FINAL REPORT

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure

Data Requirement(s)

Series 875 - Occupational and Residential Exposure Test Guidelines
(875.1000, 875.1200, and 875.1600)
OECD guidelines (OECD, 1997)
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/Author

Mégan T. Boatwright, B.S.

Completion Date

June 23, 2017

Testing Facility/Study Location

Golden Pacific Laboratories, LLC (GPL)
4720 W. Jennifer Ave., Suite 105
Fresno, CA 93722

Study Identifications

GPL Study Number: 130503
AEATF II Study Number: AEA08

Sponsor

American Chemistry Council
Antimicrobial Exposure Assessment Task Force II
c/o Has Shah, Ph.D.
700 2nd Street, NE
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: Hamukh Shah 12-28-17
Sponsor Representative Date

Title: Manager, AEATF

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

I hereby certify that all data generated and collected during 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:

The 1,2-Benzisothiazol-3(2H)-one-$^{13}C_6$ internal standard were purchased from a reputable chemical manufacturer. Although, a certificate of analysis was received with each standard, the analysis was not conducted according to the GLPs.

Submitter: Hamukh Shah — Has Shah, Ph.D. — Manager, AEATF — 12-28-17 — Date

Sponsor: Hamukh Shah — Has Shah, Ph.D. — 12-28-17 — Date

Title: Sponsor Representative — Manager, AEATF

Study Director: Mégan Boatwright — Mégan T. Boatwright, B.S. — 06/23/2017 — Date

Title: Study Director

QUALITY ASSURANCE STATEMENT

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure

GPL Study Number: 130503
AEATF II Study Number: AEA08

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
Draft Protocol	05/31/2013	05/31/2013	05/31/2013
Field Phase Day 1 Group 1; Field Forts	04/07/2015	04/07/2015	04/08/2015
Extraction Hand Wash 503SET03 and Glass Stir Rods 503SET05	05/18/15	05/18/15	05/19/15
Raw and Support Data	06/22/2015 and 06/24/2015	06/24/2015	07/01/2015
Draft Report	05/10-12/2017 and 05/15/2017	05/15/17	05/15/17
Final Report	06/23/2017	06/23/2017	06/23/2017

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 06/23/17

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

SIGNATURE AND APPROVALS

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure

Submitted to Sponsor by:

Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, California 93722

Reviewed by: Margaret A Hamelin 06/23/17

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

Prepared by: Megan Boatwright 06/23/2017

Mégan T. Boatwright, B.S. — Date
Study Director
Golden Pacific Laboratories, LLC

Approved by: Robert J Testman 06/23/17

Robert J. Testman, M.B.A. — Date
Testing Facility Management
Golden Pacific Laboratories, LLC

GENERAL INFORMATION

Contributors

The following contributed to this study in the capacities indicated:

Study Personnel:

Name	Title
Mégan T. Boatwright	Study Director/Principal Investigator/Laboratory Manager
Thomas F. Moate, M.S.	General Manager/Field Research Associate (English)
Natan R. Chavez	Laboratory Technician/Field Research Associate (English and Spanish)
Cynthia M. Mora	Field Phase Consultant
Willa Harkey-Berglund	Registered Nurse
Kimon P. Acedo	Analytical Coordinator/Chemist
Delia A. Centeno	Data Coordinator
Elisabeth A. Schoenau	Chemist
John Thao	Chemist
Rigo Z. Don Diego	Laboratory Assistant

Study Dates

Study Initiation Date:	February 19, 2015
Experimental Start Date:	April 7, 2015
Experimental Termination Date:	May 20, 2015
Study Completion Date:	June 23, 2017

Retention of Samples

Study samples and analytical standards were 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; Exposure of BIT to applicators applying paint by brush and roller. This study was conducted to determine the removal efficiency of BIT in latex paint from human hands.

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.

A total of 40 subjects were enrolled in the study in response to the newspaper advertisements. After the enrollment period ended, subjects were assigned numbers in a consecutive order. The subject numbers were randomized, with the first 28 subjects in the generated randomized list placed into 4 monitoring events with 7 subjects each. The remaining subjects were held as extras for potential entry into the study in the sequence determined by the randomization process. The first five subjects in the monitoring event were assigned to participate while the last two subjects were alternates, available if one of the assigned five could not participate or complete the event. The subjects were contacted and scheduled to come to the laboratory on a specific day and time. Each of the four monitoring events was completed by five subjects.

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.

Study Design

Subjects were assigned into two groups. The first group had their hands fortified with 100 µL of paint containing approximately 154 ppm of BIT. The second group had their hands fortified with 100 µL of paint containing approximately 547 ppm of BIT The study was conducted on two days and each day monitored five subjects in the morning and five subjects in the afternoon. The total amount of BIT applied to the hands of each subject during the monitoring event was calculated by weighing the applicator before and after application.

Upon arrival at the study location, the subjects were reminded that they could withdraw from the study at any time and 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 the sink area to wash their hands with Ivory soap and water and then seated in their designated chair at the table.

Once the subjects were comfortable, a 100 µL aliquot of the assigned paint was applied across both the right and the left palms of the subject and a timer was set and started for 45 minutes. During the 45-minute drying time, subjects were offered water, talked among themselves, and watched a movie. Subjects were asked to keep their palms facing upwards and fingers mainly extended during that time.

After the 45-minute drying time was completed, the subject was taken to the designated area where the paint was washed off the hands using a wash and wipe procedure. The isopropyl alcohol/water (50:50, v/v) solution and wipes used to wash the hands were collected in a glass jar and capped. All samples were placed in frozen storage at GPL. After the sample was collected, the subject washed their hands with Ivory soap and water. 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 each day of the study to assess the stability of the active ingredient under field and storage conditions in the sampling material. Four samples containing a package of wipes and 500 mL of isopropyl alcohol/water (50:50, v/v) solution were fortified with two known concentrations of BIT (low and high). An unfortified control was reserved as a field control sample.

As samples were collected, GPL personnel logged the samples into frozen storage (<-10 °C) and the samples remained in frozen storage pending analysis.

Results

The study took place in the conference room at Golden Pacific Laboratories, LLC in Fresno, CA, on April 7, 2015 and April 9, 2015.

Study sample analysis was initiated on May 18, 2015 and completed on May 20, 2015. 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.

The active ingredient, BIT, was analyzed in study samples by shaking the samples for 15 minutes. An aliquot of the sample was diluted 1:1 with a deuterated internal standard (IS) solution and then analyzed by LC-MS/MS, using a previously validated method. The limit of quantitation (LOQ) for the hand wash samples is 1.0 ng/mL.

The concentration (ng/mL) of BIT detected in the samples was interpolated from a six-point standard calibration curve.

Laboratory fortification samples were prepared with each analytical set. Each sample set consisted of one laboratory control and two laboratory fortification samples. No residues of BIT were detected in either of the laboratory control samples. The overall laboratory fortification recovery for hand wash samples was 94.2% ± 5.47% with a RSD of 5.81% (n = 4).

The overall mean recoveries were within the acceptable range of 70% to 120% demonstrating that BIT was adequately determined from the hand wash samples.

The mean field fortification recoveries of BIT in hand wash samples was 102% ± 4.90% with a CV of 4.80% (n = 8). Sample results were not corrected for either laboratory or field fortification recoveries.

The concentrations of BIT in the paint were determined and used to calculate the total amount of active ingredient applied. The concentrations of BIT in the paint was found to be 154 ppm and 547 ppm.

Analysis of the hand wash samples demonstrated that BIT could be removed from the hands using the wash and wipe procedure. The wash and wipe procedure removed 73.3% of the amount applied at the low concentration and 60.3% for the high concentration. Overall, the wash and wipe procedure removed 66.8% of the BIT applied to the hands.

2.0 INTRODUCTION AND BACKGROUND

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; a brush and roller application study. The objective of this study was to determine the removal efficiency of BIT in latex paint from human hands. 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:	WE05 45HN 00118 JKG RDJ
Active ingredients:	1,2-Benzisothiazolin-3-one (BIT)
CAS numbers:	BIT: 2634-33-5
Storage conditions:	Room Temperature (20 ± 5 °C)
Dates received:	March 31, 2015
Expiration date:	NA

BIT is added to latex paint by the manufacturer to inhibit the growth of microbes. The concentration of BIT in the paint is estimated to be 120 ppm, however is not certified. The concentration of the base paint was determined at GPL prior to use. The average concentration of the base paint was found to be 154 ppm (µg BIT/g paint). Based on the determined concentration of base paint, a subsample of the paint was fortified with BIT in diethylene glycol to prepare paint at a higher concentration. The concentration of the supplemented paint was determined by GPL and found to be 547 ppm (µg BIT/g paint). A retention sample from each concentration of paint is archived at Golden Pacific Laboratories, LLC.

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:	94.2%
Expiration date:	December 18, 2015
Physical characteristics:	White Powder
Storage conditions:	Ambient

The reference substance was used to prepare a stock solution in diethylene glycol to dose the paint to a higher level 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 B. 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)

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

4.0 RECRUITMENT PHASE PROCEDURES

4.1 Local Newspaper Advertisements

Following approval of the protocol by Schulman Associates Investigational Review Board (SAIRB), the California Department of Pesticide Regulations (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 A as part of the Protocol. 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 SAIRB approved scripts were used at the time of call-in. The approved scripts in both English and Spanish are shown in Appendix A as part of the Protocol.

A third newspaper, The California Advocate, which is widely circulated in the African-American community, was contacted several times to place the advertisement. However, after receiving a quote, size of space, and confirmation that the advertisement would run during the recruitment period,

staff at the newspaper did not follow up, resulting in no publication in the California Advocate.

4.2 Enrollment of Subjects

Interested callers were phone-interviewed to determine whether they met the inclusion criteria. 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. 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 met with the Study Director and/or a Spanish-speaking Field Research Associate. The Study Director or Spanish-speaking 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 SAIRB approved Informed Consent Form which included the "Experimental Subject's Bill of Rights a copy of the product label, and a copy of the Material Safety Data Sheet (MSDS). These forms are attached in Appendix A as part of the Protocol.

The subject was asked to first fill out Part I: Interview questions of the Qualification Worksheet. The Study Director or Field Research Associate reviewed the answers to the five questions with the subject. If none of the answers disqualified the subject from participation, the Study Director or Field Research Associate read the Informed Consent Form and 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. Potential subjects were also encouraged to take the forms and information home with them to discuss the study with family and friends. The Study Director or 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 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 40 subjects were enrolled to participate in the study. The first 28 numbers in the generated randomized list determined the initial group of participating subjects. The remaining subjects would not be called to directly participate in the study but were held as extras in case needed to fill in for subjects that became unavailable. If needed, their order for potential entry into the study would be determined by their order in the randomization process.

The first 28 randomized subjects were split into 2 groups: the first group would have 100 µL of paint at 154 ppm applied to their hands and the second group would have 100 µL of paint at 547 ppm applied to their hands. The first set of fourteen subjects (1-14) were split into a morning session (1-7) and an afternoon session (8-14) to be conducted. The second set of fourteen subjects (15-28) were also split into a morning session (15-21) and an afternoon session (22-28).

Within each group of seven, the first five subjects (primary subjects) were assigned to have paint applied to their hands. The last two subjects in each group of seven were considered as alternates and remained on site in case any subject did not show up or was unable to complete the task. If additional subjects above the 28 initially selected were required, subject 29 was contacted followed by 30 and so on, until a total of 20 monitoring events were completed in the study.

4.4 Scheduling of Subjects

Once assigned to a specific group and session, subjects were contacted and informed of the day and time to report to GPL. For group 1, morning session, the subject assigned to monitoring event RE-01 could not be reached and therefore was replaced with the first alternate of that group. The first subject in the pool of extras was contacted to replace the alternate who became a participant. For group 2, morning session, the subject assigned to monitoring event RE-12 dropped out when contacted because of a new job and the subject assigned to monitoring event RE-14 never replied to be scheduled. These subjects were replaced with the alternates and the next two available extras were

assigned as alternates for this group session. For group 2, afternoon session, the second assigned alternate had gotten a new job and dropped out when contacted for scheduling, thus being replaced with the next available subject from the pool of extras.

