	Fortification Sample, ME 03, Hand Wash, 3rd Low Level
AEA09-FF-03-HW-H1	Fortification Sample, ME 03, Hand Wash, 1st High Level
AEA09-FF-03-HW-H2	Fortification Sample, ME 03, Hand Wash, 2nd High Level
AEA09-FF-03-HW-H3	Fortification Sample, ME 03, Hand Wash, 3rd High Level
AEA09-FF-03-FW-C1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Control
AEA09-FF-03-FW-C2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Control
AEA09-FF-03-FW-L1	Fortification Sample, ME 03, Face and Neck Wipe, 1st Low Level
AEA09-FF-03-FW-L2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd Low Level
AEA09-FF-03-FW-L3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd Low Level
AEA09-FF-03-FW-H1	Fortification Sample, ME 03, Face and Neck Wipe, 1st High Level
AEA09-FF-03-FW-H2	Fortification Sample, ME 03, Face and Neck Wipe, 2nd High Level
AEA09-FF-03-FW-H3	Fortification Sample, ME 03, Face and Neck Wipe, 3rd High Level
AEA09-FF-03-ID-C1	Fortification Sample, ME 03, Inner Dosimeter, 1st Control
AEA09-FF-03-ID-C2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Control
AEA09-FF-03-ID-L1	Fortification Sample, ME 03, Inner Dosimeter, 1st Low Level
AEA09-FF-03-ID-L2	Fortification Sample, ME 03, Inner Dosimeter, 2nd Low Level
AEA09-FF-03-ID-L3	Fortification Sample, ME 03, Inner Dosimeter, 3rd Low Level
AEA09-FF-03-ID-H1	Fortification Sample, ME 03, Inner Dosimeter, 1st High Level
AEA09-FF-03-ID-H2	Fortification Sample, ME 03, Inner Dosimeter, 2nd High Level
AEA09-FF-03-ID-H3	Fortification Sample, ME 03, Inner Dosimeter, 3rd High Level
AEA09-FF-03-OD-C1	Fortification Sample, ME 03, Outer Dosimeter, 1st Control
AEA09-FF-03-OD-C2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Control
AEA09-FF-03-OD-L1	Fortification Sample, ME 03, Outer Dosimeter, 1st Low Level
AEA09-FF-03-OD-L2	Fortification Sample, ME 03, Outer Dosimeter, 2nd Low Level
AEA09-FF-03-OD-L3	Fortification Sample, ME 03, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description

AEA09-FF-03-OD-H1	Fortification Sample, ME 03, Outer Dosimeter, 1st High Level
AEA09-FF-03-OD-H2	Fortification Sample, ME 03, Outer Dosimeter, 2nd High Level
AEA09-FF-03-OD-H3	Fortification Sample, ME 03, Outer Dosimeter, 3rd High Level
AEA09-FF-04-PH-C1	Fortification Sample, ME 04, Painter's Hat, 1st Control
AEA09-FF-04-PH-C2	Fortification Sample, ME 04, Painter's Hat, 2nd Control
AEA09-FF-04-PH-L1	Fortification Sample, ME 04, Painter's Hat, 1st Low Level
AEA09-FF-04-PH-L2	Fortification Sample, ME 04, Painter's Hat, 2nd Low Level
AEA09-FF-04-PH-L3	Fortification Sample, ME 04, Painter's Hat, 3rd Low Level
AEA09-FF-04-PH-H1	Fortification Sample, ME 04, Painter's Hat, 1st High Level
AEA09-FF-04-PH-H2	Fortification Sample, ME 04, Painter's Hat, 2nd High Level
AEA09-FF-04-PH-H3	Fortification Sample, ME 04, Painter's Hat, 3rd High Level
AEA09-FF-04-AR-C1	Fortification Sample, ME 04, Air Sampling Tube, 1st Control
AEA09-FF-04-AR-C2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Control
AEA09-FF-04-AR-L1	Fortification Sample, ME 04, Air Sampling Tube, 1st Low Level
AEA09-FF-04-AR-L2	Fortification Sample, ME 04, Air Sampling Tube, 2nd Low Level
AEA09-FF-04-AR-L3	Fortification Sample, ME 04, Air Sampling Tube, 3rd Low Level
AEA09-FF-04-AR-H1	Fortification Sample, ME 04, Air Sampling Tube, 1st High Level
AEA09-FF-04-AR-H2	Fortification Sample, ME 04, Air Sampling Tube, 2nd High Level
AEA09-FF-04-AR-H3	Fortification Sample, ME 04, Air Sampling Tube, 3rd High Level
AEA09-FF-04-RES-C1	Fortification Sample, ME 04, RespiCon, 1st Control
AEA09-FF-04-RES-C2	Fortification Sample, ME 04, RespiCon, 2nd Control
AEA09-FF-04-RES-L1	Fortification Sample, ME 04, RespiCon, 1st Low Level
AEA09-FF-04-RES-L2	Fortification Sample, ME 04, RespiCon, 2nd Low Level
AEA09-FF-04-RES-L3	Fortification Sample, ME 04, RespiCon, 3rd Low Level
AEA09-FF-04-RES-H1	Fortification Sample, ME 04, RespiCon, 1st High Level
AEA09-FF-04-RES-H2	Fortification Sample, ME 04, RespiCon, 2nd High Level
AEA09-FF-04-RES-H3	Fortification Sample, ME 04, RespiCon, 3rd High Level
AEA09-FF-04-HW-C1	Fortification Sample, ME 04, Hand Wash, 1st Control
AEA09-FF-04-HW-C2	Fortification Sample, ME 04, Hand Wash, 2nd Control
AEA09-FF-04-HW-L1	Fortification Sample, ME 04, Hand Wash, 1st Low Level
AEA09-FF-04-HW-L2	Fortification Sample, ME 04, Hand Wash, 2nd Low Level
AEA09-FF-04-HW-L3	Fortification Sample, ME 04, Hand Wash, 3rd Low Level
AEA09-FF-04-HW-H1	Fortification Sample, ME 04, Hand Wash, 1st High Level
AEA09-FF-04-HW-H2	Fortification Sample, ME 04, Hand Wash, 2nd High Level
AEA09-FF-04-HW-H3	Fortification Sample, ME 04, Hand Wash, 3rd High Level
AEA09-FF-04-FW-C1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Control
AEA09-FF-04-FW-C2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Control
AEA09-FF-04-FW-L1	Fortification Sample, ME 04, Face and Neck Wipe, 1st Low Level
AEA09-FF-04-FW-L2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd Low Level
AEA09-FF-04-FW-L3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd Low Level
AEA09-FF-04-FW-H1	Fortification Sample, ME 04, Face and Neck Wipe, 1st High Level
AEA09-FF-04-FW-H2	Fortification Sample, ME 04, Face and Neck Wipe, 2nd High Level

Sample ID Number	Description
AEA09-FF-04-FW-H3	Fortification Sample, ME 04, Face and Neck Wipe, 3rd High Level
AEA09-FF-04-ID-C1	Fortification Sample, ME 04, Inner Dosimeter, 1st Control
AEA09-FF-04-ID-C2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Control
AEA09-FF-04-ID-L1	Fortification Sample, ME 04, Inner Dosimeter, 1st Low Level
AEA09-FF-04-ID-L2	Fortification Sample, ME 04, Inner Dosimeter, 2nd Low Level
AEA09-FF-04-ID-L3	Fortification Sample, ME 04, Inner Dosimeter, 3rd Low Level
AEA09-FF-04-ID-H1	Fortification Sample, ME 04, Inner Dosimeter, 1st High Level
AEA09-FF-04-ID-H2	Fortification Sample, ME 04, Inner Dosimeter, 2nd High Level
AEA09-FF-04-ID-H3	Fortification Sample, ME 04, Inner Dosimeter, 3rd High Level
AEA09-FF-04-OD-C1	Fortification Sample, ME 04, Outer Dosimeter, 1st Control
AEA09-FF-04-OD-C2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Control
AEA09-FF-04-OD-L1	Fortification Sample, ME 04, Outer Dosimeter, 1st Low Level
AEA09-FF-04-OD-L2	Fortification Sample, ME 04, Outer Dosimeter, 2nd Low Level
AEA09-FF-04-OD-L3	Fortification Sample, ME 04, Outer Dosimeter, 3rd Low Level
AEA09-FF-04-OD-H1	Fortification Sample, ME 04, Outer Dosimeter, 1st High Level
AEA09-FF-04-OD-H2	Fortification Sample, ME 04, Outer Dosimeter, 2nd High Level
AEA09-FF-04-OD-H3	Fortification Sample, ME 04, Outer Dosimeter, 3rd High Level
AEA09-FF-05-PH-C1	Fortification Sample, ME 05, Painter's Hat, 1st Control
AEA09-FF-05-PH-C2	Fortification Sample, ME 05, Painter's Hat, 2nd Control
AEA09-FF-05-PH-L1	Fortification Sample, ME 05, Painter's Hat, 1st Low Level
AEA09-FF-05-PH-L2	Fortification Sample, ME 05, Painter's Hat, 2nd Low Level
AEA09-FF-05-PH-L3	Fortification Sample, ME 05, Painter's Hat, 3rd Low Level
AEA09-FF-05-PH-H1	Fortification Sample, ME 05, Painter's Hat, 1st High Level
AEA09-FF-05-PH-H2	Fortification Sample, ME 05, Painter's Hat, 2nd High Level
AEA09-FF-05-PH-H3	Fortification Sample, ME 05, Painter's Hat, 3rd High Level
AEA09-FF-05-AR-C1	Fortification Sample, ME 05, Air Sampling Tube, 1st Control
AEA09-FF-05-AR-C2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Control
AEA09-FF-05-AR-L1	Fortification Sample, ME 05, Air Sampling Tube, 1st Low Level
AEA09-FF-05-AR-L2	Fortification Sample, ME 05, Air Sampling Tube, 2nd Low Level
AEA09-FF-05-AR-L3	Fortification Sample, ME 05, Air Sampling Tube, 3rd Low Level
AEA09-FF-05-AR-H1	Fortification Sample, ME 05, Air Sampling Tube, 1st High Level
AEA09-FF-05-AR-H2	Fortification Sample, ME 05, Air Sampling Tube, 2nd High Level
AEA09-FF-05-AR-H3	Fortification Sample, ME 05, Air Sampling Tube, 3rd High Level
AEA09-FF-05-RES-C1	Fortification Sample, ME 05, RespiCon, 1st Control
AEA09-FF-05-RES-C2	Fortification Sample, ME 05, RespiCon, 2nd Control
AEA09-FF-05-RES-L1	Fortification Sample, ME 05, RespiCon, 1st Low Level
AEA09-FF-05-RES-L2	Fortification Sample, ME 05, RespiCon, 2nd Low Level
AEA09-FF-05-RES-L3	Fortification Sample, ME 05, RespiCon, 3rd Low Level
AEA09-FF-05-RES-H1	Fortification Sample, ME 05, RespiCon, 1st High Level
AEA09-FF-05-RES-H2	Fortification Sample, ME 05, RespiCon, 2nd High Level
AEA09-FF-05-RES-H3	Fortification Sample, ME 05, RespiCon, 3rd High Level
AEA09-FF-05-HW-C1	Fortification Sample, ME 05, Hand Wash, 1st Control
AEA09-FF-05-HW-C2	Fortification Sample, ME 05, Hand Wash, 2nd Control
AEA09-FF-05-HW-L1	Fortification Sample, ME 05, Hand Wash, 1st Low Level
AEA09-FF-05-HW-L2	Fortification Sample, ME 05, Hand Wash, 2nd Low Level
AEA09-FF-05-HW-L3	Fortification Sample, ME 05, Hand Wash, 3rd Low Level