The day before the scheduled assignment, subjects were contacted and reminded of their scheduled monitoring. The subject assigned to RE-09 could not be reached to confirm participation so the next available subject from the pool of extras was contacted to participate.

On the scheduled day, the subject assigned to RE-03 in group one, morning session, did not show up and an alternate was monitored instead and a subject assigned as an alternate in group 2, morning session, was dismissed due to a cut on the left thumb.

A complete accounting of subjects is given in Tables 3 through 5.

5.0 FIELD PHASE PROCEDURES

5.1 Test Site Set Up

On each day of the study, the conference room at GPL was used as the test site. The conference room at GPL consists of a table with six chairs around it and at the far end of the room, there is a nook with a small bar sink set in a small counter. Off the nook is a restroom with a toilet and sink. For the study, the conference table was set for five subjects at a time, with a small television set up at one end that played a nature movie for the subject's entertainment. At each seat, an X-large towel was folded and used to create a comfortable surface for the subjects to rest their arms on during the testing period. Along one wall, additional seating was set up for the alternates. During the study, water was available to the subjects using a straw and with help from the research team.

Next to the small counter in the nook area, a narrow table was set up for conducting the removal of the paint from the subject's hands at the appropriate time. The narrow table was covered with bench paper and on top of the bench paper were absorbent pads, which were changed between each subject. The bench paper was changed between each group session on each day of the study.

A large deep sided metal mixing bowl for collecting the wash, a package of dressing sponges, and a 1-liter glass jar pre-labeled for the subject were set up on the table.

Field fortification samples were prepared each day of the study in the laboratory section of GPL. The bench was covered with bench paper and on top of the bench paper were absorbent pads.

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

5.2 Environmental Monitoring

Air temperature and relative humidity of the conference room for the duration of study were monitored by automated instrumentation logging and recording (data loggers). The maximum, minimum, and average temperature and the maximum, minimum, and average relative humidity for each session are summarized in Table 7.

5.3 Calibration of Application Equipment

A measured aliquot of paint was applied to the subject's hands using a positive displacement micropipette. The micropipette is sent to the factory annually for calibration, however, prior to use in the study, the micropipette was verified at the lab to determine accuracy and precision of delivery. Five aliquots of test substance paint were delivered by the micropipette and the weight of each aliquot was recorded. The average and standard deviation of the five weights were calculated and approved by the Study Director before use in the study. The average and standard deviation of the five deliveries was 0.1426 g ± 0.0006 g.

5.4 Exposure Monitoring Procedures

On the first day, ten subjects (five in the morning and five in the afternoon) had a 100 µL aliquot of paint containing 154 ppm of BIT applied to their hands. On the second day, ten subjects (five in the morning and five in the afternoon) had a 100 µL of paint containing 547 ppm of BIT applied to their hands. The paint was applied to both hands and then spread out as evenly as possible using a glass stir rod with rounded annealed ends. The application of paint to the subject's hands were staggered by approximately ten minutes between subjects.

5.5 Subject Preparation

Upon arrival to the study location, the subjects were greeted and identified as an assigned participant or an alternate. Each subject was welcomed by the Study Director/PI 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. Subjects who were not comfortable speaking English were offered the option of having a Spanish speaking study investigator present to assist with translation. Once cleared by the nurse, subjects were shown to their seat at the table, where they were asked to get comfortable.

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.

SOP AEATF II-8B.3, entitled Hand Wash Samples, was followed when preparing subjects for monitoring. Once the five subjects had settled into their seats, one by one, the subjects went to the bathroom sink or the nook sink and washed their hands with Ivory soap and water, then dried their hands with paper towels. Subjects were reminded not to touch anything and to place their hands palm side up. A research associate helped each subject settle back into their seat comfortably without touching anything. The time each subject washed their hands was documented in the raw data.

5.6 Conduct of the Monitoring Event

The paint was applied to the first subject's hand using a positive displacement micropipette containing approximately 100 µL of paint containing BIT. The research associate applied the paint as evenly as possible between the two hands and the Study Director/PI followed behind spreading the paint across the palms using a glass stir rod with rounded annealed ends. The goal was to distribute the paint consistently over the palmar surface. Once the paint was distributed, the Study Director/PI started a timer unique to each subject and the time the paint was applied was recorded. Ten minutes (± 1 minute) later, paint was applied to the palms of the next subject in the same manner. The glass rods were unique to each subject and were retained as a sample in properly labeled glass test tubes for analysis. This process was continued until all five subjects had paint on their palms.

During the drying period, subjects sat with their palms facing up and hands open. Subjects talked among themselves and watched a movie. If subjects wanted to stand to stretch their legs, they could, however they were asked not to walk around. If any adjustments were needed for their comfort, the nurse and researcher helped with those needs. Water was offered to the subjects and 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.

5.6.1 Field Study Personnel

There were always three to four study personnel available during the monitoring sessions.

The Study Director/PI and the Spanish-speaking research associate were available throughout the monitoring sessions to assist the

subjects with any of their needs. The Study Director/PI and the Spanish-speaking research associate worked together to collect and place the samples into storage.

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

A registered nurse was always on site to monitor the well-being of the subject during the monitoring sessions and help with drinks for subjects if requested.

For one session, a quality assurance representative conducted a field phase audit.

Another researcher was assigned to performing field fortifications and was also responsible for weighing and applying the paint to the subject's hands.

5.6.2 Photographs/Videos

Photographs and video were taken throughout the sessions, showing the room setup, subject preparation, the application of the paint to the hands, the wash procedure, and field fortification procedures. To avoid identification, the face of each subject was never shown. Video files were edited to remove any scenes where subjects might be identifiable. Photographs and videos are archived with the study raw data.

5.6.3 Observations

During the morning session the first day, the first subject felt as if falling when sitting back into the chair after washing hands and instinctively grabbed the chair to catch oneself, therefore needing to wash the hands once more. At the morning session the second day, an alternate was dismissed due to a cut on the left thumb.

5.7 Sample Collection

After 45 minutes, the first subject was escorted over to the table in the nook area where the Study Director washed the paint off their hands. Before beginning, the Study Director briefly described the process to be used to remove the paint and continued to talk them through the process as their hands were washed and scrubbed over a metal mixing bowl used to collect the wash sample. The sample collection start time was recorded for each subject.

The Study Director wore a lab coat, safety glasses, and gloves while working with each subject.

Over the 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 dry paint. With the wet gauze wipe, the Study Director 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. The Study Director then slowly 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. The subject was 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 the Study Director directed them to rub and rinse their hands without touching the grey water in the bowl for a final clean rinse. Once the entire 500 mL of isopropyl alcohol/water (50:50, v/v) was poured over the hands, the subjects were instructed to let the solution drip off, then gently shake and flick their fingers slightly in order to collect as much as possible. Once it was determined the collection was complete, subjects washed their hands again with Ivory soap and water, dried their hands with paper towels, and met with the nurse who check the hands for redness or other signs of irritation. Meanwhile, the Study Director transferred the wipes, using a clean pair of forceps, and then poured the solution into a 1 Liter glass jar, capping the sample with a Teflon lined lid. The research associate walked the sample to frozen storage in the walk-in freezer in the lab and recorded the time. The Study Director paid the subject $100, thanked them for participating, and let them go on their way.

The washing procedure was complete in three to five minutes. In between subject's, the research associate cleaned the bowl. When the next 45-minute drying time was complete, the subject was taken to the table in the nook and the process was repeated until all subjects had their hands washed.

5.8 Field Fortification Procedures

AEATF II-8E.1, entitled Fortification of Matrix Samples, was followed when preparing field fortification samples.

Field fortification was conducted to assess the stability of the active ingredient under field and storage conditions in the sampling material. Sample matrix fortifications were performed in the lab area (away from any potential contamination), each day of the study.

The paint with a concentration of 154 ppm BIT and the paint with a concentration of 547 ppm of BIT were the fortification solutions used to fortify the field fortification samples. These are the same fortification solutions that were applied to the subject's hands.

Field fortification samples were fortified at 44x LOQ (~22 µg/sample) and 150x LOQ (~75 µg/sample).

On both study days, duplicate samples were fortified at ~22 µg/sample and duplicate samples were fortified at ~75 µg/sample. One unfortified control was reserved as a field control sample on each day.

Field fortification samples were prepared by adding 500 mL of isopropyl alcohol/water (50:50, v/v) into a pre-labeled 1-liter glass jar and adding 1 package (2 wipes) of gauze wipes. The samples were fortified with 100 µL (~0.14 g) of paint containing the appropriate concentration of BIT. The samples were weathered on the bench at room temperature for at least an hour then placed into frozen storage in the laboratory. The amount of paint in grams added to each sample was recorded, as well as, the time fortified and the time placed in frozen storage.

6.0 SAMPLE IDENTIFICATION, SHIPPING AND STORAGE

Samples were walked from either the conference room or lab bench to a walk-in freezer to be stored until analyzed. Subject samples were placed promptly into frozen storage (<-10 °C) and field fortification samples were placed in frozen storage promptly after a 1-1.5-hour weathering. Table 13 summarizes the chain of custody of the study samples including the date each sample was sampled, the date extracted, the date analyzed, 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 analytical ID AEA08-RE-01-PL:

AEA08 = Task Force Study Number
RE = Removal Efficiency Sample
01 = Subject 1 in chronological order of participation
P = Paint
L = Low Concentration

An additional designation was H for High Concentration.

In the analytical laboratory, samples were referenced by the Analytical ID (AEA08-RE-01-PL), not by subject number or by monitoring event. Table 6 lists the Analytical ID, the monitoring event, and subject number each Analytical ID correlates to.

7.0 ANALYTICAL PHASE PROCEDURES

Study sample analysis was initiated on May 18, 2015 and was completed on May 20, 2015. A total of 50 samples, 20 hand wash samples, 10 field fortification samples, and 20 glass stir rods, were extracted and analyzed. Samples were grouped based on the

type of matrix (hand wash sample or stir rod) and the concentration of paint. Study samples were analyzed in 4 sets. Hand wash sets consisted of a solvent blank, an untreated control sample, two laboratory fortification samples, 10 hand wash samples, one control field fortification sample, and four fortified field fortification samples. The field fortification samples in each set were generated the same day as the field samples within the set. Stir rod sets consisted of a solvent blank and 10 stir rod samples.

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., 503SET03-1). The original sample identity and laboratory code were documented on the master laboratory worksheet in each raw data set.

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 a higher level (discussed in section 7.2) and to prepare a stock solution in methanol for the preparation of calibration standards.

A stock solution of BIT (544 µg/mL after correcting for purity) was prepared by weighing 0.0578 g of BIT reference substance into a 100 mL volumetric flask and diluting to volume with methanol. The stock solution was stored refrigerated and assigned an expiration date equivalent to the reference substance.

A diluted intermediate solution was prepared at 400 ng/mL by adding 0.05 mL of the stock solution to 68 mL of methanol. The intermediate solution was 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 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 will be 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 0.25 mL of the stock solution into 509.75 mL of methanol/water/formic acid (70:30:0.016, v/v/v) or by adding 0.05 mL of the stock solution into 101.95 mL 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 (Fortification Solutions)

A stock solution of reference substance, BIT technical was prepared in diethylene glycol at a concentration of 19.9 mg/mL after correcting for purity. The concentration of BIT in diethylene glycol in terms of mg/g was 17.8 mg/g. The stock solution of BIT in diethylene glycol was used to increase the concentration of BIT in the paint. The stock solution was stored at ambient.