Sample ID Number	Description
AEA09-FF-05-HW-H1	Fortification Sample, ME 05, Hand Wash, 1st High Level
AEA09-FF-05-HW-H2	Fortification Sample, ME 05, Hand Wash, 2nd High Level
AEA09-FF-05-HW-H3	Fortification Sample, ME 05, Hand Wash, 3rd High Level
AEA09-FF-05-FW-C1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Control
AEA09-FF-05-FW-C2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Control
AEA09-FF-05-FW-L1	Fortification Sample, ME 05, Face and Neck Wipe, 1st Low Level
AEA09-FF-05-FW-L2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd Low Level
AEA09-FF-05-FW-L3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd Low Level
AEA09-FF-05-FW-H1	Fortification Sample, ME 05, Face and Neck Wipe, 1st High Level
AEA09-FF-05-FW-H2	Fortification Sample, ME 05, Face and Neck Wipe, 2nd High Level
AEA09-FF-05-FW-H3	Fortification Sample, ME 05, Face and Neck Wipe, 3rd High Level
AEA09-FF-05-ID-C1	Fortification Sample, ME 05, Inner Dosimeter, 1st Control
AEA09-FF-05-ID-C2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Control
AEA09-FF-05-ID-L1	Fortification Sample, ME 05, Inner Dosimeter, 1st Low Level
AEA09-FF-05-ID-L2	Fortification Sample, ME 05, Inner Dosimeter, 2nd Low Level
AEA09-FF-05-ID-L3	Fortification Sample, ME 05, Inner Dosimeter, 3rd Low Level
AEA09-FF-05-ID-H1	Fortification Sample, ME 05, Inner Dosimeter, 1st High Level
AEA09-FF-05-ID-H2	Fortification Sample, ME 05, Inner Dosimeter, 2nd High Level
AEA09-FF-05-ID-H3	Fortification Sample, ME 05, Inner Dosimeter, 3rd High Level
AEA09-FF-05-OD-C1	Fortification Sample, ME 05, Outer Dosimeter, 1st Control
AEA09-FF-05-OD-C2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Control
AEA09-FF-05-OD-L1	Fortification Sample, ME 05, Outer Dosimeter, 1st Low Level
AEA09-FF-05-OD-L2	Fortification Sample, ME 05, Outer Dosimeter, 2nd Low Level
AEA09-FF-05-OD-L3	Fortification Sample, ME 05, Outer Dosimeter, 3rd Low Level
AEA09-FF-05-OD-H1	Fortification Sample, ME 05, Outer Dosimeter, 1st High Level
AEA09-FF-05-OD-H2	Fortification Sample, ME 05, Outer Dosimeter, 2nd High Level
AEA09-FF-05-OD-H3	Fortification Sample, ME 05, Outer Dosimeter, 3rd High Level
AEA09-FF-06-PH-C1	Fortification Sample, ME 06, Painter's Hat, 1st Control
AEA09-FF-06-PH-C2	Fortification Sample, ME 06, Painter's Hat, 2nd Control
AEA09-FF-06-PH-L1	Fortification Sample, ME 06, Painter's Hat, 1st Low Level
AEA09-FF-06-PH-L2	Fortification Sample, ME 06, Painter's Hat, 2nd Low Level
AEA09-FF-06-PH-L3	Fortification Sample, ME 06, Painter's Hat, 3rd Low Level
AEA09-FF-06-PH-H1	Fortification Sample, ME 06, Painter's Hat, 1st High Level
AEA09-FF-06-PH-H2	Fortification Sample, ME 06, Painter's Hat, 2nd High Level
AEA09-FF-06-PH-H3	Fortification Sample, ME 06, Painter's Hat, 3rd High Level
AEA09-FF-06-AR-C1	Fortification Sample, ME 06, Air Sampling Tube, 1st Control
AEA09-FF-06-AR-C2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Control
AEA09-FF-06-AR-L1	Fortification Sample, ME 06, Air Sampling Tube, 1st Low Level
AEA09-FF-06-AR-L2	Fortification Sample, ME 06, Air Sampling Tube, 2nd Low Level
AEA09-FF-06-AR-L3	Fortification Sample, ME 06, Air Sampling Tube, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-AR-H1	Fortification Sample, ME 06, Air Sampling Tube, 1st High Level
AEA09-FF-06-AR-H2	Fortification Sample, ME 06, Air Sampling Tube, 2nd High Level
AEA09-FF-06-AR-H3	Fortification Sample, ME 06, Air Sampling Tube, 3rd High Level
AEA09-FF-06-RES-C1	Fortification Sample, ME 06, RespiCon, 1st Control
AEA09-FF-06-RES-C2	Fortification Sample, ME 06, RespiCon, 2nd Control
AEA09-FF-06-RES-L1	Fortification Sample, ME 06, RespiCon, 1st Low Level
AEA09-FF-06-RES-L2	Fortification Sample, ME 06, RespiCon, 2nd Low Level
AEA09-FF-06-RES-L3	Fortification Sample, ME 06, RespiCon, 3rd Low Level
AEA09-FF-06-RES-H1	Fortification Sample, ME 06, RespiCon, 1st High Level
AEA09-FF-06-RES-H2	Fortification Sample, ME 06, RespiCon, 2nd High Level
AEA09-FF-06-RES-H3	Fortification Sample, ME 06, RespiCon, 3rd High Level
AEA09-FF-06-HW-C1	Fortification Sample, ME 06, Hand Wash, 1st Control
AEA09-FF-06-HW-C2	Fortification Sample, ME 06, Hand Wash, 2nd Control
AEA09-FF-06-HW-L1	Fortification Sample, ME 06, Hand Wash, 1st Low Level
AEA09-FF-06-HW-L2	Fortification Sample, ME 06, Hand Wash, 2nd Low Level
AEA09-FF-06-HW-L3	Fortification Sample, ME 06, Hand Wash, 3rd Low Level
AEA09-FF-06-HW-H1	Fortification Sample, ME 06, Hand Wash, 1st High Level
AEA09-FF-06-HW-H2	Fortification Sample, ME 06, Hand Wash, 2nd High Level
AEA09-FF-06-HW-H3	Fortification Sample, ME 06, Hand Wash, 3rd High Level
AEA09-FF-06-FW-C1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Control
AEA09-FF-06-FW-C2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Control
AEA09-FF-06-FW-L1	Fortification Sample, ME 06, Face and Neck Wipe, 1st Low Level
AEA09-FF-06-FW-L2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd Low Level
AEA09-FF-06-FW-L3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd Low Level
AEA09-FF-06-FW-H1	Fortification Sample, ME 06, Face and Neck Wipe, 1st High Level
AEA09-FF-06-FW-H2	Fortification Sample, ME 06, Face and Neck Wipe, 2nd High Level
AEA09-FF-06-FW-H3	Fortification Sample, ME 06, Face and Neck Wipe, 3rd High Level
AEA09-FF-06-ID-C1	Fortification Sample, ME 06, Inner Dosimeter, 1st Control
AEA09-FF-06-ID-C2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Control
AEA09-FF-06-ID-L1	Fortification Sample, ME 06, Inner Dosimeter, 1st Low Level
AEA09-FF-06-ID-L2	Fortification Sample, ME 06, Inner Dosimeter, 2nd Low Level
AEA09-FF-06-ID-L3	Fortification Sample, ME 06, Inner Dosimeter, 3rd Low Level
AEA09-FF-06-ID-H1	Fortification Sample, ME 06, Inner Dosimeter, 1st High Level
AEA09-FF-06-ID-H2	Fortification Sample, ME 06, Inner Dosimeter, 2nd High Level
AEA09-FF-06-ID-H3	Fortification Sample, ME 06, Inner Dosimeter, 3rd High Level
AEA09-FF-06-OD-C1	Fortification Sample, ME 06, Outer Dosimeter, 1st Control
AEA09-FF-06-OD-C2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Control
AEA09-FF-06-OD-L1	Fortification Sample, ME 06, Outer Dosimeter, 1st Low Level
AEA09-FF-06-OD-L2	Fortification Sample, ME 06, Outer Dosimeter, 2nd Low Level
AEA09-FF-06-OD-L3	Fortification Sample, ME 06, Outer Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-06-OD-H1	Fortification Sample, ME 06, Outer Dosimeter, 1st High Level
AEA09-FF-06-OD-H2	Fortification Sample, ME 06, Outer Dosimeter, 2nd High Level
AEA09-FF-06-OD-H3	Fortification Sample, ME 06, Outer Dosimeter, 3rd High Level
AEA09-FF-07-PH-C1	Fortification Sample, ME 07, Painter's Hat, 1st Control
AEA09-FF-07-PH-C2	Fortification Sample, ME 07, Painter's Hat, 2nd Control
AEA09-FF-07-PH-L1	Fortification Sample, ME 07, Painter's Hat, 1st Low Level
AEA09-FF-07-PH-L2	Fortification Sample, ME 07, Painter's Hat, 2nd Low Level
AEA09-FF-07-PH-L3	Fortification Sample, ME 07, Painter's Hat, 3rd Low Level
AEA09-FF-07-PH-H1	Fortification Sample, ME 07, Painter's Hat, 1st High Level
AEA09-FF-07-PH-H2	Fortification Sample, ME 07, Painter's Hat, 2nd High Level
AEA09-FF-07-PH-H3	Fortification Sample, ME 07, Painter's Hat, 3rd High Level
AEA09-FF-07-AR-C1	Fortification Sample, ME 07, Air Sampling Tube, 1st Control
AEA09-FF-07-AR-C2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Control
AEA09-FF-07-AR-L1	Fortification Sample, ME 07, Air Sampling Tube, 1st Low Level
AEA09-FF-07-AR-L2	Fortification Sample, ME 07, Air Sampling Tube, 2nd Low Level
AEA09-FF-07-AR-L3	Fortification Sample, ME 07, Air Sampling Tube, 3rd Low Level
AEA09-FF-07-AR-H1	Fortification Sample, ME 07, Air Sampling Tube, 1st High Level
AEA09-FF-07-AR-H2	Fortification Sample, ME 07, Air Sampling Tube, 2nd High Level
AEA09-FF-07-AR-H3	Fortification Sample, ME 07, Air Sampling Tube, 3rd High Level
AEA09-FF-07-RES-C1	Fortification Sample, ME 07, RespiCon, 1st Control
AEA09-FF-07-RES-C2	Fortification Sample, ME 07, RespiCon, 2nd Control
AEA09-FF-07-RES-L1	Fortification Sample, ME 07, RespiCon, 1st Low Level
AEA09-FF-07-RES-L2	Fortification Sample, ME 07, RespiCon, 2nd Low Level
AEA09-FF-07-RES-L3	Fortification Sample, ME 07, RespiCon, 3rd Low Level
AEA09-FF-07-RES-H1	Fortification Sample, ME 07, RespiCon, 1st High Level
AEA09-FF-07-RES-H2	Fortification Sample, ME 07, RespiCon, 2nd High Level
AEA09-FF-07-RES-H3	Fortification Sample, ME 07, RespiCon, 3rd High Level
AEA09-FF-07-HW-C1	Fortification Sample, ME 07, Hand Wash, 1st Control
AEA09-FF-07-HW-C2	Fortification Sample, ME 07, Hand Wash, 2nd Control
AEA09-FF-07-HW-L1	Fortification Sample, ME 07, Hand Wash, 1st Low Level
AEA09-FF-07-HW-L2	Fortification Sample, ME 07, Hand Wash, 2nd Low Level
AEA09-FF-07-HW-L3	Fortification Sample, ME 07, Hand Wash, 3rd Low Level
AEA09-FF-07-HW-H1	Fortification Sample, ME 07, Hand Wash, 1st High Level
AEA09-FF-07-HW-H2	Fortification Sample, ME 07, Hand Wash, 2nd High Level
AEA09-FF-07-HW-H3	Fortification Sample, ME 07, Hand Wash, 3rd High Level
AEA09-FF-07-FW-C1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Control
AEA09-FF-07-FW-C2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Control
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L1	Fortification Sample, ME 07, Face and Neck Wipe, 1st Low Level
AEA09-FF-07-FW-L2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd Low Level
AEA09-FF-07-FW-L3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd Low Level
AEA09-FF-07-FW-H1	Fortification Sample, ME 07, Face and Neck Wipe, 1st High Level

Sample ID Number	Description
AEA09-FF-07-FW-H2	Fortification Sample, ME 07, Face and Neck Wipe, 2nd High Level
AEA09-FF-07-FW-H3	Fortification Sample, ME 07, Face and Neck Wipe, 3rd High Level
AEA09-FF-07-ID-C1	Fortification Sample, ME 07, Inner Dosimeter, 1st Control
AEA09-FF-07-ID-C2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Control
AEA09-FF-07-ID-L1	Fortification Sample, ME 07, Inner Dosimeter, 1st Low Level
AEA09-FF-07-ID-L2	Fortification Sample, ME 07, Inner Dosimeter, 2nd Low Level
AEA09-FF-07-ID-L3	Fortification Sample, ME 07, Inner Dosimeter, 3rd Low Level
AEA09-FF-07-ID-H1	Fortification Sample, ME 07, Inner Dosimeter, 1st High Level
AEA09-FF-07-ID-H2	Fortification Sample, ME 07, Inner Dosimeter, 2nd High Level
AEA09-FF-07-ID-H3	Fortification Sample, ME 07, Inner Dosimeter, 3rd High Level
AEA09-FF-07-OD-C1	Fortification Sample, ME 07, Outer Dosimeter, 1st Control
AEA09-FF-07-OD-C2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Control
AEA09-FF-07-OD-L1	Fortification Sample, ME 07, Outer Dosimeter, 1st Low Level
AEA09-FF-07-OD-L2	Fortification Sample, ME 07, Outer Dosimeter, 2nd Low Level
AEA09-FF-07-OD-L3	Fortification Sample, ME 07, Outer Dosimeter, 3rd Low Level
AEA09-FF-07-OD-H1	Fortification Sample, ME 07, Outer Dosimeter, 1st High Level
AEA09-FF-07-OD-H2	Fortification Sample, ME 07, Outer Dosimeter, 2nd High Level
AEA09-FF-07-OD-H3	Fortification Sample, ME 07, Outer Dosimeter, 3rd High Level
AEA09-FF-08-PH-C1	Fortification Sample, ME 08, Painter's Hat, 1st Control
AEA09-FF-08-PH-C2	Fortification Sample, ME 08, Painter's Hat, 2nd Control
AEA09-FF-08-PH-L1	Fortification Sample, ME 08, Painter's Hat, 1st Low Level
AEA09-FF-08-PH-L2	Fortification Sample, ME 08, Painter's Hat, 2nd Low Level
AEA09-FF-08-PH-L3	Fortification Sample, ME 08, Painter's Hat, 3rd Low Level
AEA09-FF-08-PH-H1	Fortification Sample, ME 08, Painter's Hat, 1st High Level
AEA09-FF-08-PH-H2	Fortification Sample, ME 08, Painter's Hat, 2nd High Level
AEA09-FF-08-PH-H3	Fortification Sample, ME 08, Painter's Hat, 3rd High Level
AEA09-FF-08-AR-C1	Fortification Sample, ME 08, Air Sampling Tube, 1st Control
AEA09-FF-08-AR-C2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Control
AEA09-FF-08-AR-L1	Fortification Sample, ME 08, Air Sampling Tube, 1st Low Level
AEA09-FF-08-AR-L2	Fortification Sample, ME 08, Air Sampling Tube, 2nd Low Level
AEA09-FF-08-AR-L3	Fortification Sample, ME 08, Air Sampling Tube, 3rd Low Level
AEA09-FF-08-AR-H1	Fortification Sample, ME 08, Air Sampling Tube, 1st High Level
AEA09-FF-08-AR-H2	Fortification Sample, ME 08, Air Sampling Tube, 2nd High Level
AEA09-FF-08-AR-H3	Fortification Sample, ME 08, Air Sampling Tube, 3rd High Level
AEA09-FF-08-RES-C1	Fortification Sample, ME 08, RespiCon, 1st Control
AEA09-FF-08-RES-C2	Fortification Sample, ME 08, RespiCon, 2nd Control
AEA09-FF-08-RES-L1	Fortification Sample, ME 08, RespiCon, 1st Low Level
AEA09-FF-08-RES-L2	Fortification Sample, ME 08, RespiCon, 2nd Low Level
AEA09-FF-08-RES-L3	Fortification Sample, ME 08, RespiCon, 3rd Low Level
AEA09-FF-08-RES-H1	Fortification Sample, ME 08, RespiCon, 1st High Level
AEA09-FF-08-RES-H2	Fortification Sample, ME 08, RespiCon, 2nd High Level
AEA09-FF-08-RES-H3	Fortification Sample, ME 08, RespiCon, 3rd High Level
AEA09-FF-08-HW-C1	Fortification Sample, ME 08, Hand Wash, 1st Control
AEA09-FF-08-HW-C2	Fortification Sample, ME 08, Hand Wash, 2nd Control

Sample ID Number	Description
AEA09-FF-08-HW-L1	Fortification Sample, ME 08, Hand Wash, 1st Low Level
AEA09-FF-08-HW-L2	Fortification Sample, ME 08, Hand Wash, 2nd Low Level
AEA09-FF-08-HW-L3	Fortification Sample, ME 08, Hand Wash, 3rd Low Level
AEA09-FF-08-HW-H1	Fortification Sample, ME 08, Hand Wash, 1st High Level
AEA09-FF-08-HW-H2	Fortification Sample, ME 08, Hand Wash, 2nd High Level
AEA09-FF-08-HW-H3	Fortification Sample, ME 08, Hand Wash, 3rd High Level
AEA09-FF-08-FW-C1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Control
AEA09-FF-08-FW-C2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Control
AEA09-FF-08-FW-L1	Fortification Sample, ME 08, Face and Neck Wipe, 1st Low Level
AEA09-FF-08-FW-L2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd Low Level
AEA09-FF-08-FW-L3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd Low Level
AEA09-FF-08-FW-H1	Fortification Sample, ME 08, Face and Neck Wipe, 1st High Level
AEA09-FF-08-FW-H2	Fortification Sample, ME 08, Face and Neck Wipe, 2nd High Level
AEA09-FF-08-FW-H3	Fortification Sample, ME 08, Face and Neck Wipe, 3rd High Level
AEA09-FF-08-ID-C1	Fortification Sample, ME 08, Inner Dosimeter, 1st Control
AEA09-FF-08-ID-C2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Control
AEA09-FF-08-ID-L1	Fortification Sample, ME 08, Inner Dosimeter, 1st Low Level
AEA09-FF-08-ID-L2	Fortification Sample, ME 08, Inner Dosimeter, 2nd Low Level
AEA09-FF-08-ID-L3	Fortification Sample, ME 08, Inner Dosimeter, 3rd Low Level
AEA09-FF-08-ID-H1	Fortification Sample, ME 08, Inner Dosimeter, 1st High Level
AEA09-FF-08-ID-H2	Fortification Sample, ME 08, Inner Dosimeter, 2nd High Level
AEA09-FF-08-ID-H3	Fortification Sample, ME 08, Inner Dosimeter, 3rd High Level
AEA09-FF-08-OD-C1	Fortification Sample, ME 08, Outer Dosimeter, 1st Control
AEA09-FF-08-OD-C2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Control
AEA09-FF-08-OD-L1	Fortification Sample, ME 08, Outer Dosimeter, 1st Low Level
AEA09-FF-08-OD-L2	Fortification Sample, ME 08, Outer Dosimeter, 2nd Low Level
AEA09-FF-08-OD-L3	Fortification Sample, ME 08, Outer Dosimeter, 3rd Low Level
AEA09-FF-08-OD-H1	Fortification Sample, ME 08, Outer Dosimeter, 1st High Level
AEA09-FF-08-OD-H2	Fortification Sample, ME 08, Outer Dosimeter, 2nd High Level
AEA09-FF-08-OD-H3	Fortification Sample, ME 08, Outer Dosimeter, 3rd High Level
AEA09-FF-09-PH-C1	Fortification Sample, ME 09, Painter's Hat, 1st Control
AEA09-FF-09-PH-C2	Fortification Sample, ME 09, Painter's Hat, 2nd Control
AEA09-FF-09-PH-L1	Fortification Sample, ME 09, Painter's Hat, 1st Low Level
AEA09-FF-09-PH-L2	Fortification Sample, ME 09, Painter's Hat, 2nd Low Level
AEA09-FF-09-PH-L3	Fortification Sample, ME 09, Painter's Hat, 3rd Low Level
AEA09-FF-09-PH-H1	Fortification Sample, ME 09, Painter's Hat, 1st High Level
AEA09-FF-09-PH-H2	Fortification Sample, ME 09, Painter's Hat, 2nd High Level
AEA09-FF-09-PH-H3	Fortification Sample, ME 09, Painter's Hat, 3rd High Level
AEA09-FF-09-AR-C1	Fortification Sample, ME 09, Air Sampling Tube, 1st Control
AEA09-FF-09-AR-C2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Control

Sample ID Number	Description
AEA09-FF-09-AR-L1	Fortification Sample, ME 09, Air Sampling Tube, 1st Low Level
AEA09-FF-09-AR-L2	Fortification Sample, ME 09, Air Sampling Tube, 2nd Low Level
AEA09-FF-09-AR-L3	Fortification Sample, ME 09, Air Sampling Tube, 3rd Low Level
AEA09-FF-09-AR-H1	Fortification Sample, ME 09, Air Sampling Tube, 1st High Level
AEA09-FF-09-AR-H2	Fortification Sample, ME 09, Air Sampling Tube, 2nd High Level
AEA09-FF-09-AR-H3	Fortification Sample, ME 09, Air Sampling Tube, 3rd High Level
AEA09-FF-09-RES-C1	Fortification Sample, ME 09, RespiCon, 1st Control
AEA09-FF-09-RES-C2	Fortification Sample, ME 09, RespiCon, 2nd Control
AEA09-FF-09-RES-L1	Fortification Sample, ME 09, RespiCon, 1st Low Level
AEA09-FF-09-RES-L2	Fortification Sample, ME 09, RespiCon, 2nd Low Level
AEA09-FF-09-RES-L3	Fortification Sample, ME 09, RespiCon, 3rd Low Level
AEA09-FF-09-RES-H1	Fortification Sample, ME 09, RespiCon, 1st High Level
AEA09-FF-09-RES-H2	Fortification Sample, ME 09, RespiCon, 2nd High Level
AEA09-FF-09-RES-H3	Fortification Sample, ME 09, RespiCon, 3rd High Level
AEA09-FF-09-HW-C1	Fortification Sample, ME 09, Hand Wash, 1st Control
AEA09-FF-09-HW-C2	Fortification Sample, ME 09, Hand Wash, 2nd Control
AEA09-FF-09-HW-L1	Fortification Sample, ME 09, Hand Wash, 1st Low Level
AEA09-FF-09-HW-L2	Fortification Sample, ME 09, Hand Wash, 2nd Low Level
AEA09-FF-09-HW-L3	Fortification Sample, ME 09, Hand Wash, 3rd Low Level
AEA09-FF-09-HW-H1	Fortification Sample, ME 09, Hand Wash, 1st High Level
AEA09-FF-09-HW-H2	Fortification Sample, ME 09, Hand Wash, 2nd High Level
AEA09-FF-09-HW-H3	Fortification Sample, ME 09, Hand Wash, 3rd High Level
AEA09-FF-09-FW-C1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Control
AEA09-FF-09-FW-C2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Control
AEA09-FF-09-FW-L1	Fortification Sample, ME 09, Face and Neck Wipe, 1st Low Level
AEA09-FF-09-FW-L2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd Low Level
AEA09-FF-09-FW-L3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd Low Level
AEA09-FF-09-FW-H1	Fortification Sample, ME 09, Face and Neck Wipe, 1st High Level
AEA09-FF-09-FW-H2	Fortification Sample, ME 09, Face and Neck Wipe, 2nd High Level
AEA09-FF-09-FW-H3	Fortification Sample, ME 09, Face and Neck Wipe, 3rd High Level
AEA09-FF-09-ID-C1	Fortification Sample, ME 09, Inner Dosimeter, 1st Control
AEA09-FF-09-ID-C2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Control
AEA09-FF-09-ID-L1	Fortification Sample, ME 09, Inner Dosimeter, 1st Low Level
AEA09-FF-09-ID-L2	Fortification Sample, ME 09, Inner Dosimeter, 2nd Low Level
AEA09-FF-09-ID-L3	Fortification Sample, ME 09, Inner Dosimeter, 3rd Low Level
AEA09-FF-09-ID-H1	Fortification Sample, ME 09, Inner Dosimeter, 1st High Level
AEA09-FF-09-ID-H2	Fortification Sample, ME 09, Inner Dosimeter, 2nd High Level
AEA09-FF-09-ID-H3	Fortification Sample, ME 09, Inner Dosimeter, 3rd High Level
AEA09-FF-09-OD-C1	Fortification Sample, ME 09, Outer Dosimeter, 1st Control
AEA09-FF-09-OD-C2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Control

Sample ID Number	Description
AEA09-FF-09-OD-L1	Fortification Sample, ME 09, Outer Dosimeter, 1st Low Level
AEA09-FF-09-OD-L2	Fortification Sample, ME 09, Outer Dosimeter, 2nd Low Level
AEA09-FF-09-OD-L3	Fortification Sample, ME 09, Outer Dosimeter, 3rd Low Level
AEA09-FF-09-OD-H1	Fortification Sample, ME 09, Outer Dosimeter, 1st High Level
AEA09-FF-09-OD-H2	Fortification Sample, ME 09, Outer Dosimeter, 2nd High Level
AEA09-FF-09-OD-H3	Fortification Sample, ME 09, Outer Dosimeter, 3rd High Level
AEA09-FF-10-PH-C1	Fortification Sample, ME 10, Painter's Hat, 1st Control
AEA09-FF-10-PH-C2	Fortification Sample, ME 10, Painter's Hat, 2nd Control
AEA09-FF-10-PH-L1	Fortification Sample, ME 10, Painter's Hat, 1st Low Level
AEA09-FF-10-PH-L2	Fortification Sample, ME 10, Painter's Hat, 2nd Low Level
AEA09-FF-10-PH-L3	Fortification Sample, ME 10, Painter's Hat, 3rd Low Level
AEA09-FF-10-PH-H1	Fortification Sample, ME 10, Painter's Hat, 1st High Level
AEA09-FF-10-PH-H2	Fortification Sample, ME 10, Painter's Hat, 2nd High Level
AEA09-FF-10-PH-H3	Fortification Sample, ME 10, Painter's Hat, 3rd High Level
AEA09-FF-10-AR-C1	Fortification Sample, ME 10, Air Sampling Tube, 1st Control
AEA09-FF-10-AR-C2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Control
AEA09-FF-10-AR-L1	Fortification Sample, ME 10, Air Sampling Tube, 1st Low Level
AEA09-FF-10-AR-L2	Fortification Sample, ME 10, Air Sampling Tube, 2nd Low Level
AEA09-FF-10-AR-L3	Fortification Sample, ME 10, Air Sampling Tube, 3rd Low Level
AEA09-FF-10-AR-H1	Fortification Sample, ME 10, Air Sampling Tube, 1st High Level
AEA09-FF-10-AR-H2	Fortification Sample, ME 10, Air Sampling Tube, 2nd High Level
AEA09-FF-10-AR-H3	Fortification Sample, ME 10, Air Sampling Tube, 3rd High Level
AEA09-FF-10-RES-C1	Fortification Sample, ME 10, RespiCon, 1st Control
AEA09-FF-10-RES-C2	Fortification Sample, ME 10, RespiCon, 2nd Control
AEA09-FF-10-RES-L1	Fortification Sample, ME 10, RespiCon, 1st Low Level
AEA09-FF-10-RES-L2	Fortification Sample, ME 10, RespiCon, 2nd Low Level
AEA09-FF-10-RES-L3	Fortification Sample, ME 10, RespiCon, 3rd Low Level
AEA09-FF-10-RES-H1	Fortification Sample, ME 10, RespiCon, 1st High Level
AEA09-FF-10-RES-H2	Fortification Sample, ME 10, RespiCon, 2nd High Level
AEA09-FF-10-RES-H3	Fortification Sample, ME 10, RespiCon, 3rd High Level
AEA09-FF-10-HW-C1	Fortification Sample, ME 10, Hand Wash, 1st Control
AEA09-FF-10-HW-C2	Fortification Sample, ME 10, Hand Wash, 2nd Control
AEA09-FF-10-HW-L1	Fortification Sample, ME 10, Hand Wash, 1st Low Level
AEA09-FF-10-HW-L2	Fortification Sample, ME 10, Hand Wash, 2nd Low Level
AEA09-FF-10-HW-L3	Fortification Sample, ME 10, Hand Wash, 3rd Low Level
AEA09-FF-10-HW-H1	Fortification Sample, ME 10, Hand Wash, 1st High Level
AEA09-FF-10-HW-H2	Fortification Sample, ME 10, Hand Wash, 2nd High Level
AEA09-FF-10-HW-H3	Fortification Sample, ME 10, Hand Wash, 3rd High Level
AEA09-FF-10-FW-C1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Control
AEA09-FF-10-FW-C2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Control
AEA09-FF-10-FW-L1	Fortification Sample, ME 10, Face and Neck Wipe, 1st Low Level
AEA09-FF-10-FW-L2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd Low Level
AEA09-FF-10-FW-L3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-10-FW-H1	Fortification Sample, ME 10, Face and Neck Wipe, 1st High Level
AEA09-FF-10-FW-H2	Fortification Sample, ME 10, Face and Neck Wipe, 2nd High Level
AEA09-FF-10-FW-H3	Fortification Sample, ME 10, Face and Neck Wipe, 3rd High Level
AEA09-FF-10-ID-C1	Fortification Sample, ME 10, Inner Dosimeter, 1st Control
AEA09-FF-10-ID-C2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Control
AEA09-FF-10-ID-L1	Fortification Sample, ME 10, Inner Dosimeter, 1st Low Level
AEA09-FF-10-ID-L2	Fortification Sample, ME 10, Inner Dosimeter, 2nd Low Level
AEA09-FF-10-ID-L3	Fortification Sample, ME 10, Inner Dosimeter, 3rd Low Level
AEA09-FF-10-ID-H1	Fortification Sample, ME 10, Inner Dosimeter, 1st High Level
AEA09-FF-10-ID-H2	Fortification Sample, ME 10, Inner Dosimeter, 2nd High Level
AEA09-FF-10-ID-H3	Fortification Sample, ME 10, Inner Dosimeter, 3rd High Level
AEA09-FF-10-OD-C1	Fortification Sample, ME 10, Outer Dosimeter, 1st Control
AEA09-FF-10-OD-C2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Control
AEA09-FF-10-OD-L1	Fortification Sample, ME 10, Outer Dosimeter, 1st Low Level
AEA09-FF-10-OD-L2	Fortification Sample, ME 10, Outer Dosimeter, 2nd Low Level
AEA09-FF-10-OD-L3	Fortification Sample, ME 10, Outer Dosimeter, 3rd Low Level
AEA09-FF-10-OD-H1	Fortification Sample, ME 10, Outer Dosimeter, 1st High Level
AEA09-FF-10-OD-H2	Fortification Sample, ME 10, Outer Dosimeter, 2nd High Level
AEA09-FF-10-OD-H3	Fortification Sample, ME 10, Outer Dosimeter, 3rd High Level
AEA09-FF-11-PH-C1	Fortification Sample, ME 11, Painter's Hat, 1st Control
AEA09-FF-11-PH-C2	Fortification Sample, ME 11, Painter's Hat, 2nd Control
AEA09-FF-11-PH-L1	Fortification Sample, ME 11, Painter's Hat, 1st Low Level
AEA09-FF-11-PH-L2	Fortification Sample, ME 11, Painter's Hat, 2nd Low Level
AEA09-FF-11-PH-L3	Fortification Sample, ME 11, Painter's Hat, 3rd Low Level
AEA09-FF-11-PH-H1	Fortification Sample, ME 11, Painter's Hat, 1st High Level
AEA09-FF-11-PH-H2	Fortification Sample, ME 11, Painter's Hat, 2nd High Level
AEA09-FF-11-PH-H3	Fortification Sample, ME 11, Painter's Hat, 3rd High Level
AEA09-FF-11-AR-C1	Fortification Sample, ME 11, Air Sampling Tube, 1st Control
AEA09-FF-11-AR-C2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Control
AEA09-FF-11-AR-L1	Fortification Sample, ME 11, Air Sampling Tube, 1st Low Level
AEA09-FF-11-AR-L2	Fortification Sample, ME 11, Air Sampling Tube, 2nd Low Level
AEA09-FF-11-AR-L3	Fortification Sample, ME 11, Air Sampling Tube, 3rd Low Level
AEA09-FF-11-AR-H1	Fortification Sample, ME 11, Air Sampling Tube, 1st High Level
AEA09-FF-11-AR-H2	Fortification Sample, ME 11, Air Sampling Tube, 2nd High Level
AEA09-FF-11-AR-H3	Fortification Sample, ME 11, Air Sampling Tube, 3rd High Level
AEA09-FF-11-RES-C1	Fortification Sample, ME 11, RespiCon, 1st Control
AEA09-FF-11-RES-C2	Fortification Sample, ME 11, RespiCon, 2nd Control
AEA09-FF-11-RES-L1	Fortification Sample, ME 11, RespiCon, 1st Low Level
AEA09-FF-11-RES-L2	Fortification Sample, ME 11, RespiCon, 2nd Low Level
AEA09-FF-11-RES-L3	Fortification Sample, ME 11, RespiCon, 3rd Low Level
AEA09-FF-11-RES-H1	Fortification Sample, ME 11, RespiCon, 1st High Level
AEA09-FF-11-RES-H2	Fortification Sample, ME 11, RespiCon, 2nd High Level
AEA09-FF-11-RES-H3	Fortification Sample, ME 11, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-11-HW-C1	Fortification Sample, ME 11, Hand Wash, 1st Control
AEA09-FF-11-HW-C2	Fortification Sample, ME 11, Hand Wash, 2nd Control
AEA09-FF-11-HW-L1	Fortification Sample, ME 11, Hand Wash, 1st Low Level
AEA09-FF-11-HW-L2	Fortification Sample, ME 11, Hand Wash, 2nd Low Level
AEA09-FF-11-HW-L3	Fortification Sample, ME 11, Hand Wash, 3rd Low Level
AEA09-FF-11-HW-H1	Fortification Sample, ME 11, Hand Wash, 1st High Level
AEA09-FF-11-HW-H2	Fortification Sample, ME 11, Hand Wash, 2nd High Level
AEA09-FF-11-HW-H3	Fortification Sample, ME 11, Hand Wash, 3rd High Level
AEA09-FF-11-FW-C1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Control
AEA09-FF-11-FW-C2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Control
AEA09-FF-11-FW-L1	Fortification Sample, ME 11, Face and Neck Wipe, 1st Low Level
AEA09-FF-11-FW-L2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd Low Level
AEA09-FF-11-FW-L3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd Low Level
AEA09-FF-11-FW-H1	Fortification Sample, ME 11, Face and Neck Wipe, 1st High Level
AEA09-FF-11-FW-H2	Fortification Sample, ME 11, Face and Neck Wipe, 2nd High Level
AEA09-FF-11-FW-H3	Fortification Sample, ME 11, Face and Neck Wipe, 3rd High Level
AEA09-FF-11-ID-C1	Fortification Sample, ME 11, Inner Dosimeter, 1st Control
AEA09-FF-11-ID-C2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Control
AEA09-FF-11-ID-L1	Fortification Sample, ME 11, Inner Dosimeter, 1st Low Level
AEA09-FF-11-ID-L2	Fortification Sample, ME 11, Inner Dosimeter, 2nd Low Level
AEA09-FF-11-ID-L3	Fortification Sample, ME 11, Inner Dosimeter, 3rd Low Level
AEA09-FF-11-ID-H1	Fortification Sample, ME 11, Inner Dosimeter, 1st High Level
AEA09-FF-11-ID-H2	Fortification Sample, ME 11, Inner Dosimeter, 2nd High Level
AEA09-FF-11-ID-H3	Fortification Sample, ME 11, Inner Dosimeter, 3rd High Level
AEA09-FF-11-OD-C1	Fortification Sample, ME 11, Outer Dosimeter, 1st Control
AEA09-FF-11-OD-C2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Control
AEA09-FF-11-OD-L1	Fortification Sample, ME 11, Outer Dosimeter, 1st Low Level
AEA09-FF-11-OD-L2	Fortification Sample, ME 11, Outer Dosimeter, 2nd Low Level
AEA09-FF-11-OD-L3	Fortification Sample, ME 11, Outer Dosimeter, 3rd Low Level
AEA09-FF-11-OD-H1	Fortification Sample, ME 11, Outer Dosimeter, 1st High Level
AEA09-FF-11-OD-H2	Fortification Sample, ME 11, Outer Dosimeter, 2nd High Level
AEA09-FF-11-OD-H3	Fortification Sample, ME 11, Outer Dosimeter, 3rd High Level
AEA09-FF-12-PH-C1	Fortification Sample, ME 12, Painter's Hat, 1st Control
AEA09-FF-12-PH-C2	Fortification Sample, ME 12, Painter's Hat, 2nd Control
AEA09-FF-12-PH-L1	Fortification Sample, ME 12, Painter's Hat, 1st Low Level
AEA09-FF-12-PH-L2	Fortification Sample, ME 12, Painter's Hat, 2nd Low Level
AEA09-FF-12-PH-L3	Fortification Sample, ME 12, Painter's Hat, 3rd Low Level
AEA09-FF-12-PH-H1	Fortification Sample, ME 12, Painter's Hat, 1st High Level
AEA09-FF-12-PH-H2	Fortification Sample, ME 12, Painter's Hat, 2nd High Level
AEA09-FF-12-PH-H3	Fortification Sample, ME 12, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-AR-C1	Fortification Sample, ME 12, Air Sampling Tube, 1st Control
AEA09-FF-12-AR-C2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Control
AEA09-FF-12-AR-L1	Fortification Sample, ME 12, Air Sampling Tube, 1st Low Level
AEA09-FF-12-AR-L2	Fortification Sample, ME 12, Air Sampling Tube, 2nd Low Level
AEA09-FF-12-AR-L3	Fortification Sample, ME 12, Air Sampling Tube, 3rd Low Level
AEA09-FF-12-AR-H1	Fortification Sample, ME 12, Air Sampling Tube, 1st High Level
AEA09-FF-12-AR-H2	Fortification Sample, ME 12, Air Sampling Tube, 2nd High Level
AEA09-FF-12-AR-H3	Fortification Sample, ME 12, Air Sampling Tube, 3rd High Level
AEA09-FF-12-RES-C1	Fortification Sample, ME 12, RespiCon, 1st Control
AEA09-FF-12-RES-C2	Fortification Sample, ME 12, RespiCon, 2nd Control
AEA09-FF-12-RES-L1	Fortification Sample, ME 12, RespiCon, 1st Low Level
AEA09-FF-12-RES-L2	Fortification Sample, ME 12, RespiCon, 2nd Low Level
AEA09-FF-12-RES-L3	Fortification Sample, ME 12, RespiCon, 3rd Low Level
AEA09-FF-12-RES-H1	Fortification Sample, ME 12, RespiCon, 1st High Level
AEA09-FF-12-RES-H2	Fortification Sample, ME 12, RespiCon, 2nd High Level
AEA09-FF-12-RES-H3	Fortification Sample, ME 12, RespiCon, 3rd High Level
AEA09-FF-12-HW-C1	Fortification Sample, ME 12, Hand Wash, 1st Control
AEA09-FF-12-HW-C2	Fortification Sample, ME 12, Hand Wash, 2nd Control
AEA09-FF-12-HW-L1	Fortification Sample, ME 12, Hand Wash, 1st Low Level
AEA09-FF-12-HW-L2	Fortification Sample, ME 12, Hand Wash, 2nd Low Level
AEA09-FF-12-HW-L3	Fortification Sample, ME 12, Hand Wash, 3rd Low Level
AEA09-FF-12-HW-H1	Fortification Sample, ME 12, Hand Wash, 1st High Level
AEA09-FF-12-HW-H2	Fortification Sample, ME 12, Hand Wash, 2nd High Level
AEA09-FF-12-HW-H3	Fortification Sample, ME 12, Hand Wash, 3rd High Level
AEA09-FF-12-FW-C1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Control
AEA09-FF-12-FW-C2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Control
AEA09-FF-12-FW-L1	Fortification Sample, ME 12, Face and Neck Wipe, 1st Low Level
AEA09-FF-12-FW-L2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd Low Level
AEA09-FF-12-FW-L3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd Low Level
AEA09-FF-12-FW-H1	Fortification Sample, ME 12, Face and Neck Wipe, 1st High Level
AEA09-FF-12-FW-H2	Fortification Sample, ME 12, Face and Neck Wipe, 2nd High Level
AEA09-FF-12-FW-H3	Fortification Sample, ME 12, Face and Neck Wipe, 3rd High Level
AEA09-FF-12-ID-C1	Fortification Sample, ME 12, Inner Dosimeter, 1st Control
AEA09-FF-12-ID-C2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Control
AEA09-FF-12-ID-L1	Fortification Sample, ME 12, Inner Dosimeter, 1st Low Level
AEA09-FF-12-ID-L2	Fortification Sample, ME 12, Inner Dosimeter, 2nd Low Level
AEA09-FF-12-ID-L3	Fortification Sample, ME 12, Inner Dosimeter, 3rd Low Level
AEA09-FF-12-ID-H1	Fortification Sample, ME 12, Inner Dosimeter, 1st High Level
AEA09-FF-12-ID-H2	Fortification Sample, ME 12, Inner Dosimeter, 2nd High Level
AEA09-FF-12-ID-H3	Fortification Sample, ME 12, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-12-OD-C1	Fortification Sample, ME 12, Outer Dosimeter, 1st Control
AEA09-FF-12-OD-C2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Control
AEA09-FF-12-OD-L1	Fortification Sample, ME 12, Outer Dosimeter, 1st Low Level
AEA09-FF-12-OD-L2	Fortification Sample, ME 12, Outer Dosimeter, 2nd Low Level
AEA09-FF-12-OD-L3	Fortification Sample, ME 12, Outer Dosimeter, 3rd Low Level
AEA09-FF-12-OD-H1	Fortification Sample, ME 12, Outer Dosimeter, 1st High Level
AEA09-FF-12-OD-H2	Fortification Sample, ME 12, Outer Dosimeter, 2nd High Level
AEA09-FF-12-OD-H3	Fortification Sample, ME 12, Outer Dosimeter, 3rd High Level
AEA09-FF-13-PH-C1	Fortification Sample, ME 13, Painter's Hat, 1st Control
AEA09-FF-13-PH-C2	Fortification Sample, ME 13, Painter's Hat, 2nd Control
AEA09-FF-13-PH-L1	Fortification Sample, ME 13, Painter's Hat, 1st Low Level
AEA09-FF-13-PH-L2	Fortification Sample, ME 13, Painter's Hat, 2nd Low Level
AEA09-FF-13-PH-L3	Fortification Sample, ME 13, Painter's Hat, 3rd Low Level
AEA09-FF-13-PH-H1	Fortification Sample, ME 13, Painter's Hat, 1st High Level
AEA09-FF-13-PH-H2	Fortification Sample, ME 13, Painter's Hat, 2nd High Level
AEA09-FF-13-PH-H3	Fortification Sample, ME 13, Painter's Hat, 3rd High Level
AEA09-FF-13-AR-C1	Fortification Sample, ME 13, Air Sampling Tube, 1st Control
AEA09-FF-13-AR-C2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Control
AEA09-FF-13-AR-L1	Fortification Sample, ME 13, Air Sampling Tube, 1st Low Level
AEA09-FF-13-AR-L2	Fortification Sample, ME 13, Air Sampling Tube, 2nd Low Level
AEA09-FF-13-AR-L3	Fortification Sample, ME 13, Air Sampling Tube, 3rd Low Level
AEA09-FF-13-AR-H1	Fortification Sample, ME 13, Air Sampling Tube, 1st High Level
AEA09-FF-13-AR-H2	Fortification Sample, ME 13, Air Sampling Tube, 2nd High Level
AEA09-FF-13-AR-H3	Fortification Sample, ME 13, Air Sampling Tube, 3rd High Level
AEA09-FF-13-RES-C1	Fortification Sample, ME 13, RespiCon, 1st Control
AEA09-FF-13-RES-C2	Fortification Sample, ME 13, RespiCon, 2nd Control
AEA09-FF-13-RES-L1	Fortification Sample, ME 13, RespiCon, 1st Low Level
AEA09-FF-13-RES-L2	Fortification Sample, ME 13, RespiCon, 2nd Low Level
AEA09-FF-13-RES-L3	Fortification Sample, ME 13, RespiCon, 3rd Low Level
AEA09-FF-13-RES-H1	Fortification Sample, ME 13, RespiCon, 1st High Level
AEA09-FF-13-RES-H2	Fortification Sample, ME 13, RespiCon, 2nd High Level
AEA09-FF-13-RES-H3	Fortification Sample, ME 13, RespiCon, 3rd High Level
AEA09-FF-13-HW-C1	Fortification Sample, ME 13, Hand Wash, 1st Control
AEA09-FF-13-HW-C2	Fortification Sample, ME 13, Hand Wash, 2nd Control
AEA09-FF-13-HW-L1	Fortification Sample, ME 13, Hand Wash, 1st Low Level
AEA09-FF-13-HW-L2	Fortification Sample, ME 13, Hand Wash, 2nd Low Level
AEA09-FF-13-HW-L3	Fortification Sample, ME 13, Hand Wash, 3rd Low Level
AEA09-FF-13-HW-H1	Fortification Sample, ME 13, Hand Wash, 1st High Level
AEA09-FF-13-HW-H2	Fortification Sample, ME 13, Hand Wash, 2nd High Level
AEA09-FF-13-HW-H3	Fortification Sample, ME 13, Hand Wash, 3rd High Level
AEA09-FF-13-FW-C1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Control
AEA09-FF-13-FW-C2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Control
AEA09-FF-13-FW-L1	Fortification Sample, ME 13, Face and Neck Wipe, 1st Low Level
AEA09-FF-13-FW-L2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd Low Level
AEA09-FF-13-FW-L3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd Low Level