The base paint, Sherwin-Williams SuperPaint® Interior Acrylic Latex Paint, was assayed to determine the concentration of BIT already present. Three aliquots of base paint, 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. The concentration of BIT in the paint was determined to be 154 ppm (µg BIT/g paint).

Based on the determined concentration of base paint, a subsample of the paint weighing 165.65 grams was fortified with 4.15 g of the 17.8 mg/g stock solution of BIT in diethylene glycol and shaken for 30 minutes to prepare a sample of paint at a higher concentration. The concentration of the supplemented paint was determined by GPL in the same manner as the base paint. The average concentration of the supplemented paint was found to be 547 ppm (µg BIT/g paint).

A diluted solution of the base paint was prepared by adding 0.3383 g of base paint (154 ppm) to a 100-mL volumetric flask and brought to volume (100 mL) with water. The concentration of the diluted paint solution was 521 ng/mL and was used to fortify laboratory QC samples at the LOQ.

7.3 Analytical Method GPL-MTH-081 (Revision 1)

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 1), "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 C) was used to analyze the samples.

BIT was extracted from study samples by shaking the samples on a platform shaker. Sample extracts were appropriately diluted using methanol/water/formic acid (70:30:0.016, v/v/v). An aliquot of the diluted extract was vialed 1:1 with BIT internal standard (IS) solution (50 ng/mL) and analyzed by LC-MS/MS. No cleanup of the samples was needed.

7.3.2 Limits of Quantitation (LOQ)

The limit of quantitation (LOQ) for hand wash samples is 0.5 µg/sample (1.0 ng/mL). A sample size for the hand wash samples is 500 mL.

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 fortified QC hand wash

sample were prepared by adding 500 mL of isopropyl alcohol/water (50:50, v/v) into a pre-labeled 1-liter glass jar and adding 1 package (2 wipes) of gauze wipes. Laboratory fortifications were prepared by directly fortifying untreated control samples. Laboratory QC samples at the LOQ level were fortified with 1 mL of a 521 ng/mL diluted paint solution. Laboratory QC samples at the high level were fortified with ~0.14 g (~100 µL) of the 547 ppm supplemented paint.

7.4 Sample Analysis

Laboratory fortified QC samples, field fortified samples, and study samples were extracted and analyzed within the same analytical set. A solvent blank of methanol/water/formic acid (70:30:0.016, v/v/v) was analyzed with each analytical set. On both days of the field phase, two control samples, two low level fortified field fortification samples, and two high level field fortification samples were collected. With each set of hand wash samples, one control sample, two low level fortified field fortification samples, and two high level field fortification samples collected the same day as the hand wash samples in the set were analyzed.

7.4.1 Hand Wash Samples

Laboratory fortified QC samples were prepared as described in Section 7.3.3.

BIT was extracted from hand wash samples by shaking the samples on a platform shaker for 15 minutes at approximately 200 rpm. Sample extracts were appropriately diluted using methanol/water/formic acid (70:30:0.016, v/v/v). The high QC sample and high field fortification samples were diluted 51 fold, while all study samples were diluted 10 fold. The control samples and samples fortified at the LOQ were not diluted. Aliquots of the prepared extracts were vialed 1:1 with BIT internal standard (IS) solution (50 ng/mL) and analyzed by LC-MS/MS. No cleanup of the samples was needed.

7.4.2 Glass Stir Rod Samples

No laboratory fortified QC samples were analyzed with the glass stir rod sets.

BIT was extracted from the glass stir rod samples by adding 40 mL of methanol/water (10:90, v/v) and shaking the samples on a platform shaker for 30 minutes at approximately 200 rpm. An aliquot of the diluted extract was vialed 1:1 with BIT internal standard (IS) solution (50 ng/mL) and 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

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

Data System: Analyst Chromatography Data System version 1.5, AB Sciex.

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: 10 µL
Retention Time: BIT and IS ~3.5 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)

(BIT-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 1.5) was used to acquire, integrate, and calculate the concentration of BIT as ng/mL using the linear regression function with 1/x weighting.

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 1.5 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 0.9989.

Calibration standards were injected to bracket a maximum of six sample injections as well as at the beginning and ending of the injection sequence. Six 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.

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/IS concentration)
b = intercept of the regression line

peak area ratio = a(analyte/IS concentration ratio) + 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:

BIT in µg/sample = **[Equation 3]**

$$\frac{\text{(BIT ng/mL from curve) x (final vol. in mL) x 1 µg}}{\text{(1 sample)(1000 ng)}}$$

BIT in µg/sample = total µg of BIT present per sample analyzed. One sample is 500 mL of hand wash

BIT 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. Field samples were not corrected for average laboratory fortification recoveries or field fortification recoveries.

7.7.1 Hand Wash Samples

An example calculation for a BIT laboratory fortification in set 503SET3, sample 503SET03-2, Laboratory Spike at 0.521 µg/sample is as follows:

standard curve equation: $y = 1.65 (x) + 0.00189$
BIT peak area = 1319.4
IS peak area = 37292.0
IS concentration = 25.0 ng/mL

Using Equation 2, BIT ng/mL from the curve =

$$\frac{[(1319.4/37292.0) - 0.00189]}{1.65} \times (25.0 \text{ ng/mL}) = 0.508 \text{ ng/mL}$$

Using Equation 3, BIT in µg/sample =

$$\frac{(0.508\ \text{ng/mL})\ (1000\ \text{mL}) \times 1\ \mu\text{g}}{(1\ \text{sample})\ (1000\ \text{ng})} = 0.508\ \mu\text{g/sample}$$

Using the recovery equation,

$$\%\ \text{Recovery} = \frac{0.508\ \mu\text{g/sample}}{0.521\ \mu\text{g/sample}} \times 100 = 97.5\%$$

BIT concentration in study samples of hand washes and glass stir rods, and field fortified samples was calculated using the same procedures. However, final volume varied according due to dilution factors applied to individual samples.

7.8 Statistics

Statistical evaluations performed on the residue data include mean, standard deviation, and relative standard deviation calculations of fortified samples analyzed and on removal efficiency results. Relative Standard Deviation (RSD) is calculated as a percentage by dividing the standard deviation by the mean and multiplying by 100. Linear regression analysis with 1/x weighting was used to determine the slope and intercept values of the calibration curves. All residue values are reported in the analytical data summary spreadsheets (Appendix D) to three significant figures. Recovery values are also reported in the analytical data summary spreadsheets to three significant figures. Minor variations in values between example calculations, the report tables, and the data sheet originate from adjusting data to three significant figures.

8.0 DATA CALCULATIONS

8.1 Active Ingredient in Test Substance

The concentration of BIT in the test substance (Sherwin-Williams SuperPaint® Interior Acrylic Latex Paint) was determined for the base paint and the supplemented paint by analyzing triplicate aliquots of paint and calculating the total amount of active ingredient present in ppm (µg/g).

The amount of BIT was expected to be approximately 120 ppm although it is not documented by the manufacturer. The average amount of BIT found in lot #WE05 45HN 00118 JKG RDJ was found to be 154 ppm. After supplementing an aliquot of base paint with more BIT, the amount of BIT was determined to be 547 ppm.

8.2 Amount of Active Ingredient Applied to Subject's Hands

For each application to a subject's hands, the weight of the micropipettor and the aliquot of paint was recorded, the paint was applied to the palms of the

subject's hands, and the weight of the emptied micropipettor was recorded. The weights were recorded on a monitoring event form and the mass of the paint applied was calculated for each subject.

The amount of active ingredient (BIT) applied to each subject's hands was calculated using the amount of BIT (154 ppm or 547 ppm) found per the analysis in the paint and the weight of the paint applied to the hands. This yielded Equation A as follows:

Equation A

Total Amount Active Ingredient Applied (BIT in µg) =

(concentration of BIT in Paint (µg/g) * mass of paint applied to hands (g)

The amount of paint left on the glass rod used to spread the paint over the hands was determined by analyzing the stir rod for each subject. The determined amount of BIT in µg left on the glass stir rod was subtracted from the calculated amount of BIT that was applied to the hands.

8.3 Determination of Removal Efficiency

The removal efficiency of BIT from the skin using the isopropyl alcohol/water wash and wipe procedure was determined by calculating the amount of BIT removed from the hands of each subject. By analyzing the hand wash samples, the amount of BIT removed from the hands was determined. The removal efficiency was calculated using the following equation.

Equation B

$$\text{Removal Efficiency (\%)} = \frac{\text{Amount of BIT Removed from Hands (µg)}}{\text{Amount of BIT Applied to Hands (µg)}} \times 100$$

The removal efficiency of the isopropyl alcohol/water wash and wipe procedure was calculated by averaging the removal efficiency determined for each individual subject.

8.4 Residue Adjustments of Hand Wash Fortification Samples

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. Per AEATF II SOP 9B.3, 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. Since the average recovery of the field fortified samples were above 100% in this study no corrections were made.

9.0 RESULTS

9.1 Overview

A total of 40 subjects were randomized into the study. Twenty subjects completed monitoring events in the study, 5 per each session. No adverse effects were reported by any subject.

9.2 Chronological Listing of Events

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

9.3 Recruitment

A total of 40 subjects were enrolled and randomized into the study.

9.3.1 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 forty (40) subjects came to GPL for the interview and all 40 signed the Informed Consent Forms and filled out the Qualification worksheet, enrolling them into the study. 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 40 randomized subjects is presented in Tables 3 through 5. The table below summarizes the demographic information of the 40 randomized subjects.

	Randomized Subjects	Monitored Subjects	Alternate/Extra Subjects
Male	22	12	10
Female	18	8	10
English	37	18	19
Spanish	3	2	1
Age Range	18-67	25-67	18-67
Mean Age	44.5	50	39

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 was predominately English (37

subjects) although there were 3 subjects who requested a Spanish Informed Consent Form. Subjects' age ranged from 18 years old to 67 years old.

c. **Randomization**

Each subject was given a number (1-40) based on the date of enrollment. The subjects were randomized and divided into two groups and the "extra pool". The randomized list is kept in GPL's archives and is summarized in Table 2.

The first 28 randomized subjects were split into 2 groups. The groups were assigned to a study day and then the group was split into a morning and an afternoon session. The first set of seven numbers was grouped into the first day's morning session, the second set of seven numbers was grouped into the first day's afternoon session, the third set of seven numbers was grouped into the second day's morning session, and the fourth set of seven numbers was grouped into the second day's afternoon session. The remaining twelve numbers were assigned as extras to be contacted in their randomized order as necessary. These assignments are presented in Table 2.

d. **Scheduling of Subjects**

Following randomization and assignment, the subjects were contacted, session by session, to schedule them into their assigned group and monitoring event. Tables 3 through 5 present the assignment of each subject after randomization to groups, as well as each subject's demographics. These tables also include notes and explanations of reasons for replacement and reassignment of subjects.

9.3.2 Conduct of Monitoring Events

Table 6 connects the subjects' number, the monitoring event conducted by the subject, and the code assigned to the subjects' collected samples (analytical ID).

9.4 Environmental Conditions

The environmental conditions during the monitoring sessions were recorded using a mobile data logger and are summarized in Table 7.