Sample ID Number	Description
AEA09-FF-13-FW-H1	Fortification Sample, ME 13, Face and Neck Wipe, 1st High Level
AEA09-FF-13-FW-H2	Fortification Sample, ME 13, Face and Neck Wipe, 2nd High Level
AEA09-FF-13-FW-H3	Fortification Sample, ME 13, Face and Neck Wipe, 3rd High Level
AEA09-FF-13-ID-C1	Fortification Sample, ME 13, Inner Dosimeter, 1st Control
AEA09-FF-13-ID-C2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Control
AEA09-FF-13-ID-L1	Fortification Sample, ME 13, Inner Dosimeter, 1st Low Level
AEA09-FF-13-ID-L2	Fortification Sample, ME 13, Inner Dosimeter, 2nd Low Level
AEA09-FF-13-ID-L3	Fortification Sample, ME 13, Inner Dosimeter, 3rd Low Level
AEA09-FF-13-ID-H1	Fortification Sample, ME 13, Inner Dosimeter, 1st High Level
AEA09-FF-13-ID-H2	Fortification Sample, ME 13, Inner Dosimeter, 2nd High Level
AEA09-FF-13-ID-H3	Fortification Sample, ME 13, Inner Dosimeter, 3rd High Level
AEA09-FF-13-OD-C1	Fortification Sample, ME 13, Outer Dosimeter, 1st Control
AEA09-FF-13-OD-C2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Control
AEA09-FF-13-OD-L1	Fortification Sample, ME 13, Outer Dosimeter, 1st Low Level
AEA09-FF-13-OD-L2	Fortification Sample, ME 13, Outer Dosimeter, 2nd Low Level
AEA09-FF-13-OD-L3	Fortification Sample, ME 13, Outer Dosimeter, 3rd Low Level
AEA09-FF-13-OD-H1	Fortification Sample, ME 13, Outer Dosimeter, 1st High Level
AEA09-FF-13-OD-H2	Fortification Sample, ME 13, Outer Dosimeter, 2nd High Level
AEA09-FF-13-OD-H3	Fortification Sample, ME 13, Outer Dosimeter, 3rd High Level
AEA09-FF-14-PH-C1	Fortification Sample, ME 14, Painter's Hat, 1st Control
AEA09-FF-14-PH-C2	Fortification Sample, ME 14, Painter's Hat, 2nd Control
AEA09-FF-14-PH-L1	Fortification Sample, ME 14, Painter's Hat, 1st Low Level
AEA09-FF-14-PH-L2	Fortification Sample, ME 14, Painter's Hat, 2nd Low Level
AEA09-FF-14-PH-L3	Fortification Sample, ME 14, Painter's Hat, 3rd Low Level
AEA09-FF-14-PH-H1	Fortification Sample, ME 14, Painter's Hat, 1st High Level
AEA09-FF-14-PH-H2	Fortification Sample, ME 14, Painter's Hat, 2nd High Level
AEA09-FF-14-PH-H3	Fortification Sample, ME 14, Painter's Hat, 3rd High Level
AEA09-FF-14-AR-C1	Fortification Sample, ME 14, Air Sampling Tube, 1st Control
AEA09-FF-14-AR-C2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Control
AEA09-FF-14-AR-L1	Fortification Sample, ME 14, Air Sampling Tube, 1st Low Level
AEA09-FF-14-AR-L2	Fortification Sample, ME 14, Air Sampling Tube, 2nd Low Level
AEA09-FF-14-AR-L3	Fortification Sample, ME 14, Air Sampling Tube, 3rd Low Level
AEA09-FF-14-AR-H1	Fortification Sample, ME 14, Air Sampling Tube, 1st High Level
AEA09-FF-14-AR-H2	Fortification Sample, ME 14, Air Sampling Tube, 2nd High Level
AEA09-FF-14-AR-H3	Fortification Sample, ME 14, Air Sampling Tube, 3rd High Level
AEA09-FF-14-RES-C1	Fortification Sample, ME 14, RespiCon, 1st Control
AEA09-FF-14-RES-C2	Fortification Sample, ME 14, RespiCon, 2nd Control
AEA09-FF-14-RES-L1	Fortification Sample, ME 14, RespiCon, 1st Low Level
AEA09-FF-14-RES-L2	Fortification Sample, ME 14, RespiCon, 2nd Low Level
AEA09-FF-14-RES-L3	Fortification Sample, ME 14, RespiCon, 3rd Low Level
AEA09-FF-14-RES-H1	Fortification Sample, ME 14, RespiCon, 1st High Level
AEA09-FF-14-RES-H2	Fortification Sample, ME 14, RespiCon, 2nd High Level
AEA09-FF-14-RES-H3	Fortification Sample, ME 14, RespiCon, 3rd High Level