9.5 Laboratory and Field Fortification

9.5.1 Laboratory Control and Fortification Hand Wash Samples

The results of the analysis of non-fortified laboratory control and laboratory fortified control samples are shown in Table 8. No residues of BIT were detected in any of the laboratory control samples. The

recoveries of individual laboratory fortified control samples, fortified at 0.521 µg per sample and ~79.6 µg per sample, were excellent. A summary of the mean recoveries of the laboratory fortified hand wash solution is shown below:

Fortification Level	n	Measured Residue (µg/sample)	Percent Recovery (%)	Average % Recovery
LOQ	2	0.508, 0.505	97.5, 96.9	97.2
160 x LOQ	2	75.0, 69.9	96.3, 86.0	91.2
Overall Mean ± Standard Deviation (RSD) =				**94.2 ± 5.47 (5.81)**

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

9.5.2 Field Control and Fortification Hand Wash Samples

The results of the analysis of non-fortified field control and field fortified control samples are shown in Table 9. No residues of BIT were detected in any of the field control samples. The recoveries of individual field fortified control samples, fortified at ~22.3 µg per sample and 77.2 µg per sample, were excellent. A summary of the mean recoveries of the field fortified hand wash samples is shown below:

Fortification Level	n	Measured Residue (µg/sample)	Percent Recovery (%)	Mean ± Standard Deviation (RSD)
44 x LOQ	4	23.2, 23.2, 23.0, 22.8	103, 105, 104, 103	104 ± 0.957 (0.920)
150 x LOQ	4	83.1, 76.0, 76.5, 73.4	110, 96.0, 99.7, 95.1	100 ± 6.83 (6.83)
Overall Mean ± Standard Deviation (RSD) =				**102 ± 4.90 (4.80)**

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

9.6 Analysis of Study Samples

9.6.1 Analysis of Hand Wash Samples

Tables 10, 11, and 12 calculate and present the removal efficiency of the isopropyl alcohol/water wash and wipe procedure used to remove BIT from the hands of 20 subjects. Each table summarizes the Sample ID, the concentration of BIT in the paint, the mass of the paint applied, the amount of BIT applied, the amount of BIT left on the glass stir rod, the amount of BIT on the hands, the amount of BIT removed from the hands, and the removal efficiency.

Table 10 summarizes the results of the analysis of hand wash samples and the corresponding glass stir rod samples for residues of BIT for subjects whose hands were applied with base paint. The table presents the mean removal efficiency of base paint. When removing base paint, the removal efficiency of the isopropyl alcohol/water wash and wipe procedure is 73.3%.

Table 11 summarizes the results of the analysis of hand wash samples and the corresponding glass stir rod samples for residues of BIT for subjects whose hands were applied with supplemented paint. The table presents the mean removal efficiency of supplemented paint. When removing supplemented paint, the removal efficiency of the isopropyl alcohol/water wash and wipe procedure is 60.3%.

Table 12 summarizes all the results of the analysis of hand wash samples and the corresponding glass stir rod samples for residues of BIT. The table presents the mean removal efficiency of the isopropyl alcohol/water wash and wipe procedure, which is 66.8%.

9.6.2 Sample Tracking

A summary of the date sampled, date extracted, date analyzed, and days in storage for each field-generated sample is listed in Table 13.

9.6.3 Example Chromatography

Example chromatography of the LC-MS/MS calibration standards, internal standard, standard calibration curve, control samples, fortified control samples, and field samples representing the hand wash samples and glass stir rod matrix are presented in Appendix E.

9.7 Data Not Used Sets

There were no Data Not Used Sets in this study.

10.0 CONCLUSIONS

The removal efficiency of the isopropyl alcohol/water wash and wipe procedure is 66.8% when removing BIT contained in latex paint.

11.0 RECORDS TO BE MAINTAINED

The original, signed copy of the final study report will be archived at GPL until the Sponsor requests that the report be transferred to another facility. All study-specific raw data will be archived and turned over to the AEATF II when requested, or at the completion of the study. 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. A hard copy of the report and electronic copies of the report and raw data will also be maintained at GPL.

12.0 SUMMARY OF AMENDMENTS AND DEVIATIONS

12.1 Protocol Amendments

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

1. Amendment No. 1 adjusted the volume of paint to be applied to the subject's hands from 0.5 mL to 0.1 mL, changed the inclusion criteria to include surrounding areas not just Fresno County for residency, and clarified the procedure for assigning the initial subject number.
2. Amendment No. 2 corrected the analytical method number and title.

12.2 Protocol Deviations

The following protocol deviations occurred during the conduct of this study:

1. The study advertisement did not run in the California Advocate.
2. Diethylene glycol instead of dipropylene glycol was used to prepare the BIT solution that was used to dose the paint.
3. Text stated duplicate control matrix samples will be prepared for field fortified samples, however the field sample identification codes table only provided for one control matrix sample. During the study only one control matrix sample was prepared each day.

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

12.3 SOP Deviations

The following SOP deviations occurred during the conduct of this study:

1. The temperature of the refrigerator storing the neat reference substance and calibration standards for the study, dropped below the allowed temperature range of 4 ± 5°C during the week of sample analysis.
2. The minimum and maximum temperatures were not recorded on the weeks of September 20, 2013, February 6, 2015, and February 20, 2015. The internal standard and reference substance were being stored at these times.
3. The temperature of the freezer that stored the internal standard raised above the allowed temperature of ≤ -10 °C reaching -7 °C and then -4 °C a week later.
4. An audit report was not addressed by the Study Director in a timely manner.

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

13.0 **TABLES**

Table 1 Chronological Listing of Events

4 Nov 2013	Submission of protocol 130503 to CDPR
8 Nov 2013	GPL submission of Protocol 130503, Site Submission Form, CVs and NIH Certificates for the PI and Sub-Investigators, Inform Consent Form, and EPA Inspections to SAIRB
13 Nov 2013	SAIRB requested justification of why protocol is draft vs. final and submission of material supporting on-site health professional
14 Nov 2013	GPL responded to SAIRB request with justification and license and NIH Certificate for nurse
14 Nov 2013	SAIRB conditionally approved the protocol and supporting materials pending submission of final protocol along with documentation from CDPR and HSRB indicating their review and approval.
4 Dec 2013	GPL response to SAIRB question to the recording of pregnancy test
10 Dec 2013	SAIRB notification that two of the conditions for approval had been met
19 Dec 2013	CDPR reviewed protocol submitted on 4 Nov 2013 and provided summary of requested revisions to GPL
24 Jan 2014	GPL re-submission of revised protocol 130503 dated 23 Jan 2014 and Response letter to their request on 19 Dec 2013
5 Feb 2014	Submission of 130503 protocol and supporting material to EPA
26 Feb 2014	CDPR notified GPL of acceptance of response on 24 Jan 2014
14 Mar 2014	EPA Science Review of Protocol
18 Mar 2014	EPA 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	SAIRB issued re-approval letter for the continuation of 130503
9 Dec 2014	SAIRB issued a memorandum and revised conditional approval letter for 130503
5 Feb 2015	SAIRB responded to review leaving status conditional approval pending responses to their findings
6 Feb 2015	GPL submitted response letter to address findings and revised protocol (05 Feb 2015) to SAIRB
9 Feb 2015	SAIRB notified GPL responses satisfied the conditions of approval
9 Feb 2015	SAIRB approved study issuing Initial Approval Letter and Initial Informed Consent (English)
10 Feb 2015	SAIRB issued approved Spanish translated documents
12 Feb 2015	SAIRB issued approved Spanish translated Informed Consent Form
13 Feb 2015	SAIRB issued corrected approved Spanish translated Informed Consent Form
19 Feb 2015	"Study Initiation" (p. 6) [Date on which SD signed protocol]
23 Feb 2015	GPL sent CDPR a CD containing the Final protocol, the letter to the EPA addressing EPA requested changes and verifications, and the IRB approval letter
3 Mar 2015	CDPR grants final approval of the protocol 130503
8 Mar 2015	Start of newspaper advertisement initializing the two-week enrollment process
10 Mar 2015	First subject enrolled into the study

22 Mar 2015	End of the two-week enrollment
27 Mar 2015	GPL submission of Amendment 1 changing the aliquot size of paint to be added to the hands from 0.5 mL to 0.1 ml to SAIRB and CDPR.
27 May 2015	SAIRB approval of Amendment 1.
6 Apr 2015	GPL submission of SAIRB approval letter to CDPR
6 Apr 2015	CDPR acknowledgement of receipt of Amendment 1 and SAIRB approval
6 Apr 2015	First day of subject monitoring; "Experimental Start"
9 Apr 2015	Second and last day of subject monitoring
9 Apr 2015	Representative of CDPR observed subject monitoring during the morning
20 May 2015	"Experimental Termination" (p. 6) "Last day of data collection"
14 July 2015	GPL submission of Amendment 2 correcting method reference to SAIRB
15 July 2015	SAIRB approval of Amendment 2
20 July 2015	CDPR sent GPL a Review Report
12 Oct 2015	GPL submission of Deviation 1 documenting one newspaper did not publish advertisement to SAIRB
12 Oct 2015	GPL submission of annual progress report "Single Site Study Periodic and Continuing Review Report" to SAIRB along with CDPR Review Report
12 Oct 2015	SAIRB acknowledgement of receipt of Protocol Deviation 1 and submission form
12 Oct 2015	SAIRB acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report and CDPR Review Report
15 Oct 2015	SAIRB request for edits and clarification of answers in Single Site Study Periodic and Continuing Review Report
15 Oct 2015	GPL responded to SAIRB request providing required documents and explanations
22 Oct 2015	SAIRB issued Re-Approval Letter
12 Sept 2016	GPL submission of annual progress report "Single Site Study Periodic and Continuing Review Report" to SAIRB along with Completed Informed Consent Forms in both languages
12 Sept 2016	SAIRB acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report and Informed Consent Forms
27 Sept 2015	SAIRB issued Re-Approval Letter
14 Mar 2107	GPL submission of Deviation 2 documenting use of diethylene glycol instead of dipropylene glycol to SAIRB
14 Mar 2017	SAIRB acknowledgement of receipt of Deviation 2
5 Apr 2017	GPL submission to CDPR of Protocol Amendment 2 and Protocol Deviations 1 and 2 even though not required by protocol
23 May 2017	GPL submission of Deviation 3 to SAIRB
23 May 2017	GPL submission of closeout report to SAIRB
25 May 2017	SAIRB acceptance of closeout report (letter dated 05/25/2017)
23 June 2017	"Study Completion" [Final report Signed by Study Director]

Table 2 Randomized Order of the 40 Enrolled Subjects

Randomized Order	Subject Number	Assignment
1	24	Tuesday April 7, 2015 9:00-11:00 AM
2	18	
3	6	
4	2	
5	35	
6	31	
7	14	
8	12	Tuesday April 7, 2015 3:00-5:00 PM
9	34	
10	11	
11	4	
12	39	
13	26	
14	10	
15	21	Thursday April 9, 2015 9:00-11:00 AM
16	28	
17	15	
18	23	
19	3	
20	36	
21	25	
22	1	Thursday April 9, 2015 3:00-5:00 PM
23	38	
24	32	
25	8	
26	22	
27	9	
28	20	
29	33	Pool
30	16	
31	29	
32	7	
33	13	
34	19	
35	30	
36	5	
37	40	
38	27	
39	37	
40	17	

Table 3 Subject Demographics – Tuesday April 7, 2015

Group	Monitoring Event Assigned After Randomization	Monitoring Event Conducted	Subject Number	Age	Sex	Language	Notes
1	Alternate	RE-01	31	38	M	English	Replaced 24
1	RE-02	RE-02	18	44	M	English	
1	Extra	RE-03	33	57	M	Spanish	Initially assigned as alternate slot when 31 had to fill in for 24; assigned an ME when 6 did not show up
1	RE-04	RE-04	2	58	F	English	
1	RE-05	RE-05	35	48	F	English	
1	Alternate	-	14	40	M	English	
1	RE-01	Could not reach	24	54	F	English	Replaced with 31
	RE-03	Did not show	6	26	M	English	Replaced with 33
1	RE-06	RE-06	12	49	M	English	
1	RE-07	RE-07	34	57	F	Spanish	
1	RE-08	RE-08	11	55	M	English	
1	Extra	RE-09	19	31	M	English	Replaced 4
1	RE-10	RE-10	39	47	F	English	
	Alternate	-	26	18	F	English	
	Alternate	-	10	65	F	English	
1	RE-09	Could not confirm participation	4	67	M	English	Replaced with 19

Table 4 Subject Demographics – Thursday April 9, 2015

Group	Monitoring Event Assigned After Randomization	Monitoring Event Conducted	Subject Number	Age	Sex	Language	Notes
2	RE-11	RE-11	21	44	M	English	
2	Alternate	RE-12	36	40	F	English	Replaced 28
2	Extra	RE-13	29	25	M	English	Initially assigned as alternate slot when 36 had to fill in for 28; assigned an ME when 15 showed up late
2	Alternate	RE-14	25	52	M	English	Replaced 23
2	RE-15	RE-15	3	63	F	English	
2	RE-12	Got new job, dropped out	28	27	F	English	Replaced with 36
2	RE-13	-	15	33	M	English	Replaced with 29; stayed as an alternate
2	RE-14	No Reply	23	27	M	English	Replaced with 25
2	Extra	-	7	54	M	English	Initially assigned as alternate slot when 25 had to fill in for 23; dismissed due to cut on left thumb
2	RE-16	RE-16	1	58	M	English	
2	RE-17	RE-17	38	51	M	English	
2	RE-18	RE-18	32	67	M	English	
2	RE-19	RE-19	8	56	F	English	
2	RE-20	RE-20	22	57	F	English	
2	Extra		13	30	F	English	
2	Alternate		20	55	F	English	
2	Alternate	Got new job, dropped out	9	20	M	English	Replaced with 13

Table 5 Subject Demographics - Extras

Group	Monitoring Event Assigned After Randomization	Monitoring Event Conducted	Subject Number	Age	Sex	Language	Notes
-	Extra	-	16	44	F	English	Moved, no forwarding number
-	Extra	-	30	28	F	Spanish	
-	Extra	-	5	22	F	English	
-	Extra	-	40	23	M	English	
-	Extra	-	27	53	M	English	
-	Extra	-	37	58	F	English	
-	Extra	-	17	39	M	English	

Table 6 Field Codes and Analytical Codes

Day	Analytical ID	Monitoring Event	Subject Number
Day 1	AEA08-RE-01-PL	RE-01	31
	AEA08-RE-02-PL	RE-02	18
	AEA08-RE-03-PL	RE-03	33
	AEA08-RE-04-PL	RE-04	2
	AEA08-RE-05-PL	RE-05	35
	AEA08-RE-06-PL	RE-06	12
	AEA08-RE-07-PL	RE-07	34
	AEA08-RE-08-PL	RE-08	11
	AEA08-RE-09-PL	RE-09	19
	AEA08-RE-10-PL	RE-10	39
Day 2	AEA08-RE-11-PH	RE-11	21
	AEA08-RE-12-PH	RE-12	36
	AEA08-RE-13-PH	RE-13	29
	AEA08-RE-14-PH	RE-14	25
	AEA08-RE-15-PH	RE-15	3
	AEA08-RE-16-PH	RE-16	1
	AEA08-RE-17-PH	RE-17	38
	AEA08-RE-18-PH	RE-18	32
	AEA08-RE-19-PH	RE-19	8
	AEA08-RE-20-PH	RE-20	22

Table 7 Environmental Conditions during Monitoring Events

Monitoring Date	04/07/2015 AM	04/07/2015 PM	04/09/2015 AM	04/09/2015 PM
Time Duration[1]	8:57 – 10:52	2:47 – 4:42	8:52 – 10:47	2:42 – 4:42
Monitoring Duration[2]	9:14 – 10:51	3:09 – 4:46	9:05 – 10:44	2:58 – 4:37
Max Humidity (%)	43.1	48.3	44.6	45.8
Min Humidity (%)	36.2	42.3	39.5	41.9
Average Humidity (%)	40.0	45.7	42.4	43.9
Max Temp (ºF)	71.5	71.8	71.5	71.8
Min Temp (ºF)	70.9	70.5	69.6	70.0
Average Temp (ºF)	71.3	71.2	70.7	70.9

[1] Time Duration is the time range Temperature and Humidity was recorded and the range used to determine the maximum, minimum, and average.
[2] Monitoring Duration is the time from the first subject washing their hands to the time the last collected hand wash was placed in the freezer.

Table 8 Summary of BIT Laboratory Fortification Results on Removal Efficiency Hand Washes

Laboratory ID	Fortification Amount (µg/sample)	Measured Residue (µg/sample)	Percent Recovery (%)
Control			
503SET03-1	NA	ND	NA
503SET04-1	NA	ND	NA
~LOQ			
503SET03-2	0.521	0.508	97.5
503SET04-2	0.521	0.505	96.9
	Average =	**0.507**	**97.2**
~160 x LOQ			
503SET03-3	77.9	75.0	96.3
503SET04-3	81.3	69.9	86.0
	Average =	**72.5**	**91.2**
Overall		**Mean =**	**94.2**
		Standard Deviation =	**5.47**
		RSD =	**5.81**
		n =	**4**

NA = Not Applicable
ND = Non-Detect
LOQ = 1 ng/mL (0.500 µg/sample for 500-mL samples)

Table 9 Summary of BIT Field Fortification Results on Removal Efficiency Hand Washes

Laboratory ID	Sample ID	Fortification Amount (µg/sample)	Measured Residue (µg/sample)	Percent Recovery (%)
Control				
503SET03-14	AEA08-FF-P-01-C	NA	ND	NA
503SET04-14	AEA08-FF-P-02-C	NA	ND	NA
44 x LOQ				
503SET03-15	AEA08-FF-P-01-L1	22.6	23.2	103
503SET03-16	AEA08-FF-P-01-L2	22.1	23.2	105
503SET04-15	AEA08-FF-P-02-L1	22.2	23.0	104
503SET04-16	AEA08-FF-P-02-L2	22.1	22.8	103
			Mean =	**104**
			Standard Deviation =	**0.957**
			RSD =	**0.920**
150 x LOQ				
503SET03-17	AEA08-FF-P-01-H1	75.8	83.1	110
503SET03-18	AEA08-FF-P-01-H2	79.2	76.0	96.0
503SET04-17	AEA08-FF-P-02-H1	76.7	76.5	99.7
503SET04-18	AEA08-FF-P-02-H2	77.2	73.4	95.1
			Mean =	**100**
			Standard Deviation =	**6.83**
			RSD =	**6.83**
			Mean =	**102**
Overall			**Standard Deviation =**	**4.90**
			RSD =	**4.80**

NA = Not Applicable
ND = Non-Detect
LOQ = 1 ng/mL (0.500 µg/sample for 500-mL samples)

Table 10 Summary of Sample Residue Results on Removal Efficiency Hand Washes – Low Level

Sample ID	Concentration of BIT in Paint (µg/g)	Mass of Paint Applied (g)	Amount of BIT Applied (µg)[1]	BIT Left on Glass Rod (µg)	Amount of BIT on Hands (µg)[2]	Amount of BIT Removed from Hands (µg)	Removal Efficiency (%)[3]
AEA08-RE-01-PL	154	0.1415	21.791	0.0325	21.759	14.4	66.2
AEA08-RE-02-PL	154	0.1416	21.806	0.120	21.686	12.6	58.1
AEA08-RE-03-PL	154	0.1403	21.606	0.317	21.289	19.2	90.2
AEA08-RE-04-PL	154	0.1452	22.361	0.0358	22.325	19.3	86.5
AEA08-RE-05-PL	154	0.1444	22.238	0.0405	22.198	17.8	80.2
AEA08-RE-06-PL	154	0.1408	21.683	0.0713	21.612	14.2	65.7
AEA08-RE-07-PL	154	0.1479	22.777	0.115	22.662	15.0	66.2
AEA08-RE-08-PL	154	0.1494	23.008	0.0442	22.964	16.4	71.4
AEA08-RE-09-PL	154	0.1413	21.760	0.119	21.641	13.3	61.5
AEA08-RE-10-PL	154	0.1473	22.684	0.108	22.576	19.6	86.8
						Mean =	**73.3**
						Standard Deviation =	**11.7**
						RSD =	**16.0**

[1] Amount of BIT Applied (µg) = Concentration of BIT in Paint (µg/g) x Mass of Paint Applied (g)
[2] Amount of BIT on Hands (µg) = Amount of BIT Applied (µg) – BIT Left on Glass Rod (µg)
[3] Removal Efficiency (%) = (Amount of BIT Removed from Hands (µg) ÷ Amount of BIT on Hands (µg)) x 100

Table 11 Summary of Sample Residue Results on Removal Efficiency Hand Washes – High Level

Sample ID	Concentration of BIT in Paint (µg/g)	Mass of Paint Applied (g)	Amount of BIT Applied (µg)[1]	BIT Left on Glass Rod (µg)	Amount of BIT on Hands (µg)[2]	Amount of BIT Removed from Hands (µg)	Removal Efficiency (%)[3]
AEA08-RE-11-PH	547	0.1405	76.854	0.370	76.484	41.4	54.1
AEA08-RE-12-PH	547	0.1419	77.619	0.282	77.337	48.6	62.8
AEA08-RE-13-PH	547	0.1396	76.361	0.0546	76.306	33.3	43.6
AEA08-RE-14-PH	547	0.1382	75.595	0.236	75.359	48.3	64.1
AEA08-RE-15-PH	547	0.1366	74.720	0.305	74.415	44.5	59.8
AEA08-RE-16-PH	547	0.1394	76.252	0.0766	76.175	44.4	58.3
AEA08-RE-17-PH	547	0.1417	77.510	0.174	77.336	42.7	55.2
AEA08-RE-18-PH	547	0.1390	76.033	0.189	75.844	55.1	72.6
AEA08-RE-19-PH	547	0.1411	77.182	0.996	76.186	41.0	53.8
AEA08-RE-20-PH	547	0.1393	76.197	0.254	75.943	59.7	78.6
						Mean =	**60.3**
						Standard Deviation =	**9.98**
						RSD =	**16.6**

[1] Amount of BIT Applied (µg) = Concentration of BIT in Paint (µg/g) x Mass of Paint Applied (g)
[2] Amount of BIT on Hands (µg) = Amount of BIT Applied (µg) – BIT Left on Glass Rod (µg)
[3] Removal Efficiency (%) = (Amount of BIT Removed from Hands (µg) ÷ Amount of BIT on Hands (µg)) x 100

Table 12 Summary of Sample Residue Results on Removal Efficiency Hand Washes

Sample ID	Concentration of BIT in Paint (µg/g)	Mass of Paint Applied (g)	Amount of BIT Applied (µg)[1]	BIT Left on Glass Rod (µg)	Amount of BIT on Hands (µg)[2]	Amount of BIT Removed from Hands (µg)	Removal Efficiency (%)[3]
AEA08-RE-01-PL	154	0.1415	21.791	0.0325	21.759	14.4	66.2
AEA08-RE-02-PL	154	0.1416	21.806	0.120	21.686	12.6	58.1
AEA08-RE-03-PL	154	0.1403	21.606	0.317	21.289	19.2	90.2
AEA08-RE-04-PL	154	0.1452	22.361	0.0358	22.325	19.3	86.5
AEA08-RE-05-PL	154	0.1444	22.238	0.0405	22.198	17.8	80.2
AEA08-RE-06-PL	154	0.1408	21.683	0.0713	21.612	14.2	65.7
AEA08-RE-07-PL	154	0.1479	22.777	0.115	22.662	15.0	66.2
AEA08-RE-08-PL	154	0.1494	23.008	0.0442	22.964	16.4	71.4
AEA08-RE-09-PL	154	0.1413	21.760	0.119	21.641	13.3	61.5
AEA08-RE-10-PL	154	0.1473	22.684	0.108	22.576	19.6	86.8
AEA08-RE-11-PH	547	0.1405	76.854	0.370	76.484	41.4	54.1
AEA08-RE-12-PH	547	0.1419	77.619	0.282	77.337	48.6	62.8
AEA08-RE-13-PH	547	0.1396	76.361	0.0546	76.306	33.3	43.6
AEA08-RE-14-PH	547	0.1382	75.595	0.236	75.359	48.3	64.1
AEA08-RE-15-PH	547	0.1366	74.720	0.305	74.415	44.5	59.8
AEA08-RE-16-PH	547	0.1394	76.252	0.0766	76.175	44.4	58.3
AEA08-RE-17-PH	547	0.1417	77.510	0.174	77.336	42.7	55.2
AEA08-RE-18-PH	547	0.1390	76.033	0.189	75.844	55.1	72.6
AEA08-RE-19-PH	547	0.1411	77.182	0.996	76.186	41.0	53.8
AEA08-RE-20-PH	547	0.1393	76.197	0.254	75.943	59.7	78.6
						Mean =	**66.8**
						Standard Deviation =	**12.5**
						RSD =	**18.7**