Sample ID Number	Description
AEA09-FF-14-HW-C1	Fortification Sample, ME 14, Hand Wash, 1st Control
AEA09-FF-14-HW-C2	Fortification Sample, ME 14, Hand Wash, 2nd Control
AEA09-FF-14-HW-L1	Fortification Sample, ME 14, Hand Wash, 1st Low Level
AEA09-FF-14-HW-L2	Fortification Sample, ME 14, Hand Wash, 2nd Low Level
AEA09-FF-14-HW-L3	Fortification Sample, ME 14, Hand Wash, 3rd Low Level
AEA09-FF-14-HW-H1	Fortification Sample, ME 14, Hand Wash, 1st High Level
AEA09-FF-14-HW-H2	Fortification Sample, ME 14, Hand Wash, 2nd High Level
AEA09-FF-14-HW-H3	Fortification Sample, ME 14, Hand Wash, 3rd High Level
AEA09-FF-14-FW-C1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Control
AEA09-FF-14-FW-C2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Control
AEA09-FF-14-FW-L1	Fortification Sample, ME 14, Face and Neck Wipe, 1st Low Level
AEA09-FF-14-FW-L2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd Low Level
AEA09-FF-14-FW-L3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd Low Level
AEA09-FF-14-FW-H1	Fortification Sample, ME 14, Face and Neck Wipe, 1st High Level
AEA09-FF-14-FW-H2	Fortification Sample, ME 14, Face and Neck Wipe, 2nd High Level
AEA09-FF-14-FW-H3	Fortification Sample, ME 14, Face and Neck Wipe, 3rd High Level
AEA09-FF-14-ID-C1	Fortification Sample, ME 14, Inner Dosimeter, 1st Control
AEA09-FF-14-ID-C2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Control
AEA09-FF-14-ID-L1	Fortification Sample, ME 14, Inner Dosimeter, 1st Low Level
AEA09-FF-14-ID-L2	Fortification Sample, ME 14, Inner Dosimeter, 2nd Low Level
AEA09-FF-14-ID-L3	Fortification Sample, ME 14, Inner Dosimeter, 3rd Low Level
AEA09-FF-14-ID-H1	Fortification Sample, ME 14, Inner Dosimeter, 1st High Level
AEA09-FF-14-ID-H2	Fortification Sample, ME 14, Inner Dosimeter, 2nd High Level
AEA09-FF-14-ID-H3	Fortification Sample, ME 14, Inner Dosimeter, 3rd High Level
AEA09-FF-14-OD-C1	Fortification Sample, ME 14, Outer Dosimeter, 1st Control
AEA09-FF-14-OD-C2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Control
AEA09-FF-14-OD-L1	Fortification Sample, ME 14, Outer Dosimeter, 1st Low Level
AEA09-FF-14-OD-L2	Fortification Sample, ME 14, Outer Dosimeter, 2nd Low Level
AEA09-FF-14-OD-L3	Fortification Sample, ME 14, Outer Dosimeter, 3rd Low Level
AEA09-FF-14-OD-H1	Fortification Sample, ME 14, Outer Dosimeter, 1st High Level
AEA09-FF-14-OD-H2	Fortification Sample, ME 14, Outer Dosimeter, 2nd High Level
AEA09-FF-14-OD-H3	Fortification Sample, ME 14, Outer Dosimeter, 3rd High Level
AEA09-FF-15-PH-C1	Fortification Sample, ME 15, Painter's Hat, 1st Control
AEA09-FF-15-PH-C2	Fortification Sample, ME 15, Painter's Hat, 2nd Control
AEA09-FF-15-PH-L1	Fortification Sample, ME 15, Painter's Hat, 1st Low Level
AEA09-FF-15-PH-L2	Fortification Sample, ME 15, Painter's Hat, 2nd Low Level
AEA09-FF-15-PH-L3	Fortification Sample, ME 15, Painter's Hat, 3rd Low Level
AEA09-FF-15-PH-H1	Fortification Sample, ME 15, Painter's Hat, 1st High Level
AEA09-FF-15-PH-H2	Fortification Sample, ME 15, Painter's Hat, 2nd High Level
AEA09-FF-15-PH-H3	Fortification Sample, ME 15, Painter's Hat, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-AR-C1	Fortification Sample, ME 15, Air Sampling Tube, 1st Control
AEA09-FF-15-AR-C2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Control
AEA09-FF-15-AR-L1	Fortification Sample, ME 15, Air Sampling Tube, 1st Low Level
AEA09-FF-15-AR-L2	Fortification Sample, ME 15, Air Sampling Tube, 2nd Low Level
AEA09-FF-15-AR-L3	Fortification Sample, ME 15, Air Sampling Tube, 3rd Low Level
AEA09-FF-15-AR-H1	Fortification Sample, ME 15, Air Sampling Tube, 1st High Level
AEA09-FF-15-AR-H2	Fortification Sample, ME 15, Air Sampling Tube, 2nd High Level
AEA09-FF-15-AR-H3	Fortification Sample, ME 15, Air Sampling Tube, 3rd High Level
AEA09-FF-15-RES-C1	Fortification Sample, ME 15, RespiCon, 1st Control
AEA09-FF-15-RES-C2	Fortification Sample, ME 15, RespiCon, 2nd Control
AEA09-FF-15-RES-L1	Fortification Sample, ME 15, RespiCon, 1st Low Level
AEA09-FF-15-RES-L2	Fortification Sample, ME 15, RespiCon, 2nd Low Level
AEA09-FF-15-RES-L3	Fortification Sample, ME 15, RespiCon, 3rd Low Level
AEA09-FF-15-RES-H1	Fortification Sample, ME 15, RespiCon, 1st High Level
AEA09-FF-15-RES-H2	Fortification Sample, ME 15, RespiCon, 2nd High Level
AEA09-FF-15-RES-H3	Fortification Sample, ME 15, RespiCon, 3rd High Level
AEA09-FF-15-HW-C1	Fortification Sample, ME 15, Hand Wash, 1st Control
AEA09-FF-15-HW-C2	Fortification Sample, ME 15, Hand Wash, 2nd Control
AEA09-FF-15-HW-L1	Fortification Sample, ME 15, Hand Wash, 1st Low Level
AEA09-FF-15-HW-L2	Fortification Sample, ME 15, Hand Wash, 2nd Low Level
AEA09-FF-15-HW-L3	Fortification Sample, ME 15, Hand Wash, 3rd Low Level
AEA09-FF-15-HW-H1	Fortification Sample, ME 15, Hand Wash, 1st High Level
AEA09-FF-15-HW-H2	Fortification Sample, ME 15, Hand Wash, 2nd High Level
AEA09-FF-15-HW-H3	Fortification Sample, ME 15, Hand Wash, 3rd High Level
AEA09-FF-15-FW-C1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Control
AEA09-FF-15-FW-C2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Control
AEA09-FF-15-FW-L1	Fortification Sample, ME 15, Face and Neck Wipe, 1st Low Level
AEA09-FF-15-FW-L2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd Low Level
AEA09-FF-15-FW-L3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd Low Level
AEA09-FF-15-FW-H1	Fortification Sample, ME 15, Face and Neck Wipe, 1st High Level
AEA09-FF-15-FW-H2	Fortification Sample, ME 15, Face and Neck Wipe, 2nd High Level
AEA09-FF-15-FW-H3	Fortification Sample, ME 15, Face and Neck Wipe, 3rd High Level
AEA09-FF-15-ID-C1	Fortification Sample, ME 15, Inner Dosimeter, 1st Control
AEA09-FF-15-ID-C2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Control
AEA09-FF-15-ID-L1	Fortification Sample, ME 15, Inner Dosimeter, 1st Low Level
AEA09-FF-15-ID-L2	Fortification Sample, ME 15, Inner Dosimeter, 2nd Low Level
AEA09-FF-15-ID-L3	Fortification Sample, ME 15, Inner Dosimeter, 3rd Low Level
AEA09-FF-15-ID-H1	Fortification Sample, ME 15, Inner Dosimeter, 1st High Level
AEA09-FF-15-ID-H2	Fortification Sample, ME 15, Inner Dosimeter, 2nd High Level
AEA09-FF-15-ID-H3	Fortification Sample, ME 15, Inner Dosimeter, 3rd High Level

Sample ID Number	Description
AEA09-FF-15-OD-C1	Fortification Sample, ME 15, Outer Dosimeter, 1st Control
AEA09-FF-15-OD-C2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Control
AEA09-FF-15-OD-L1	Fortification Sample, ME 15, Outer Dosimeter, 1st Low Level
AEA09-FF-15-OD-L2	Fortification Sample, ME 15, Outer Dosimeter, 2nd Low Level
AEA09-FF-15-OD-L3	Fortification Sample, ME 15, Outer Dosimeter, 3rd Low Level
AEA09-FF-15-OD-H1	Fortification Sample, ME 15, Outer Dosimeter, 1st High Level
AEA09-FF-15-OD-H2	Fortification Sample, ME 15, Outer Dosimeter, 2nd High Level
AEA09-FF-15-OD-H3	Fortification Sample, ME 15, Outer Dosimeter, 3rd High Level
AEA09-FF-16-PH-C1	Fortification Sample, ME 16, Painter's Hat, 1st Control
AEA09-FF-16-PH-C2	Fortification Sample, ME 16, Painter's Hat, 2nd Control
AEA09-FF-16-PH-L1	Fortification Sample, ME 16, Painter's Hat, 1st Low Level
AEA09-FF-16-PH-L2	Fortification Sample, ME 16, Painter's Hat, 2nd Low Level
AEA09-FF-16-PH-L3	Fortification Sample, ME 16, Painter's Hat, 3rd Low Level
AEA09-FF-16-PH-H1	Fortification Sample, ME 16, Painter's Hat, 1st High Level
AEA09-FF-16-PH-H2	Fortification Sample, ME 16, Painter's Hat, 2nd High Level
AEA09-FF-16-PH-H3	Fortification Sample, ME 16, Painter's Hat, 3rd High Level
AEA09-FF-16-AR-C1	Fortification Sample, ME 16, Air Sampling Tube, 1st Control
AEA09-FF-16-AR-C2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Control
AEA09-FF-16-AR-L1	Fortification Sample, ME 16, Air Sampling Tube, 1st Low Level
AEA09-FF-16-AR-L2	Fortification Sample, ME 16, Air Sampling Tube, 2nd Low Level
AEA09-FF-16-AR-L3	Fortification Sample, ME 16, Air Sampling Tube, 3rd Low Level
AEA09-FF-16-AR-H1	Fortification Sample, ME 16, Air Sampling Tube, 1st High Level
AEA09-FF-16-AR-H2	Fortification Sample, ME 16, Air Sampling Tube, 2nd High Level
AEA09-FF-16-AR-H3	Fortification Sample, ME 16, Air Sampling Tube, 3rd High Level
AEA09-FF-16-RES-C1	Fortification Sample, ME 16, RespiCon, 1st Control
AEA09-FF-16-RES-C2	Fortification Sample, ME 16, RespiCon, 2nd Control
AEA09-FF-16-RES-L1	Fortification Sample, ME 16, RespiCon, 1st Low Level
AEA09-FF-16-RES-L2	Fortification Sample, ME 16, RespiCon, 2nd Low Level
AEA09-FF-16-RES-L3	Fortification Sample, ME 16, RespiCon, 3rd Low Level
AEA09-FF-16-RES-H1	Fortification Sample, ME 16, RespiCon, 1st High Level
AEA09-FF-16-RES-H2	Fortification Sample, ME 16, RespiCon, 2nd High Level
AEA09-FF-16-RES-H3	Fortification Sample, ME 16, RespiCon, 3rd High Level
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-HW-C2	Fortification Sample, ME 16, Hand Wash, 2nd Control
AEA09-FF-16-HW-L1	Fortification Sample, ME 16, Hand Wash, 1st Low Level
AEA09-FF-16-HW-L2	Fortification Sample, ME 16, Hand Wash, 2nd Low Level
AEA09-FF-16-HW-L3	Fortification Sample, ME 16, Hand Wash, 3rd Low Level
AEA09-FF-16-HW-H1	Fortification Sample, ME 16, Hand Wash, 1st High Level
AEA09-FF-16-HW-H2	Fortification Sample, ME 16, Hand Wash, 2nd High Level
AEA09-FF-16-HW-H3	Fortification Sample, ME 16, Hand Wash, 3rd High Level
AEA09-FF-16-FW-C1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Control
AEA09-FF-16-FW-C2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Control
AEA09-FF-16-HW-C1	Fortification Sample, ME 16, Hand Wash, 1st Control
AEA09-FF-16-FW-L1	Fortification Sample, ME 16, Face and Neck Wipe, 1st Low Level
AEA09-FF-16-FW-L2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd Low Level

Sample ID Number	Description
AEA09-FF-16-FW-L3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd Low Level
AEA09-FF-16-FW-H1	Fortification Sample, ME 16, Face and Neck Wipe, 1st High Level
AEA09-FF-16-FW-H2	Fortification Sample, ME 16, Face and Neck Wipe, 2nd High Level
AEA09-FF-16-FW-H3	Fortification Sample, ME 16, Face and Neck Wipe, 3rd High Level
AEA09-FF-16-ID-C1	Fortification Sample, ME 16, Inner Dosimeter, 1st Control
AEA09-FF-16-ID-C2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Control
AEA09-FF-16-ID-L1	Fortification Sample, ME 16, Inner Dosimeter, 1st Low Level
AEA09-FF-16-ID-L2	Fortification Sample, ME 16, Inner Dosimeter, 2nd Low Level
AEA09-FF-16-ID-L3	Fortification Sample, ME 16, Inner Dosimeter, 3rd Low Level
AEA09-FF-16-ID-H1	Fortification Sample, ME 16, Inner Dosimeter, 1st High Level
AEA09-FF-16-ID-H2	Fortification Sample, ME 16, Inner Dosimeter, 2nd High Level
AEA09-FF-16-ID-H3	Fortification Sample, ME 16, Inner Dosimeter, 3rd High Level
AEA09-FF-16-OD-C1	Fortification Sample, ME 16, Outer Dosimeter, 1st Control
AEA09-FF-16-OD-C2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Control
AEA09-FF-16-OD-L1	Fortification Sample, ME 16, Outer Dosimeter, 1st Low Level
AEA09-FF-16-OD-L2	Fortification Sample, ME 16, Outer Dosimeter, 2nd Low Level
AEA09-FF-16-OD-L3	Fortification Sample, ME 16, Outer Dosimeter, 3rd Low Level
AEA09-FF-16-OD-H1	Fortification Sample, ME 16, Outer Dosimeter, 1st High Level
AEA09-FF-16-OD-H2	Fortification Sample, ME 16, Outer Dosimeter, 2nd High Level
AEA09-FF-16-OD-H3	Fortification Sample, ME 16, Outer Dosimeter, 3rd High Level
AEA09-FF-17-PH-C1	Fortification Sample, ME 17, Painter's Hat, 1st Control
AEA09-FF-17-PH-C2	Fortification Sample, ME 17, Painter's Hat, 2nd Control
AEA09-FF-17-PH-L1	Fortification Sample, ME 17, Painter's Hat, 1st Low Level
AEA09-FF-17-PH-L2	Fortification Sample, ME 17, Painter's Hat, 2nd Low Level
AEA09-FF-17-PH-L3	Fortification Sample, ME 17, Painter's Hat, 3rd Low Level
AEA09-FF-17-PH-H1	Fortification Sample, ME 17, Painter's Hat, 1st High Level
AEA09-FF-17-PH-H2	Fortification Sample, ME 17, Painter's Hat, 2nd High Level
AEA09-FF-17-PH-H3	Fortification Sample, ME 17, Painter's Hat, 3rd High Level
AEA09-FF-17-AR-C1	Fortification Sample, ME 17, Air Sampling Tube, 1st Control
AEA09-FF-17-AR-C2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Control
AEA09-FF-17-AR-L1	Fortification Sample, ME 17, Air Sampling Tube, 1st Low Level
AEA09-FF-17-AR-L2	Fortification Sample, ME 17, Air Sampling Tube, 2nd Low Level
AEA09-FF-17-AR-L3	Fortification Sample, ME 17, Air Sampling Tube, 3rd Low Level
AEA09-FF-17-AR-H1	Fortification Sample, ME 17, Air Sampling Tube, 1st High Level
AEA09-FF-17-AR-H2	Fortification Sample, ME 17, Air Sampling Tube, 2nd High Level
AEA09-FF-17-AR-H3	Fortification Sample, ME 17, Air Sampling Tube, 3rd High Level
AEA09-FF-17-RES-C1	Fortification Sample, ME 17, RespiCon, 1st Control
AEA09-FF-17-RES-C2	Fortification Sample, ME 17, RespiCon, 2nd Control
AEA09-FF-17-RES-L1	Fortification Sample, ME 17, RespiCon, 1st Low Level
AEA09-FF-17-RES-L2	Fortification Sample, ME 17, RespiCon, 2nd Low Level
AEA09-FF-17-RES-L3	Fortification Sample, ME 17, RespiCon, 3rd Low Level