[1] Amount of BIT Applied (µg) = Concentration of BIT in Paint (µg/g) x Mass of Paint Applied (g)

[2] Amount of BIT on Hands (µg) = Amount of BIT Applied (µg) – BIT Left on Glass Rod (µg)

[3] Removal Efficiency (%) = (Amount of BIT Removed from Hands (µg) ÷ Amount of BIT on Hands (µg)) x 100

Table 13 Sample Chain of Custody Summary

Laboratory ID	Sample Number	Matrix	Date Sampled	Date Extracted	Date Analyzed	Days in Storage[1]
503SET03-4	AEA08-RE-01-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-5	AEA08-RE-02-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-6	AEA08-RE-03-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-7	AEA08-RE-04-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-8	AEA08-RE-05-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-9	AEA08-RE-06-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-10	AEA08-RE-07-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-11	AEA08-RE-08-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-12	AEA08-RE-09-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-13	AEA08-RE-10-PL	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET04-4	AEA08-RE-11-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-5	AEA08-RE-12-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-6	AEA08-RE-13-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-7	AEA08-RE-14-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-8	AEA08-RE-15-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-9	AEA08-RE-16-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-10	AEA08-RE-17-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-11	AEA08-RE-18-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-12	AEA08-RE-19-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-13	AEA08-RE-20-PH	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET05-1	AEA08-RE-01-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-2	AEA08-RE-02-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15	41

[1] "Days in Storage" refers to the elapsed time between the date sampled and the date extracted.

Table 13 Sample Chain of Custody Summary (continued)

Laboratory ID	Sample Number	Matrix	Date Sampled	Date Extracted	Date Analyzed	Days in Storage[1]
503SET05-3	AEA08-RE-03-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15	41
503SET05-4	AEA08-RE-04-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-5	AEA08-RE-05-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-6	AEA08-RE-06-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-7	AEA08-RE-07-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-8	AEA08-RE-08-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-9	AEA08-RE-09-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET05-10	AEA08-RE-10-PL	Glass Stir Rod	04/07/15	05/18/15	05/18/15 05/20/15	41
503SET06-1	AEA08-RE-11-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-2	AEA08-RE-12-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-3	AEA08-RE-13-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-4	AEA08-RE-14-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-5	AEA08-RE-15-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39

[1] "Days in Storage" refers to the elapsed time between the date sampled and the date extracted.

Table 13 Sample Chain of Custody Summary (continued)

Laboratory ID	Sample Number	Matrix	Date Sampled	Date Extracted	Date Analyzed	Days in Storage[1]
503SET06-6	AEA08-RE-16-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-7	AEA08-RE-17-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-8	AEA08-RE-18-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET06-9	AEA08-RE-19-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15	39
503SET06-10	AEA08-RE-20-PH	Glass Stir Rod	04/09/15	05/18/15	05/19/15 05/20/15	39
503SET03-14	AEA08-FF-P-01-C	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-15	AEA08-FF-P-01-L1	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-16	AEA08-FF-P-01-L2	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-17	AEA08-FF-P-01-H1	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET03-18	AEA08-FF-P-01-H2	Hand Wash	04/07/15	05/18/15	05/18/15	41
503SET04-14	AEA08-FF-P-02-C	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-15	AEA08-FF-P-02-L1	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-16	AEA08-FF-P-02-L2	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-17	AEA08-FF-P-02-H1	Hand Wash	04/09/15	05/18/15	05/18/15	39
503SET04-18	AEA08-FF-P-02-H2	Hand Wash	04/09/15	05/18/15	05/18/15	39

[1] "Days in Storage" refers to the elapsed time between the date sampled and the date extracted.

APPENDIX A.

PROTOCOL INCLUDING AMENDMENTS AND DEVIATIONS

PROTOCOL

05 February 2015

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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

March 2015

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 105

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1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date: March 2015

Proposed Experimental Termination Date: June 2015

Proposed Final Report Issue Date: October 2015

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular SOP may be listed.

SOP Number	Topic	Section Reference
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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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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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

The test substance in this study is latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5. The latex paint will be

tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 20 subjects at one of two concentrations (10 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to interpret data from painter exposure monitoring studies. In this study, at least 20 subjects (10 for each concentration) will be monitored in order to capture the expected variation in skin differences, and BIT concentration using paint as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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.

This protocol does not contain instructions offering subjects the option to receive their personal results. When guidance on subject result reporting is received from HSRB those instructions will be amended to the protocol.

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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than the dermal exposure assumed by

EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used for cleaning the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. 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.

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. Society may benefit from continued ability to use antimicrobials that

improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint from human skin is not available. Removal efficiency studies which have been conducted with other active ingredients do not provide for interpretation of BIT removal, or the removal of any active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substance for this study is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT). BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name: Sherwin-Williams Latex Paint A86W00151

Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

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 in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

C. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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

BIT in paint will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

E. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass stirring rod with rounded annealed ends. The glass stirring rod will be placed into a test tube and retained for analysis.

The paint will be left on the hands to dry for 45 minutes. The hands will then be washed. The researchers will scrub the subjects hands with gauze

sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. The solution and gauze sponge will be collected as a single sample for both hands of each subject, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance

with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold both hands over a stainless steel bowl while researchers scrub the hand with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1	500 µL of latex paint containing ca. 120 ppm BIT
Group 2	500 µL of latex paint containing ca. 600 ppm BIT

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into two groups, each corresponding to one of the two test substance/concentration combinations. The first set of fourteen subjects will be placed into Group 1 and the second set of fourteen subjects will be placed into Group 2.

Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into two groups, subjects from the first group will be scheduled into the study. No more than one group will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., ten subjects for each of two groups). As described above, an additional eight subjects (four per group) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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. 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- 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

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 or sensitivities to latex paint, soaps. isopropyl alcohol, BIT 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)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Video Recording and Photography of Study

The study procedures involving subjects, including preparation, application, drying, and removal procedures will be recorded using video and may include photography. Efforts will be made during recording to avoid recording personally identifiable characteristics of subjects such as faces, tattoos, etc. The recording will be made under the supervision of the principal investigator and access to the unedited recordings will be limited by the principal investigator to research staff directly involved in recording or editing. The recorded material will be edited by research staff to ensure any personally identifiable characteristics are removed or obscured. Edited recordings will be reviewed by the principal investigator and quality assurance, and approved as not containing personally identifiable information. Following approval of the edited recordings, the raw recordings will be destroyed, and the destruction documented by the principal investigator. Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training, presentations, or publication in scientific journals.

B. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

C. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

D. 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 (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
Additional designations are as follows:
H = High Concentration Level

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at $\leq$ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for

very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The glass stir rods used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the glass stir rods used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.
3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

Has Shah 02/19/2015
Has Shah, Ph.D. Date
Sponsor's Representative

Megan Boatwright 02/19/15
Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Robert J. Testman 02/19/15
Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

Margaret A Hamelin 02/19/15
Margaret A Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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.

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.

APPENDIX A: 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

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

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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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SUPERPAINT®

Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

Desde el 01/12/2012, cumple con:			
OTC	Sí	LEED® 09 CI	Sí
SCAQMD	Sí	LEED® 09 NC	Sí
CARB	Sí	LEED® 09 CS	Sí
CARB SCM 2007	Sí	LEED® 09 H	Sí
MPI N.°	53	NGBS	Sí

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

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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.

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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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

SCHULMAN APPROVED
IRB# 201307366
DATE: 02/06/15

INFORMED CONSENT FORM

Study Title: (Protocol AEA08) Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

Principal Investigator:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Research Associates:
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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. 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 rubbing alcohol (also called isopropyl alcohol or IPA) and water. This information will be provided to the U.S. Environmental Protection Agency (EPA). The EPA will use this information to evaluate how much chemical people are exposed to when painting.

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 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.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 pesticide known as BIT which helps keep bacteria from growing. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you, will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your hands facing up. We will place a small amount of paint on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe sample, you will wash your hands again with soap and water. 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 few 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 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 risks are minimal. You might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, at Golden Pacific Laboratories (559-275-9091 or 559-917-1736) 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. This may indirectly benefit you and others when you do painting. 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 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 Megan Boatwright 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. 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.

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. We may take photographs or video of the study, but we will edit these so that you cannot be identified. The edited photographs or video may be used for training other researchers, presenting the study to the people who are paying for it, or publication in scientific journals.

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
Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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# 201307366
DATE: 02/06/15

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. 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.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Megan Boatwright (559) 275-9091

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

SCHULMAN APPROVED
IRB# 201307366
DATE: 02/06/15

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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA08) Determinación de la eficacia para la eliminación de 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico y agua

Investigadora principal:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Asociados de investigación en el campo:
Natan R. Chavez (inglés y español)
Asociado de investigación en el campo (Field Research Associate)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate (inglés)
Asociado de investigación en el campo (Field Research Associate)
Gerente general (General Manager)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Localización del campo:
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono durante las 24 horas: 559-917-1736 (Megan Boatwright)

Le pedimos que piense acerca de participar en un estudio de investigación. Su participación es voluntaria. En este formulario de consentimiento informado se explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar al respecto y hablar con amigos y familiares antes de decidir si desea participar o no en el estudio. Si tiene cualquier pregunta, o si no comprende cualquier cosa de este documento, pida a alguno de nosotros que se lo expliquemos. Si prefiere hablar en español, solicítelo. Podemos explicarle el estudio en inglés o en español.

Schulman Associates Institutional Review Board, Inc. (Schulman) ha aprobado la información contenida en este documento de consentimiento y ha dado la aprobación para que el médico del estudio lleve a cabo el estudio. Un comité de revisión institucional (IRB, *institutional review board*) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado su participación en el estudio. Usted mismo debe reflexionar sobre la información incluida en este documento de consentimiento y decidir si desea participar en el estudio.

Objetivo de este estudio

Este estudio es realizado por Golden Pacific Laboratories. No gustaría saber cuánta sustancia química es eliminada de la superficie de sus palmas cuando se aplica en cada mano una pequeña cantidad de pintura de látex para interiores que contiene la sustancia química y se deja allí durante 45 minutos. Mediremos cuánta sustancia química puede ser eliminada de sus manos enjuagando y restregando las manos con una toallita de gasa mojada con una solución de alcohol isopropílico (también llamado isopropanol o IPA) y agua. Esta información se comunicará a la Agencia de Protección Ambiental de Estados Unidos (EPA, *U.S. Environmental Protection Agency*). La EPA usará la información para evaluar a cuánta sustancia química están expuestas las personas cuando pintan.

En este estudio, la pintura será la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura que se vende en muchas tiendas. El producto se usa para pintar paredes, techos, puertas y rebordes dentro de viviendas y negocios. Contiene una pequeña cantidad de una sustancia química llamada BIT, que ayuda a impedir el crecimiento de las bacterias en la lata de pintura.

Este estudio es pagado por un grupo de empresas que fabrican productos para disminuir la cantidad de mohos y bacterias. Se llaman Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos II (AEATF, *Antimicrobial Exposure Assessment Task Force II*). Estos productos están registrados por la EPA como plaguicidas.

Megan Boatwright, Thomas Moate y Natan Chavez trabajan con Golden Pacific Laboratories. Megan Boatwright es la persona que está a cargo del estudio. Thomas Moate y Natan Chavez están además capacitados para explicarle el estudio y

responder cualquier pregunta que usted pueda tener. Natan Chavez habla español. Será el principal investigador hispanoparlante (que habla español).

Producto de prueba
El producto de prueba es la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura de uso común. Este producto se usa para pintar paredes, techos, puertas y rebordes en viviendas y negocios. El producto de prueba contiene un plaguicida conocido como BIT, que contribuye a impedir el crecimiento de las bacterias. Usted recibirá una copia de la etiqueta del producto, es decir, de la pintura. Además, si lo desea, le proporcionaremos la hoja de datos de seguridad del material o "MSDS" de la pintura y de la sustancia química BIT.

Selección de sujetos
Para participar en este estudio usted debe estar sano y ser mayor de 18 años. Debe tener la capacidad de leer y hablar en inglés o en español. Tendrá que demostrar su edad mediante una identificación con fotografía emitida por el gobierno, por ejemplo, un permiso de conducir o un pasaporte. Usted debe desear participar en este estudio. Debe estar dispuesto a firmar este consentimiento, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental, y una hoja de trabajo sobre los requisitos. Se le pedirá que proporcione cierta información personal, 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 empresas que pagan la investigación, de American Chemistry Council o de un fabricante de pinturas. No podrá participar si está embarazada o amamantando; si ha tenido reacciones alérgicas o de hipersensibilidad al jabón, el alcohol isopropílico, los productos para pintura, el BIT u otros productos basados en sustancias químicas; si tiene psoriasis, eccema, llagas o cortes abiertos en la piel; si tiene diabetes grave; si tiene el sistema inmunitario inhibido, por ejemplo, por un trasplante de órgano o por quimioterapia activa, o si ha tenido problemas cardíacos o para respirar.

En este estudio participarán veinte personas, y se seleccionarán ocho personas como suplentes por si alguna persona no puede participar el día de la prueba.

Llevaremos a cabo el estudio en Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105, en Fresno. Usted podrá participar en el estudio una sola vez. Si es suplente un día y no es seleccionado, podrá participar en el estudio otro día.

Inscripción en el estudio
Usted se reunirá en el día de hoy con la investigadora principal, Megan Boatwright, o con el gerente general del laboratorio, Thomas Moate, o, si lo prefiere, con un

investigador que hable español. Esas personas le informarán más acerca de lo que se espera durante el estudio y qué se espera de usted. También responderán las preguntas que pueda tener sobre el estudio. Usted puede decidir hoy mismo si desea participar en el estudio o puede llevarse este formulario a su casa para hablar al respecto con sus familiares y amigos antes de tomar la decisión.

Le haremos preguntas sobre su salud general. Le preguntaremos su nombre y edad, y si tiene algún problema de piel en las manos. Si decidimos que reúne los requisitos para participar, y si usted decide que desea participar en el estudio, le pediremos que firme este consentimiento informado, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental.

Si lo inscribimos en el estudio le pediremos que acuda al centro de estudio cierto día y a una hora determinada. Lo llamaremos el día anterior para recordárselo y para asegurarnos de que aún desea participar en el estudio.

Procedimientos del estudio

1. Si es seleccionado como uno de los sujetos, acudirá a este lugar en Fresno: Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105; irá en el momento en que se le haya indicado y se encontrará con el equipo del estudio.

2. Megan Boatwright y el equipo de investigación revisarán con usted y otros participantes qué sucederá y usted tendrá otra oportunidad para hacer preguntas. Le recordaremos que podrá cambiar de idea acerca de la participación en el estudio en cualquier momento, antes o después del comienzo del estudio. Todo lo que tendrá que hacer será decirnos que ha cambiado de idea. No sufrirá sanciones de ningún tipo si decide retirarse del estudio.

3. Debido a que es importante que usted NO participe en el estudio si está embarazada, el día del estudio cada voluntaria mujer pasará a un área privada y se le entregará un kit para prueba de embarazo en orina como los que se pueden comprar en las farmacias. Una investigadora mujer le explicará cómo se usa el kit y responderá las preguntas. Después de que se haga usted misma la prueba, le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no le preguntaremos por qué, y los resultados de la prueba no quedarán anotados. Se le pagará $100 por acudir al centro de la prueba, y luego usted será libre de retirarse. Si desea permanecer en el estudio, una investigadora mujer capacitada comprobará nuevamente los resultados con usted. Ninguna otra persona, aparte de usted y esa investigadora, verá los resultados, pero haremos una nota de que la prueba se realizó.

4. Antes de comenzar la prueba, se lavará las manos con jabón Ivory y agua, y se las secará con toallas de papel. Le revisaremos las manos para asegurarnos de que no tenga cortes, raspaduras ni ninguna alteración que pudiera aumentar el riesgo de problemas de la piel durante la prueba.

5. Le pediremos que se siente en una silla y se asegure de estar cómodo. Le pediremos que ponga las manos sobre una superficie acolchada, en la mesa, con las palmas hacia arriba. Le pondremos una pequeña cantidad de pintura en la palma de cada mano, y luego le pediremos que mantenga las palmas hacia arriba sobre la mesa durante 45 minutos. Después de 45 minutos le restregaremos las manos con esponjas de gasa mojadas con una mezcla de alcohol isopropílico y agua, se las enjuagaremos con la misma mezcla y guardaremos el agua del enjuague.

6. Cuando hayamos tomado la muestra de la toallita de mano, usted volverá a lavarse las manos con agua y jabón. Le revisaremos las manos antes de que se retire para observar si hay enrojecimiento u otros signos de irritación. Le pagaremos $100 en efectivo y podrá retirarse.

Riesgos
Si participa en este estudio, estará expuesto a unas pocas clases de riesgos:

1. Riesgo de una reacción a la pintura de látex o al componente plaguicida (BIT) presente en la pintura. El contacto directo con la pintura puede causar comezón o irritación pasajeras de la piel, y respirar el vapor puede producir tos e irritación de la garganta. Se usará una cantidad de pintura muy pequeña, menos de una cucharadita, para que estos riesgos sean mínimos. Además, podría presentar una reacción alérgica a la pintura, sentir mareos o dolor de cabeza. Si ha tenido anteriormente una reacción alérgica a un producto para pintura, recuerde que nos debe informar eso. Si nota enrojecimiento o comezón, siente mareos, tiene dolor de cabeza, o siente alguna otra molestia, infórmelo a un investigador.

2. Riesgo de irritación de la piel por la mezcla de alcohol isopropílico y agua, y las toallitas. El alcohol isopropílico diluido que se usa para restregar y enjuagar sus manos puede arder si usted tiene algún corte o raspadura en las manos que fuera demasiado pequeño como para ser visto antes del comienzo del estudio.

3. Si usted es mujer, podría sorprenderse el día de la investigación al enterarse de que está embarazada. Ninguna persona, aparte de usted, sabrá si la prueba indica que está embarazada, y los resultados no quedarán anotados.

Riesgos desconocidos / imprevisibles
La participación en este estudio puede plantear otros riesgos de los que no tenemos conocimiento o que no podemos predecir. Si aprendemos algo nuevo que pudiera influir en su decisión de participar, lo compartiremos inmediatamente con usted.

Lesiones relacionadas con la investigación
Si usted sufre un daño o se enferma mientras participa en este estudio, se le dará atención en una institución médica cercana. Si fuera necesario, lo llevaremos hasta allí. El AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no sea pagada por su seguro ni el seguro de un tercero que le dé a usted cobertura. La investigadora principal, en consulta con el profesional médico del centro, decidirá si usted presenta una lesión o enfermedad que se deba a su participación en el estudio. Si en las 24 horas siguientes a su participación en el estudio sufre una reacción en la piel u otro efecto adverso que usted considere relacionado con su participación en el estudio, debe buscar tratamiento médico y llamar a la investigadora principal, Megan Boatwright, a Golden Pacific Laboratories (559-275-9091 o 559-917-1736), lo antes posible. Ningún expediente médico será parte del estudio.

Al firmar este formulario, usted no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio, será porque usted lo desea. No habrá ningún beneficio directo para usted si participa, y no se verá perjudicado de ningún modo si decide no participar. La decisión depende de usted.

Beneficios
Usted no obtendrá ningún beneficio directo por participar en este estudio. Lo que aprendamos en este estudio ayudará a garantizar que los productos para pintura como la pintura de látex Sherwin-Williams se puedan usar de manera segura. Esto puede ser un beneficio indirecto para usted y otras personas cuando pinten. Las personas que pagan el estudio también se beneficiarán con ese conocimiento, ya que necesitan realizar este estudio para mantener en el mercado sus productos antimicrobianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede hacerlas en cualquier momento; antes, durante o después del estudio. Simplemente hágaselas a Megan Boatwright o a cualquier otro integrante del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a

Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Costos y pago
La participación en este estudio no tendrá ningún costo. Al final de cada entrevista de consentimiento informado, se le pagará $20 en efectivo por su tiempo y las molestias de acudir a nuestro consultorio. Si es seleccionado para el estudio y acude al centro de estudio asignado, se le pagará $100 en efectivo cuando haya finalizado su día, ya sea que se le haya hecho la prueba o no.

Confidencialidad
Para este estudio le asignaremos un número de identificación especial, y anotaremos e informaremos todos los datos con ese número. Conservaremos solamente un registro que relacione su nombre con ese número de identificación, y lo guardaremos separado del resto de los datos, en un armario bajo llave. No lo identificaremos a usted por su nombre ni de ningún otro modo en los informes del estudio. Posiblemente tomemos fotografías o grabemos videos del estudio, pero los modificaremos para que usted no pueda ser identificado. Las fotografías o videos modificados se podrán usar para capacitar a otros investigadores, presentar el estudio a las personas que lo pagan o para su publicación en revistas científicas.

Restringiremos el acceso a los expedientes de este estudio; solo accederán a ellos unas pocas personas. Sin embargo, podrán revisar todos los expedientes del estudio las personas que pagan el estudio, los organismos del gobierno que revisan los informes y SAIRB, Inc., que se ocupa de cuidar la seguridad de los participantes. Por ese motivo, no podemos garantizar completamente la confidencialidad. Usted podrá obtener una copia de sus expedientes si se la solicita a la investigadora principal.

Derecho a retirarse
Usted puede retirarse del estudio en cualquier momento y por cualquier motivo. Simplemente, dígaselo a cualquier integrante del equipo de investigación. Si decide no participar en este estudio o retirarse de él, no sufrirá ninguna sanción ni perderá ningún beneficio.

Motivos para ser retirado del estudio
Megan Boatwright, la investigadora principal a cargo de este estudio, puede retirarlo del estudio incluso si usted quisiera permanecer en él. Puede retirarlo si, por ejemplo:

- Ella considera que permanecer en el estudio podría implicar un riesgo para usted.
- Usted no cumple las instrucciones de los investigadores.
- El estudio se interrumpe por otros motivos.

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

Si usted es retirado del estudio o si el estudio completo se interrumpe, aun así se le pagará por su tiempo y molestias.