Sample ID Number	Description
AEA09-FF-17-RES-H1	Fortification Sample, ME 17, RespiCon, 1st High Level
AEA09-FF-17-RES-H2	Fortification Sample, ME 17, RespiCon, 2nd High Level
AEA09-FF-17-RES-H3	Fortification Sample, ME 17, RespiCon, 3rd High Level
AEA09-FF-17-HW-C1	Fortification Sample, ME 17, Hand Wash, 1st Control
AEA09-FF-17-HW-C2	Fortification Sample, ME 17, Hand Wash, 2nd Control
AEA09-FF-17-HW-L1	Fortification Sample, ME 17, Hand Wash, 1st Low Level
AEA09-FF-17-HW-L2	Fortification Sample, ME 17, Hand Wash, 2nd Low Level
AEA09-FF-17-HW-L3	Fortification Sample, ME 17, Hand Wash, 3rd Low Level
AEA09-FF-17-HW-H1	Fortification Sample, ME 17, Hand Wash, 1st High Level
AEA09-FF-17-HW-H2	Fortification Sample, ME 17, Hand Wash, 2nd High Level
AEA09-FF-17-HW-H3	Fortification Sample, ME 17, Hand Wash, 3rd High Level
AEA09-FF-17-FW-C1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Control
AEA09-FF-17-FW-C2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Control
AEA09-FF-17-FW-L1	Fortification Sample, ME 17, Face and Neck Wipe, 1st Low Level
AEA09-FF-17-FW-L2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd Low Level
AEA09-FF-17-FW-L3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd Low Level
AEA09-FF-17-FW-H1	Fortification Sample, ME 17, Face and Neck Wipe, 1st High Level
AEA09-FF-17-FW-H2	Fortification Sample, ME 17, Face and Neck Wipe, 2nd High Level
AEA09-FF-17-FW-H3	Fortification Sample, ME 17, Face and Neck Wipe, 3rd High Level
AEA09-FF-17-ID-C1	Fortification Sample, ME 17, Inner Dosimeter, 1st Control
AEA09-FF-17-ID-C2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Control
AEA09-FF-17-ID-L1	Fortification Sample, ME 17, Inner Dosimeter, 1st Low Level
AEA09-FF-17-ID-L2	Fortification Sample, ME 17, Inner Dosimeter, 2nd Low Level
AEA09-FF-17-ID-L3	Fortification Sample, ME 17, Inner Dosimeter, 3rd Low Level
AEA09-FF-17-ID-H1	Fortification Sample, ME 17, Inner Dosimeter, 1st High Level
AEA09-FF-17-ID-H2	Fortification Sample, ME 17, Inner Dosimeter, 2nd High Level
AEA09-FF-17-ID-H3	Fortification Sample, ME 17, Inner Dosimeter, 3rd High Level
AEA09-FF-17-OD-C1	Fortification Sample, ME 17, Outer Dosimeter, 1st Control
AEA09-FF-17-OD-C2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Control
AEA09-FF-17-OD-L1	Fortification Sample, ME 17, Outer Dosimeter, 1st Low Level
AEA09-FF-17-OD-L2	Fortification Sample, ME 17, Outer Dosimeter, 2nd Low Level
AEA09-FF-17-OD-L3	Fortification Sample, ME 17, Outer Dosimeter, 3rd Low Level
AEA09-FF-17-OD-H1	Fortification Sample, ME 17, Outer Dosimeter, 1st High Level
AEA09-FF-17-OD-H2	Fortification Sample, ME 17, Outer Dosimeter, 2nd High Level
AEA09-FF-17-OD-H3	Fortification Sample, ME 17, Outer Dosimeter, 3rd High Level
AEA09-FF-18-PH-C1	Fortification Sample, ME 18, Painter's Hat, 1st Control
AEA09-FF-18-PH-C2	Fortification Sample, ME 18, Painter's Hat, 2nd Control
AEA09-FF-18-PH-L1	Fortification Sample, ME 18, Painter's Hat, 1st Low Level
AEA09-FF-18-PH-L2	Fortification Sample, ME 18, Painter's Hat, 2nd Low Level
AEA09-FF-18-PH-L3	Fortification Sample, ME 18, Painter's Hat, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-PH-H1	Fortification Sample, ME 18, Painter's Hat, 1st High Level
AEA09-FF-18-PH-H2	Fortification Sample, ME 18, Painter's Hat, 2nd High Level
AEA09-FF-18-PH-H3	Fortification Sample, ME 18, Painter's Hat, 3rd High Level
AEA09-FF-18-AR-C1	Fortification Sample, ME 18, Air Sampling Tube, 1st Control
AEA09-FF-18-AR-C2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Control
AEA09-FF-18-AR-L1	Fortification Sample, ME 18, Air Sampling Tube, 1st Low Level
AEA09-FF-18-AR-L2	Fortification Sample, ME 18, Air Sampling Tube, 2nd Low Level
AEA09-FF-18-AR-L3	Fortification Sample, ME 18, Air Sampling Tube, 3rd Low Level
AEA09-FF-18-AR-H1	Fortification Sample, ME 18, Air Sampling Tube, 1st High Level
AEA09-FF-18-AR-H2	Fortification Sample, ME 18, Air Sampling Tube, 2nd High Level
AEA09-FF-18-AR-H3	Fortification Sample, ME 18, Air Sampling Tube, 3rd High Level
AEA09-FF-18-RES-C1	Fortification Sample, ME 18, RespiCon, 1st Control
AEA09-FF-18-RES-C2	Fortification Sample, ME 18, RespiCon, 2nd Control
AEA09-FF-18-RES-L1	Fortification Sample, ME 18, RespiCon, 1st Low Level
AEA09-FF-18-RES-L2	Fortification Sample, ME 18, RespiCon, 2nd Low Level
AEA09-FF-18-RES-L3	Fortification Sample, ME 18, RespiCon, 3rd Low Level
AEA09-FF-18-RES-H1	Fortification Sample, ME 18, RespiCon, 1st High Level
AEA09-FF-18-RES-H2	Fortification Sample, ME 18, RespiCon, 2nd High Level
AEA09-FF-18-RES-H3	Fortification Sample, ME 18, RespiCon, 3rd High Level
AEA09-FF-18-HW-C1	Fortification Sample, ME 18, Hand Wash, 1st Control
AEA09-FF-18-HW-C2	Fortification Sample, ME 18, Hand Wash, 2nd Control
AEA09-FF-18-HW-L1	Fortification Sample, ME 18, Hand Wash, 1st Low Level
AEA09-FF-18-HW-L2	Fortification Sample, ME 18, Hand Wash, 2nd Low Level
AEA09-FF-18-HW-L3	Fortification Sample, ME 18, Hand Wash, 3rd Low Level
AEA09-FF-18-HW-H1	Fortification Sample, ME 18, Hand Wash, 1st High Level
AEA09-FF-18-HW-H2	Fortification Sample, ME 18, Hand Wash, 2nd High Level
AEA09-FF-18-HW-H3	Fortification Sample, ME 18, Hand Wash, 3rd High Level
AEA09-FF-18-FW-C1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Control
AEA09-FF-18-FW-C2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Control
AEA09-FF-18-FW-L1	Fortification Sample, ME 18, Face and Neck Wipe, 1st Low Level
AEA09-FF-18-FW-L2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd Low Level
AEA09-FF-18-FW-L3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd Low Level
AEA09-FF-18-FW-H1	Fortification Sample, ME 18, Face and Neck Wipe, 1st High Level
AEA09-FF-18-FW-H2	Fortification Sample, ME 18, Face and Neck Wipe, 2nd High Level
AEA09-FF-18-FW-H3	Fortification Sample, ME 18, Face and Neck Wipe, 3rd High Level
AEA09-FF-18-ID-C1	Fortification Sample, ME 18, Inner Dosimeter, 1st Control
AEA09-FF-18-ID-C2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Control
AEA09-FF-18-ID-L1	Fortification Sample, ME 18, Inner Dosimeter, 1st Low Level
AEA09-FF-18-ID-L2	Fortification Sample, ME 18, Inner Dosimeter, 2nd Low Level
AEA09-FF-18-ID-L3	Fortification Sample, ME 18, Inner Dosimeter, 3rd Low Level

Sample ID Number	Description
AEA09-FF-18-ID-H1	Fortification Sample, ME 18, Inner Dosimeter, 1st High Level
AEA09-FF-18-ID-H2	Fortification Sample, ME 18, Inner Dosimeter, 2nd High Level
AEA09-FF-18-ID-H3	Fortification Sample, ME 18, Inner Dosimeter, 3rd High Level
AEA09-FF-18-OD-C1	Fortification Sample, ME 18, Outer Dosimeter, 1st Control
AEA09-FF-18-OD-C2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Control
AEA09-FF-18-OD-L1	Fortification Sample, ME 18, Outer Dosimeter, 1st Low Level
AEA09-FF-18-OD-L2	Fortification Sample, ME 18, Outer Dosimeter, 2nd Low Level
AEA09-FF-18-OD-L3	Fortification Sample, ME 18, Outer Dosimeter, 3rd Low Level
AEA09-FF-18-OD-H1	Fortification Sample, ME 18, Outer Dosimeter, 1st High Level
AEA09-FF-18-OD-H2	Fortification Sample, ME 18, Outer Dosimeter, 2nd High Level
AEA09-FF-18-OD-H3	Fortification Sample, ME 18, Outer Dosimeter, 3rd High Level

APPROVED: 11/14/2013
EXPIRATION DATE: 11/09/2016

March 04, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Initial Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:		
• **Protocol dated 11/04/2013:**	**Full Board:**	**11/14/2013**
• **Protocol dated 01/05/2016:**	**Full Board:**	**03/03/2016**
• **Site Letter dated 02/29/2016**	**Full Board:**	**03/03/2016**
• **Informed Consent:**	**Full Board:**	**03/03/2016**
The following information is specific to the investigator referenced above:		
• **Your site(s) was approved to conduct this study:**	**Full Board:**	**11/14/2013**
• **Site specific Informed Consent(s) finalized by Schulman on:**		**03/04/2016**

The Board approved the items listed above. You must use only the "Schulman Approved" informed consent(s).

NOTE: It is the responsibility of the Principal Investigator to ensure that required subsequent reviews by EPA, by the Human Studies Review Board (HSRB,) and if the research is to be conducted in California, by the California Department of Pesticide Regulation (CDPR) have been completed before initiation of the study. Changes have also been made to the informed consent to reflect the above noted revisions.

NOTE: The Board initially conditionally approved this research study on 11/14/2013 and has since conditionally re-approved it on 11/13/2014 and 11/10/2015 pending receipt of the responses to satisfy the condition(s) of approval. Therefore, the "Expiration Date" identified in the box above is consistent with the last conditional re-approval granted by the Board on 11/10/2015.

In order to participate in this research study, an adult study subject must provide his/her own written consent for participation. An adult subject is an individual who has attained the legal age for consent to treatments or the procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. The Board **has not approved** consent of subjects via a legally authorized representative for this study. Accordingly, a subject must not be enrolled in this research study via the consent of a legally authorized representative.

This approval will last twelve (12) months.

If the study is expected to last beyond the approval period, re-approval must be requested at least eight (8) weeks prior to the expiration date noted above. The first report to the Board on the status of this study is due ten (10) months from the approval date or at the time the study closes, whichever is earlier. The appropriate form is available at www.sairb.com.

Approved investigators and sites are required to submit to Schulman for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators (PI and Sub-Is); or sites (primary and additional). Refer to www.sairb.com for comprehensive submission requirements.

Approved investigators and sites are required to notify Schulman of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study. Refer to the "Event(s) That Investigators Have to Report to Schulman" guidance document available on the Schulman WebPortal/SiteAccess and at www.sairb.com.

As a California site, you are required by California's Health & Safety Code §24173 to provide the subject or subject's conservator or guardian, or other representative, as specified in §24175, with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment. The copy must be signed and dated by the subject or the subject's conservator or guardian, or other representative. Please visit our IRB Forms page to download a copy of the California Bill of Rights.

Schulman IRB is in compliance with Part C Division 5 of the Canadian Food and Drug Regulations, the Tri-Council Policy Statement (TCPS), the International Conference on Harmonization Good Clinical Practice Guidelines, the regulations of the United States Food and Drug Administration as described in 21 CFR parts 50 and 56, and the United States Department of Health and Human Services regulations 45 CFR part 46, and the Environmental Protection Agency 40 CFR 26.

The current Board Membership List is available to download at the link on SiteAccess at www.sairb.com. Please maintain the appropriate Board Membership List with your study binder.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

Golden Pacific
LABORATORIES

February 29, 2016

Ms. Denisse Guzman
Board Liaison
Schulman IRB

RE: AEA09 Final Protocol

Dear Ms. Guzman:

As requested please find attached a table of recommendations made by the HSRB/EPA and presented in the written April 8-9, 2014 HSRB meeting report provided to SAIRB previously. The table includes the protocol modifications made as a result of the recommendations, and notes clarifying certain recommendations and responses.

Please feel free to contact me with any questions. I can be reached at (949)939-3585 or rtestman@gplabs.com.

Sincerely,

Robert Testman
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

Recommendation (Agency)	Protocol Modification	Comments
Science Review Recommendations (pages 19-22)		
1a. The middle concentration of BIT in paint should be changed to halfway between low and high concentrations (360 ppm instead of 400 ppm) to improve regression data. **(HSRB)**	The protocol was modified to change the target concentration to be 360 ppm. (Summary section p.8 and Test Substance section p.15).	
1a. Consider including additional factors such as varied types of painting equipment and wall texture to capture more diversity of exposure. **(HSRB)**	The protocol was not expanded to include additional diversity parameters. After discussion with EPA the current design was continued as EPA preferred to keep n=6 subjects per group and vary only concentration.	The HSRB suggested change to the statement that the "protocol captures the range of variation" if additional diversity parameters were not included. The referenced statement was contained in a separate document and not the study protocol.
1b. A number of statistical analyses are recommended to consider for the data analysis. **(HSRB)**	No changes.	The statistical analysis is conducted by EPA using the study data after completion of the study. These comments do not apply to the protocol.
1c. A cutoff point for active ingredient volatility should be considered when using the data from this study. **(HSRB)**	No changes.	The suggestion applies to use by EPA of the study data rather than to protocol design.
1c. A painter's sock/hood should be considered in place of a painter's hat. **(HSRB)**	Addition of a dosimeter cloth sample under the painter's hat was added (Subject Preparation section p.31, Sample Collection section p.33, Appendix I p.108-119).	After discussion with EPA a painter's hat will continue to be used as it provides better protection and comfort for the subjects, and is expected to capture at least as much paint splatter as a sock/hood. EPA also requested an additional dosimeter cloth be placed under the hat to monitor any possible penetration of paint through the hat.
1c. Subjects should be offered protective booties for their shoes. **(HSRB)**	No changes.	Subjects were already offered the option of protective shoe covers if they want them (Informed Consent Study Procedure, Item 5).

Recommendation (Agency)	Protocol Modification	Comments
1d. The test room should be ventilated with an exhaust fan to provide fresh air throughout the monitoring event. **(HSRB)**	The ceiling exhaust fan use was updated to remain on during the entire ME (Monitoring Site section p.20, ME Activities section p.31, Field Study Personnel section p.37).	EPA initially requested the fan be turned off. CDPR and HSRB agreed it should be continuously on. Room airflow will be measured and reported (Monitoring Site section p.20).
1e. The collection of wall wipes to determine background levels was questioned. **(HSRB)**	No changes.	The protocol specifies that the wall wipes will be analyzed at the Principal Investigator's discretion. They were included to aid in interpretation of results related to subject contact with previously painted surfaces.
1e. Industry standard drying times should be considered. **(HSRB)**	No changes.	The paint label and industry were already consulted in developing the drying/re-entry time specified in the protocol.
1e. The paint should be used as manufactured without further dilution. **(HSRB)**	No changes.	The protocol specifies that for mid and high concentrations of BIT in paint a minimal volume of dipropylene glycol will be used as a vehicle for the BIT. No other dilution of the paint is specified or will be performed.
1e. The paint sheen should be specified. **(HSRB)**	No changes.	The paint specified in the protocol is a "Interior Latex Flat" per label included in Appendix A.
1f. A member suggested the EPA require measurements which will characterize exposure variation. A member suggested EPA clearly enumerate conservative and non-conservative factors embedded in the study design. **(HSRB)**	No changes.	These items are directed at EPA and no guidance to implement change was received from EPA.
1f. Recommend that the companion washing protocol should be implemented first and results evaluated prior to implementing this protocol. **(HSRB)**	No changes.	The washing protocol study (AEA08) results were summarized and sent to EPA for review. Clearance was given to move forward with the brush/roller study (AEA09).
Ethics Review Recommendations (pages 26-27)		

Recommendation (Agency)	Protocol Modification	Comments
1a. Study exclusions should be expanded to include allergies and sensitivities to BIT or chemical products. **(EPA)**	Exclusion criteria were updated (p. 26).	
1b. The board disagreed with stating there is "little" incremental risk from participation in the study. **(HSRB)**	The protocol was updated to state there is "limited" incremental risk from participation in the study. (Rationale for Use of Human Subjects section p. 11)	
1c. The board recommended that researchers consider offering subjects their choice of researcher sex to help them changes clothes. **(HSRB)**	No changes.	Subjects are informed that a same sex researcher will assist them and have the option to withdraw without penalty if they are uncomfortable. Potential legal liability and research staff comfort also need to be considered.
1d. The board recommended that the use of "applicators" in reference to subjects be changed to "appliers." **(HSRB)**	The word "applicators" was changed to "appliers" globally.	
1e. Clear definition of "good" health should be added. **(HSRB)**	No changes.	Subject questionnaire asks "Do you consider your general health good enough to participate in this study as described?" This question seems appropriate and clear.
1e. Exclusion criteria for health related issues should be evaluated. Informed consent should be updated as needed. **(HSRB)**	Updated exclusion criteria to remove diabetes and immunological suppression exclusions. Added an exclusion for "Other health conditions that make participation difficult or unsafe (e.g. broken bone)." The Informed Consent was updated to reflect the revised exclusion (Subject Selection section).	Health related exclusions are necessary to reduce risk to subjects from physical exertion required during the study activities.
1e. The board recommended that section 10 of the Informed Consent Study Procedure be updated to clarify any identifying features will not be shown in photos/videos. **(HSRB)**	The Informed Consent was updated to say "faces, tattoos, or other identifying features" will not be shown.	

Recommendation (Agency)	Protocol Modification	Comments
1e. The board recommended the words "from you" be added to section 12.a of the Informed Consent Study Procedure. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the word "some" be replaced with "any" in section 1 of the Informed Consent Risks. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the use of "tested" be updated to "take part" in the Informed Consent Costs and Payments section. **(HSRB)**	The Informed Consent was updated as requested.	
1e. The board recommended the Confidentiality section of the Informed Consent be updated to clarify any identifying features will not be shown in photos/videos. **(HSRB)**	The Informed Consent was updated to say "will not show your face or other identifying features (such as tattoos)."	
1f. The board recommended that researchers complete a course of human subjects protection within 3 years of study participation. **(HSRB)**	No changes.	Our standard operating procedures require completion of the NIH human subject protection course within 3 years of any work with subjects.
Other Items		
Researchers should offer a paint edger and paint cup to subjects and allow them to decide if they want to use these items. **(EPA)**	The protocol was modified to offer these items to subjects.	

Megan Boatwright

From: Robert Testman
Sent: Thursday, March 17, 2016 4:44 PM
To: Megan Boatwright
Subject: FW: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting
Attachments: ls03-17.pdf

For the file.

Thanks

From: Escobar, Olga@CDPR [mailto:Olga.Escobar@cdpr.ca.gov]
Sent: Thursday, March 17, 2016 4:25 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>; Ting, David@OEHHA <David.Ting@oehha.ca.gov>; Salocks, Charles@OEHHA <Charles.Salocks@oehha.ca.gov>; Beauvais, Sheryl@CDPR <Sheryl.Beauvais@cdpr.ca.gov>; Nonato, Yvette@CDPR <Yvette.Nonato@cdpr.ca.gov>; Ross, Lisa@CDPR <Lisa.Ross@cdpr.ca.gov>; Laribi, Ouahiba@OEHHA <Ouahiba.Laribi@oehha.ca.gov>; Ngai, William@OEHHA <William.Ngai@oehha.ca.gov>
Subject: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Mr. Testman:

Attached is an e-version of a correspondence to you from Lisa Ross of the Department of Pesticide Regulation. I have placed the original signed letter in the mail. If you have any questions, please contact Don Richmond at 916-445-4192 or by email at drichmond@cdpr.ca.gov.

Note to cc's: A hard copy will not be sent out unless requested.

Olga Escobar
Worker Health and Safety Branch
Department of Pesticide Regulation
916-324-8849

Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

March 17, 2016

Robert Testman
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Mr. Testman:

In accordance with the provisions of the California Code of Regulations, Title 3 (3CCR), Chapter 3, Section 6710, the Director of the Department of Pesticide Regulation (DPR) grants final approval of the pesticide exposure study protocol entitled, "A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting" on March 17, 2016. This study protocol and associated consent form were reviewed and unanimously approved by the Schulman Associates Institutional Review Board of Research Triangle Park, North Carolina on March 4, 2016, in accordance with 40 CFR Part 26. This study approval will expire on November 9, 2016.

Please note that Section 6710 of 3CCR authorizes DPR staff to observe your study. Please inform Don Richmond of the date and location you will conduct the study. Site visits may include observing subject recruitment and the informed consent procedures. This section also authorizes an official observer from DPR or the county agricultural commissioner's office to terminate any study activity that jeopardizes the safety of the study subjects, the public, or the environment.

This study must be conducted according to the approved protocol and consent forms. All protocol and consent form amendments that may impact the health of the human participants must have DPR and Institutional Review Board approval prior to implementing such changes (3CCR 6710, subsection g).

If during the study, problems should arise related to the safety of the study subjects, please notify our office immediately. If you have any questions, please feel free to contact Don Richmond of my staff at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov.

Sincerely,

(original signed by L. Ross)

Lisa Ross, Ph.D.
Environmental Program Manager II
Worker Health and Safety Branch
(916) 445-6387

cc: David Ting, Ph.D., Chief, Pesticide and Environmental Toxicology Branch (PETB), Office of Environmental Health Hazard Assessment (OEHHA)
Charles Salocks, Ph.D., Senior Toxicologist, Pesticide Epidemiology Section (PES), PETB, OEHHA
William Ngai, M.D., MPH, Public Health Medical Officer II, PES, PETB, OEHHA
Ouahiba Laribi, Ph.D., MPH, Associate Toxicologist, PES, PETB, OEHHA
Sheryl Beauvais, Ph.D., Environmental Program Manager II, Human Health Assessment Branch (HHA), DPR
Don Richmond, Research Scientist II, WHS, DPR
Yvette Nonato, M.D., DPBRM, Research Scientist I, WHS, DPR

Megan Boatwright

From: Robert Testman
Sent: Tuesday, May 03, 2016 4:46 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: Protocol amendment for AEA09 - Brush/Roller Study
Attachments: 120463 - Protocol Amendment No 1.pdf

Hi Don,

Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

PROTOCOL AMENDMENT NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: April 26, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section B. Analytical Method (Protocol page 41), the fourth paragraph reads:

   "GPL Analytical Method GPL-MTH-079…"

   will now read:

   "GPL Analytical Method GPL-MTH-081…"

2. In Section B. Analytical Method (Protocol page 41), the sixth paragraph reads:

   "All subject samples, except hand wipes/washes, will be extracted using 70% methanol/30% water/0.016% formic acid, and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile/ 50% water, to quantitate."

   will now read:

   "All subject samples, except hand wipes/washes and air sampling tubes, will be extracted using methanol/water/formic acid (70:30:0.016, v/v/v) [MWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Air sampling tubes will be extracted using acetonitrile/water/formic acid (70:30:0.016, v/v/v) [AWF] and an aliquot will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. An aliquot of the hand wipe/wash sample will be transferred to a chromatography vial, mixed with internal standard solution and analyzed using HPLC/MS/MS. Samples may require dilution using MWF, to quantitate."

3. In Section 10. Monitoring Event Procedures (Protocol page 29), the additional information is added for pre-washing of outer dosimeters (due to potential background BIT residues in the matrix):

   "All outer dosimeter pants and shirts will be pre-washed to remove potential background BIT residues before use. Outer dosimeters will be washed in a commercial or residential washing machine on a cold wash cycle with no detergent

RJT 05/02/16

added. Pants and shirts are hung to dry, folded into new large plastic bags labeled with the date of the pre-washing, then considered ready for use."

Justification:

The above changes:

1. Correct a typo
2. Clarifies the analytical method summary.
3. Adds information on how to pre-wash cotton outer dosimeters.

Effect on the Study:

No adverse impact on the study.

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR:

Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE:

Has Shah, Ph.D. Date
Sponsor Representative

Robert Testman

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Wednesday, May 4, 2016 4:12 PM
To: Robert Testman
Subject: RE: Protocol amendment for AEA09 - Brush/Roller Study

Rob,

Have you received approval from SAIRB? If so, please send me a copy of their approval. I will be sending out a letter stating the amendment does not appear to an impact on the health of the participants, therefore DPR does not need to approve the amendment.

Don

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, May 03, 2016 4:46 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: Protocol amendment for AEA09 - Brush/Roller Study

Hi Don,

Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

Robert Testman

From: Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent: Friday, May 6, 2016 1:24 PM
To: Robert Testman
Cc: Ross, Lisa@CDPR; Kwok, Eric@CDPR; Richmond, Don@CDPR; Nonato, Yvette@CDPR
Subject: Study Protocol Amendment for Study AEA09.
Attachments: lr-5-05.pdf

Mr. Testman:

Attached is your electronic file copy of a letter (2 pages) from the Department of Pesticide Regulation, Lisa Ross, Ph.D., Environmental Program Manager II, Chief, Worker Health & Safety Branch (WHS), dated May 5, 2015, RE: **A Study for Measurement of Potential Dermal and Inhalation During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting**.

If you have any questions about this letter, please contact in WHS – Don Richmond at (916) 445-4192.

[A hard copy is sent only to the main recipient; hard copies to cc:s are provided upon request.]

Tina Louie
Department of Pesticide Regulation
Worker Health & Safety Branch
(916) 324-0603

dpr Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

May 5, 2016

Mr. Robert Testman
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Mr. Testman:

On May 4, 2016, the Department of Pesticide Regulation (DPR) received a protocol amendment for study AEA09, **"A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting."** The amendment corrects a typographical error of the GPL analytical method number, clarifies the analytical method summary, and adds information on the pre-wash of cotton outer dosimeters to remove potential background BIT from the dosimeters.

Title 3 California Code of Regulations (3CCR) Section 6710(h) states "the study director shall not make an amendment to the approved protocol that may impact the health of the human participants without approval from the Director. For amendments where participant health is potentially impacted, the study director shall make the request in writing."

In reviewing the submitted protocol amendment, DPR did not identify any changes that appear to present a potential impact on the health of the study's participants. Therefore, DPR does not need to approve the amendment. The protocol states that amendments are subject to review and approval by an institutional review board (IRB). Please submit a copy of the IRB approval.

The Director of DPR granted approval of the protocol on March 17, 2016. Approval expires on November 9, 2016. 3CCR 6710(k) provides requirements for the information you must submit to the Director prior to the protocol's expiration date. 3CCR 6710(i) provides the requirements you must meet should you wish to renew DPR's approval of the protocol.

Section 6710 of 3CCR authorizes DPR staff to observe your study to evaluate compliance with the protocol. Please inform Don Richmond of the date and location you will conduct the study in California. Site visits may include observing subject recruitment and the informed consent procedures. This section also authorizes an official observer from DPR or the county agricultural commissioner's office to terminate any study activity that jeopardizes the safety of the study subjects, the public, or the environment.

If you have any questions, please feel free to contact Don Richmond of my staff by telephone at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov.

Sincerely,

Lisa Ross, Ph.D.
Environmental Program Manager II
Chief, Worker Health and Safety Branch
(916) 324-4116

cc: Eric Kwok, Ph.D., D.A.B.T., Senior Toxicologist, WHS, DPR
Don Richmond, Research Scientist II, WHS, DPR
Yvette Nonato, M.D., Research Scientist I, WHS, DPR

Megan Boatwright

From: Robert Testman
Sent: Monday, May 09, 2016 8:40 AM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: RE: Protocol amendment for AEA09 - Brush/Roller Study
Attachments: AEA09_201307318_Robert_Testman_Amended_Approval_Letter_9063448.pdf

Hi Don,

A copy of the IRB approval for Amendment 1 to study AEA09 is attached.

Thanks,
Rob

From: Richmond, Don@CDPR [mailto:Don.Richmond@cdpr.ca.gov]
Sent: Wednesday, May 4, 2016 4:12 PM
To: Robert Testman <rtestman@gplabs.com>
Subject: RE: Protocol amendment for AEA09 - Brush/Roller Study

Rob,

Have you received approval from SAIRB? If so, please send me a copy of their approval. I will be sending out a letter stating the amendment does not appear to an impact on the health of the participants, therefore DPR does not need to approve the amendment.

Don

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Tuesday, May 03, 2016 4:46 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: Protocol amendment for AEA09 - Brush/Roller Study

Hi Don,

Please find attached protocol amendment 1 for study AEA09 for your review. The amended items are not expected to have an impact on the subjects.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

May 06, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Updated Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:	Review Type	Approval Date
• Protocol Amendment No. 1 dated 04/26/2016	Expedited	05/04/2016

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

Megan Boatwright

From: Robert Testman
Sent: Monday, June 20, 2016 3:16 PM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: Amendment 2 for AEA09
Attachments: AEA09_201307318_Robert_Testman_Amended_Approval_Letter_4310745.pdf; 120463 - Protocol Amendment No 2.pdf

Hi Don,

As I mentioned last week we have issued amendment 2 to the brush/roller study AEA09. I have attached a copy of the amendment and the IRB approval for your review and records.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

June 15, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Robert J. Testman
SUBJECT:	Updated Approval Documents
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The following protocol items were reviewed and approved on the dates listed below:	Review Type	Approval Date
• Protocol Amendment No. 2 dated 06/10/2016	Expedited	06/15/2016

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

PLEASE REFERENCE IRB # 201307318 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

PROTOCOL AMENDMENT NO.: 2
GPL Study # 120463
AEATF Study No.: AEA09
Effective Date: June 10, 2016

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

Description of Amendment (including justification):

1. In Section 11.B. Transportation (Protocol page 39), the paragraph reads:

   "Samples will be transported from the exposure site to the analytical laboratory on dry ice by study personnel on the day of collection. A chain of-custody record will be available for each sample." will now read:

   "Samples will be transported from the exposure site to the analytical laboratory by study personnel shortly after collection. A chain of-custody record will be available for each sample."

Justification:

Since the exposure site is in very close proximity to the analytical laboratory the samples can be placed directly into the analytical laboratory freezer and dry ice transport is not necessary.

Effect on the Study:

No adverse impact on the study.

PREPARED BY:

FIELD COORDINATOR:

Megan T. Boatwright 06/10/16
Megan T. Boatwright, B.S. Date
Golden Pacific Laboratories, LLC

REVIEWED BY:

STUDY DIRECTOR/
PRINCIPAL INVESTIGATOR:

06/10/16
Robert J. Testman, M.B.A. Date
Golden Pacific Laboratories, LLC

SPONSOR
REPRESENTATIVE:

Hasmukh Shah 06/10/16
Has Shah, Ph.D. Date
Sponsor Representative

Robert Testman

From: Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent: Thursday, June 23, 2016 5:37 PM
To: Robert Testman
Cc: Ross, Lisa@CDPR; Ford, Robert@CDPR; Richmond, Don@CDPR
Subject: Protocol Study Letter; AEA09.
Attachments: dr06-23.pdf

Mr. Testman:

Attached is our electronic copy of a letter (1 page), from the Department of Pesticide Regulation (DPR), Don Richmond, Research Scientist II, Worker Health and Safety Branch (WHS), dated June 23, 2016, RE: "**A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting**."
(The letter includes a 3 page attachment; the entire document is 4 pages.)

If you have any questions about this letter, please contact in WHS – Don Richmond at (916) 445-4192.

[A hardcopy is sent only to the main recipient; hardcopies to cc:s are provided upon request.]

Tina Louie
Department of Pesticide Regulation
Worker Health & Safety Branch
(916) 324-0603

dpr Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

June 23, 2016

Robert Testman
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Mr. Testman:

I appreciate the opportunity to have observed the pesticide exposure monitoring that you and your staff conducted as part of study AEA09, **"A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting."**

Based on my observations, the study was conducted according to the protocol approved by the Schulman Associates Institutional Review Board and the California Department of Pesticide Regulation. The study staff wore the appropriate protective clothing and equipment while working with the volunteer participants, and when handling samples. I did not observe any situation that created an unsafe environment for the participants and study staff. Attached is a copy of my observations.

If you have any questions, please feel free to contact me at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov.

Sincerely,

Donald M. Richmond
Research Scientist II
Worker Health and Safety Branch

Attachment

cc: Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Robert Ford, CIH, CSP, Environmental Program Manager I, WHS, DPR

Observations of Studies Involving Human Subjects

Study Title: **A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting**

Study Director: **Robert Testman** Observation Date: **June 15, 2016**

Location: **Fresno, California**

WHS Observers: **Don Richmond**

Participant Enrollment	Y	N	N/A	N/I
Did participant receive copies of the signed *ICF* and *BOR*?	√			
Did you observe the participant enrollment procedures? (Note: If possible ask the participant the following questions if enrollment is not observed)		√		
Were the study objectives, and procedures explained clearly?	√			
Did research staff encourage the participant to ask questions?	√			
Did research staff inform the participant of his or her rights?	√			
Did participant sign the *Informed Consent Form (ICF)* and *Bill of Rights (BOR)*?	√			

Comments:
Participants consented prior to start of the study. Study Director talked to both participants before they started painting to reiterate their participation was voluntary and asked if they had additional questions. The second participant mentioned he read through all of the material given to him. I asked the standby participant the above questions about the consenting process. His answers indicate the consenting procedures were followed.

Participant Privacy/Safety	Y	N	N/A	N/I
Did the participant have a private dressing room for changing clothes? (Note: DPR staff will not enter the dressing room during the time a participant changes clothing)	√			
Did you observe any situation that could create an unsafe work environment for the participant?		√		
If an unsafe situation occurred, did the study director take immediate action to ensure the safety of the participant?			√	

Comments:
A private room was provided to each participant. Only a researcher of the same gender was in the room with the participant to help with putting on the shirt and pants and to put the air sampling equipment on the participant. A bathroom was provided for the female participant to take a pregnancy test. I did not observe anyone reading the results, which was probably done by the researcher of the same gender when the dressing room door was close.

Research Staff

How many researchers are present at the study site? 11 at various points including a nurse.

List below the protective equipment/clothing researchers wore while monitoring workers.

List below the protective equipment researchers wore while handling samples.

Comments:
When handling the sampling equipment, the researchers wore disposable gloves. The participant observer, who was in the room with the participant, wore normal attire. The research staff that dealt with the field spikes and weathering of samples wore disposable gloves, lab coats, and safety glasses.

Y = Yes; N = No; N/A = Not Applicable; N/I = Not Inspected or Observed

Observations of Studies Involving Human Subjects

Sampling	Y	N	N/A	N/I
Is the participant wearing the *sampling dosimetry* required by the protocol?	√			
Are the researchers following the protocol on monitoring a participant wearing *sample dosimetry*?	√			

Comments:
Participants wore long sleeve shirt and long pants, painter's hat. Two air sampling pumps were attached to a belt worn by the participants. Air sampling media were attached to the front of the participant's shirt and were attached to the air sampling pumps with Tygon® tubing. Inner clothing dosimeters were presumably worn, but I did not enter the changing room to observe these being put on. The participants also wore safety glasses and disposable booties.

Application (request a copy of the pesticide label)	Y	N	N/A	N/I
Is the participant mixing/loading the pesticide according to the label directions?			√	
Is the participant applying the pesticide according to the label directions?	√			
Did participant wear the personal protective clothing and equipment required by the label? List below	√			
Did you observe any leaks or spills during mixing/loading of the pesticide?			√	
Did you observe any leaks or spills during application of the pesticide?			√	

Comments:
The antimicrobial BIT was present in the paint. If any additional BIT was added to the paint, this was done ahead of time by the research staff. There is normal spillage and splashing of paint that is part of the normal part of painting. No abnormal spills occurred. The participants had paint rags available to use to wipe up spills on their hand or the floor as the participant felt the need to use a paint rag.

Subject and Sample Handling Areas	Y	N	N/A	N/I
Is the subject preparation area located at a sufficient distance from the pesticide handling site to minimize potential contamination?	√			
Is the sample handling area located at a sufficient distance to minimize potential contamination?	√			

Comments:
Paint rooms were down the hall away from the set up area, participant changing rooms and field spiking area. I did not detect the smell of paint in this area. Painting area included 6 rooms built into a larger room, 3 rooms if necessary for each painter.

Deviations

Protocol deviations are *unplanned changes to the approved protocol that occur during the conduct of the study.*
List deviations that may impact the participants.
I observed no deviations that may have impacted the participants. Participant washed her hands and face with Ivory soap and water after she put inner and outer clothing dosimeters. This deviation had no impact on her or the study.

Y = Yes; N = No; N/A = Not Applicable; N/I = Not Inspected or Observed

Observations of Studies Involving Human Subjects

Notes

Describe any unusual or noteworthy event during the application or monitoring not mentioned previously.

Prior to the start of the study for the day, the onsite nurse checked the hands of both participants and the alternate participant.

The participants were supplied with a cart with wheels to move their painting supplies around as needed. Once inside one of the rooms, the participants were given instructions on what to paint (walls, ceiling, and baseboards). The participants chose how they would paint the room.

A Kestrel 4500 was used to monitor the temperature at the sampling site. The temperature did not rise above the mid 70s Fahrenheit inside the building while the participants painted.

A vent duct was noted in the ceiling of the paint rooms. In addition, a portable fan was placed at the entry door to provide additional ventilation.

The nurse provided water or Gatorade to the participant upon request. The nurse placed a straw into the bottle and held it while the participant drank through the straw.

Participant used a ladder to pain the upper edges of the walls and the along the edge between the wall and ceiling. She felt dizzy at one point while painting. The nurse had her rest. She chose to continue painting after the rest. Later she said she was not feeling well and stopped painting. She painted 1.8 gallons of the 2.0 gallons she was given. She met the minimum requirement applying at least 0.5 gallons of paint. The nurse was present at all times to ensure she was OK. After the collection of samples and she had dressed, the nurse talked to her about how she felt and also checked her hands for irritation. She was paid for her participation and offered a drink to go. She took a Gatorade with her.

The second participant used a step ladder to paint along the edge between the walls and the ceiling. He had some paint on his face as well as on the wrist area (extending about 2 inches above the wrist line) of one arm. I observed the paint removal process for this participant. He scrubbed his hands after some of the alcohol water solution was poured over them. The remainder of the paint was removed by the researcher with gauze wipes. The wash solution was captured in a stainless steel bowl, and then transferred to a sample jar.

Once the second participant had painted the minimum 0.5 gallons of paint, the alternate participant was paid for his time before being dismissed for the day.

Robert Testman

From:	Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent:	Friday, June 24, 2016 9:35 AM
To:	Robert Testman
Cc:	Kwok, Eric@CDPR; Ross, Lisa@CDPR; Richmond, Don@CDPR; Nonato, Yvette@CDPR; Ford, Robert@CDPR
Subject:	Protocol Amendment Letter, Study AEA09,
Attachments:	rf6-023.pdf

Mr. Testman:

Attached is your electronic file copy of a letter (1 page) from the Department of Pesticide Regulation (DPR), Robert Ford, CIH, CSP, Environmental Program Manager I, Worker Health and Safety Branch (WHS), dated June 23, 2016, RE: "**A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting**."

If you have any questions about this letter, please contact in WHS – Don Richmond at (916) 445-4192, or Robert Ford at (916) 445-3135.

[This same message & letter is resent from yesterday; if you've received it twice, please disregard one of them.]

Tina Louie
Department of Pesticide Regulation
Worker Health & Safety Branch
(916) 324-0603

June 23, 2016

Mr. Robert Testman
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Mr. Testman:

On June 20, 2016, the Department of Pesticide Regulation (DPR) received a protocol amendment for study AEA09, **"A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting."** The amendment removes the transport of samples on dry ice to the laboratory because the laboratory is in very close proximity of the exposure site. The protocol amendment was reviewed and approved by an institutional review board (IRB) on June 15, 2016.

Title 3 California Code of Regulations (3CCR) Section 6710(h) states "the study director shall not make an amendment to the approved protocol that may impact the health of the human participants without approval from the Director. For amendments where participant health is potentially impacted, the study director shall make the request in writing."

In reviewing the submitted protocol amendment, DPR did not identify any changes that appear to present a potential impact on the health of the study's participants. Therefore, DPR does not need to approve the amendment.

If you have any questions, please feel free to contact Don Richmond by telephone at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov.

Sincerely,

Robert Ford, CIH, CSP
Environmental Program Manager I
Worker Health and Safety Branch
(916) 445-3135

cc: Eric Kwok, Ph.D., D.A.B.T., Senior Toxicologist, WHS, DPR
Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Don Richmond, Research Scientist II, WHS, DPR
Yvette Nonato, M.D., Research Scientist I, WHS, DPR

Megan Boatwright

From: Robert Testman
Sent: Tuesday, October 31, 2017 11:16 AM
To: Richmond, Don@CDPR
Cc: Megan Boatwright
Subject: AEA09 Closure
Attachments: AEA09_201307318_Robert_Testman_Closure_Letter_5578557.pdf; 120463 - Protocol Deviation No 1.pdf

Hi Don,

Please find attached a closure letter from the IRB for study AEA09. Also a protocol deviation for your records, although the items did not relate to subject safety we prefer to provide you a copy. Let me know if you have any questions or comments.

Thanks,
Rob

Rob Testman
rtestman@gplabs.com
(559)275-9091 (lab)
(949)939-3585 (cell)

STUDY CLOSURE: 10/30/2017

October 30, 2017

FROM:	Schulman IRB
TO:	Robert J. Testman
SUBJECT:	Study Closure
SPONSOR:	American Chemistry Council - Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA09
PROTOCOL TITLE:	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

The Board received your Final Report on the referenced protocol.

This letter is to confirm that the Board closed the files on the referenced protocol.

WebPortal/Paperless

PROTOCOL DEVIATION NO.: 1
GPL Study # 120463
AEATF Study No.: AEA09

Study Title: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

List of Deviations, Dates, Reasons for Deviation, and Effect on Study

1. **Date of Deviation: N/A**

   Description of Deviation: For the inner dosimeter (ID) garments worn by the subjects painting in ME01, ME02, ME04, ME06, ME07, ME10, ME12, ME13, ME16 and ME17, BIT background contamination was observed at higher levels than total residues found in outer dosimeters. Summary ID residues will be reported using an EPA reviewed penetration factor applied to outer dosimeter samples for these subjects (Section 12B).

   Reason for Deviation: The analytically determined residues in ID samples for these subjects were higher than OD samples. A subsequent investigation demonstrated that some inner dosimeter lots were received contaminated with BIT from the manufacturer.

   Effect on the Study: The eight subject inner dosimeters from non-contaminated lots will be used to calculate a penetration factor which will be applied to calculate summary statistics for the study. Estimates based on using a penetration factor will allow for representative data on dermal exposure.

2. **Date of Deviation: May 5, 2016**

   Description of Deviation: The Protocol states: IRB approved recruiting advertisements (appendix E) will be simultaneously (within the same week) placed in the Fresno Bee, the California Advocate and the Fresno edition of Vida en el Valle (Section 9.A.ii). The advertisement was unable to be placed in the California Advocate.

   Reason for Deviation: Staff at the California Advocate indicated that the advertisement would be placed in the next available issue, May 20, 2016. However, no copies of the paper could be found and phone calls to confirm placement were not returned.

   Effect on the Study: No adverse impact on the study. Recruitment proceeded through the Fresno Bee and Vide en Valle newspapers which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled in the study.

3. **Date of Deviation: June 8, 2016 – June 10, 2016**

Description of Deviation: The additional BIT added to the test substance was dissolved in diethylene glycol instead of dipropylene glycol (Section 7A).

Reason for Deviation: Analytical coordinator oversight.

Effect on the Study: No adverse impact on the study. The solvent used is very similar chemically to that called for in the protocol. All paints were assayed in triplicate prior to use to ensure acceptable BIT concentration.

4. **Date of Deviation: June 7, 2016 – April 27, 2017**

Description of Deviation: The BIT internal standard was used after its September 21, 2015 retest date (Section 12Aii).

Reason for Deviation: The BIT internal standard was custom synthesized and was not retested prior to use.

Effect on the Study: No adverse impact on the study. The BIT internal standard is used consistently in both calibration standards and samples to normalize the peak area ratio of the reference substance. A currently retested internal standard substance is not required as exact purity has no effect on analytical results.

5. **Date of Deviation: May 3, 2016 – June 14, 2016**

Description of Deviation: The test substance containers were temporarily stored at ambient temperature at GPL with a data logger to monitor storage conditions until transfer to field contractor personnel. Upon downloading the data logger data, it was discovered that the device did not record any temperature data (Section 7A).

Reason for Deviation: Device malfunction.

Effect on the Study: No adverse impact on the study. Temperature min/max is recorded weekly at a nearby GPL room temperature location and the temperature range was 21 °C – 25 °C.

6. **Date of Deviation: December 12, 2016 – April 26, 2017**

Description of Deviation: Select inner dosimeter (8 sets), outer dosimeters (7 sets), painter's hats (6 sets), air sampling tube (1 set), and background wall wipe (1 set) samples were analyzed after being stored frozen for 6 months, later than the experimentally confirmed stability interval (Section 12C).

Reason for Deviation: Personnel oversight.

Effect on the Study: No adverse impact on the study. All samples, including those analyzed after the storage interval, were analyzed with field fortified samples which did not show low analyte recovery. This demonstrates that samples were stable after being stored frozen beyond 6-months.

7. **Date of Deviation: June 13, 2016 – July 1, 2016**

Description of Deviation: Study samples were generated in this study using ID suffixes not listed in Section 11A or Appendix I. These samples were generally background air sampling tubes, background wall wipes, and sweat wipes. (Section 11A).

Reason for Deviation: Example sample ID information for these matrices was inadvertently not included in the protocol when it was written.

Effect on the Study: No adverse impact on the study. The background wall wipes, air sampling tubes, and sweat wipes are all referenced in the protocol, however the ID suffixes designating sample identification was not listed in page 39 of the protocol or the study sample list.

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