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE DECLARACIÓN DE DERECHOS DE LOS SUJETOS EN INVESTIGACIÓN EXPERIMENTAL

Los derechos que se exponen a continuación son los derechos de toda persona a quien se invite a participar en un estudio de investigación. Como sujeto de investigación experimental, tengo los siguientes derechos:

1. Ser informado acerca del objetivo del estudio;
2. Ser informado acerca de qué me sucederá y si alguno de los procedimientos, plaguicidas o dispositivos es diferente o no de los que se usarían en la práctica habitual;
3. Ser informado acerca de los riesgos, efectos secundarios o molestias frecuentes y/o importantes de las cosas que me sucederán durante el estudio;
4. Ser informado acerca de si puedo esperar algún beneficio de la participación y, si lo hubiera, cuál podría ser el beneficio;
5. Ser informado acerca de las alternativas a la participación en el estudio;
6. Se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el transcurso del estudio;
7. Ser informado acerca de qué tipo de tratamiento médico está disponible si surgen complicaciones;
8. Negarme completamente a participar o cambiar de idea acerca de la participación después de que el estudio haya comenzado. Esta decisión no influirá en mi situación respecto a mi empleador;
9. Recibir una copia de este formulario de consentimiento firmado y fechado, y
10. Estar libre de presiones cuando considere si deseo participar o no en el estudio.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Si tiene otras preguntas, debe hacérselas a la investigadora principal o a los investigadores del estudio

Contactos telefónicos:

Investigadora principal: Megan Boatwright (559) 275-9091

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de derechos de los sujetos en investigación experimental, se han respondido todas mis preguntas en un lenguaje que comprendo bien. Doy mi consentimiento voluntariamente para participar en este estudio como sujeto de investigación. No renuncio a ningún derecho legal al firmar este formulario. Recibiré mi copia de este formulario con todas las firmas.

Fecha/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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

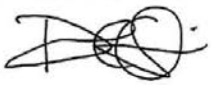
Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

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: AEA08
IRB Number: 201307366
PI: Boatwright
Material Type (if applicable): Informed Consent
Description (if applicable): N/A



DO 2/13/2015 9:00 AM (PST)

DANIEL OSORIO
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

APPENDIX D: SUBJECT SELF-REPORTING DEMOGRAPHIC FORM

Qualification Worksheet

AEATF Worker Exposure Study AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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***			
6. Name			
7. Address			
8. City, ST, Zip			
9. Telephone(s)			
10. Age in years =	11. DOB:	12. Sex ☐ M ☐ F	
13. Resident in Fresno County? ☐ Yes ☐ No			
14. Preferred Language: ☐ English ☐ Spanish	15. Reads: ☐ English ☐ Spanish		
16. Are you pregnant? ☐ NA ☐Yes ☐ No	17. Are you nursing a baby? ☐ NA ☐Yes ☐ No		
18. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No			
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐ No			
20. 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 de exposición de trabajadores AEA08 de la AEATF (Antimicrobial Exposure Assessment Task Force, Grupo de trabajo de evaluación de la exposición antimicrobiana): Determinación de la eficacia de la eliminación del 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico/agua.

Parte I: *Preguntas para 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? ¿Asma moderada o grave o enfisema? ☐Sí ☐ No	
3 ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta sin control? ☐Sí ☐ No	
4 ¿Tiene diabetes grave? ☐Sí ☐ No	
5 ¿Tiene depresión inmunológica? ¿Le han hecho algún trasplante? ¿Quimioterapia? ☐Sí ☐ No	
6 ¿Es empleado o está casado con un empleado de una compañía del AEATF, Golden Pacific Laboratories (GPL), un fabricante de pinturas o el American Chemistry Council (ACC) (el entrevistador explicará las iniciales de las distintas entidades)? ☐Sí ☐ No	

Parte II: *Para que lo llene el candidato*			
6 Nombre			
7 Dirección			
8 Ciudad, estado, código postal			
9 Teléfonos			
10 Edad en años =	11 Fecha de nacimiento:	12 Sexo ☐ M ☐ F	
13 ¿Residente del condado de Fresno? ☐ Sí ☐ No			
14 Idioma de preferencia: ☐ inglés ☐ español	15 Lee: ☐ inglés ☐ español		
16 ¿Está embarazada? ☐ NC ☐Sí ☐ No	17 ¿Está en período de lactancia? ☐ NC ☐Sí ☐ No		
18 ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio como se describió? ☐ Sí ☐ No			
19 ¿Le molesta el olor de la pintura para interiores o la sensación de la pintura para interiores en la piel más que a sus familiares o amigos? ☐Sí ☐ No			
20 ¿Le molesta frotarse la piel con alcohol o jabón más que a sus familiares o amigos? ☐Sí ☐ No			
Verificación de la edad por 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:

APPENDIX E: MATERIAL SAFETY DATA SHEET FOR SHERWIN-WILLIAMS LATEX PAINT AND BIT REFERENCE SUBSTANCE

MATERIAL SAFETY DATA SHEET

A86W151
12 00

DATE OF PREPARATION
Oct 27, 2014

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A86W151
PRODUCT NAME
SUPERPAINT® Interior Flat 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
15	14808-60-7	**Quartz**		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.1 mg/m3 as Resp. Dust	
1	14464-46-1	**Cristobalite**		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
2	1332-58-7	**Kaolin**		
		ACGIH TLV	Not Available	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	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

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.

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

PRODUCT WEIGHT	12.05 lb/gal	1443 g/l
SPECIFIC GRAVITY	1.45	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	57%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.3	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.35 lb/gal	42 g/l	Less Water and Federally Exempt Solvents
0.16 lb/gal	19 g/l	Emitted VOC

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0.41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

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			
14808-60-7	Quartz			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
1332-58-7	Kaolin			
		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.

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.

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.

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 sílice 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.

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.

SAFETY DATA SHEET

Version 4.4
Revision Date 06/30/2014
Print Date 02/02/2015

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Index-No.	:	613-088-00-6
CAS-No.	:	2634-33-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses	:	Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052

1.4 Emergency telephone number

Emergency Phone #	:	(314) 776-6555

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Acute toxicity, Oral (Category 4), H302
Skin irritation (Category 2), H315
Serious eye damage (Category 1), H318
Skin sensitisation (Category 1), H317
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word: Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.

P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P321	Specific treatment (see supplemental first aid instructions on this label).
P330	Rinse mouth.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula	:	C_7H_5NOS
Molecular Weight	:	151.19 g/mol
CAS-No.	:	2634-33-5
EC-No.	:	220-120-9
Index-No.	:	613-088-00-6

Hazardous components

Component	Classification	Concentration
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

5.3 Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information
no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: crystalline Colour: light yellow
b)	Odour	no data available
c)	Odour Threshold	no data available
d)	pH	no data available
e)	Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
f)	Initial boiling point and boiling range	no data available
g)	Flash point	no data available
h)	Evapouration rate	no data available
i)	Flammability (solid, gas)	no data available
j)	Upper/lower flammability or explosive limits	no data available
k)	Vapour pressure	no data available
l)	Vapour density	no data available

m)	Relative density	no data available
n)	Water solubility	no data available
o)	Partition coefficient: n-octanol/water	no data available
p)	Auto-ignition temperature	no data available
q)	Decomposition temperature	no data available
r)	Viscosity	no data available
s)	Explosive properties	no data available
t)	Oxidizing properties	no data available

9.2 Other safety information
no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
no data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
no data available

10.4 Conditions to avoid
no data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - no data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - 1,020 mg/kg

Inhalation: no data available

Dermal: no data available

no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitisation
Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
no data available

no data available

Specific target organ toxicity - single exposure
no data available

Specific target organ toxicity - repeated exposure
no data available

Aspiration hazard
no data available

Additional Information
RTECS: DE4620000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

12.2 Persistence and degradability
no data available

12.3 Bioaccumulative potential
no data available

12.4 Mobility in soil
no data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Dam.	Serious eye damage
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

HMIS Rating

Health hazard:	2
Chronic Health Hazard:	
Flammability:	0
Physical Hazard	0

NFPA Rating
Health hazard: 2

Fire Hazard:	0
Reactivity Hazard:	0

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Preparation Information

Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956

Version: 4.4 Revision Date: 06/30/2014 Print Date: 02/02/2015

FICHA DE DATOS DE SEGURIDAD

Versión 4.4
Fecha de revisión 06/29/2014
Fecha de impresión 02/02/2015

1. IDENTIFICACIÓN DEL PRODUCTO Y DE LA COMPAÑÍA

1.1 Identificadores del producto

Nombre del producto : 1,2-Benzisothiazol-3(2*H*)-one

Referencia : 561487
Marca : Aldrich
No. Indice : 613-088-00-6

No. CAS : 2634-33-5

1.2 Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados

Usos identificados : Reactivos para laboratorio, Fabricación de sustancias

1.3 Datos del proveedor de la ficha de datos de seguridad

Compañía : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

Teléfono : +1 800-325-5832
Fax : +1 800-325-5052

1.4 Teléfono de emergencia

Teléfono de Urgencia : (314) 776-6555

2. IDENTIFICACIÓN DE LOS PELIGROS

2.1 Clasificación de la sustancia o de la mezcla

Clasificación SGA de acuerdo con 29 CFR 1910 (OSHA HCS).
Toxicidad aguda, Oral (Categoría 4), H302
Irritación cutáneas (Categoría 2), H315
Lesiones oculares graves (Categoría 1), H318
Sensibilización cutánea (Categoría 1), H317
Toxicidad acuática aguda (Categoría 1), H400
Toxicidad acuática crónica (Categoría 1), H410

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

2.2 Elementos de las etiquetas del SGA, incluidos los consejos de prudencia

Pictograma

Palabra de advertencia: Peligro

Indicación(es) de peligro

H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Declaración(es) de prudencia

P261	Evitar respirar el polvo/ el humo/ el gas/ la niebla/ los vapores/ el aerosol.

P264	Lavarse la piel concienzudamente tras la manipulación.
P270	No comer, beber ni fumar durante su utilización.
P272	Las prendas de trabajo contaminadas no podrán sacarse del lugar de trabajo.
P273	Evitar su liberación al medio ambiente.
P280	Llevar guantes de protección/ gafas de protección/ máscara de protección.
P301 + P312	EN CASO DE INGESTIÓN: Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico si se encuentra mal.
P302 + P352	EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes.
P305 + P351 + P338	EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado.
P310	Llamar inmediatamente a un CENTRO DE INFORMACION TOXICOLOGICA o a un médico.
P321	Se necesita un tratamiento específico (véase las instrucciones suplementarias de primeros auxilios en esta etiqueta).
P330	Enjuagarse la boca.
P333 + P313	En caso de irritación o erupción cutánea: Consultar a un médico.
P362	Quitarse las prendas contaminadas y lavarlas antes de volver a usarlas.
P391	Recoger el vertido.
P501	Eliminar el contenido/ el recipiente en una planta de eliminación de residuos aprobada.

2.3 Peligros no clasificados de otra manera - ninguno(a)

3. COMPOSICIÓN/INFORMACIÓN SOBRE LOS COMPONENTES

3.1 Sustancias

Formula	:	C_7H_5NOS
Peso molecular	:	151.19 g/mol
No. CAS	:	2634-33-5
No. CE	:	220-120-9
No. Indice	:	613-088-00-6

Componentes peligrosos

Componente	Clasificación	Concentración
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

4. PRIMEROS AUXILIOS

4.1 Descripción de los primeros auxilios

Recomendaciones generales
Consultar a un médico. Mostrar esta ficha de seguridad al doctor que esté de servicio.Retire a la persona de la zona peligrosa.

Si es inhalado
Si aspiró, mueva la persona al aire fresco. Si ha parado de respirar, hacer la respiración artificial. Consultar a un médico.

En caso de contacto con la piel
Eliminar lavando con jabón y mucha agua. Consultar a un médico.

En caso de contacto con los ojos
Lávese a fondo con agua abundante durante 15 minutos por lo menos y consulte al médico.

Si es tragado
Nunca debe administrarse nada por la boca a una persona inconsciente. Enjuague la boca con agua. Consultar a un médico.

4.2 Principales síntomas y efectos, agudos y retardados
Los síntomas y efectos más importantes conocidos se describen en la etiqueta (ver sección 2.2) y / o en la sección 11

4.3 Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente
sin datos disponibles

5. MEDIDAS DE LUCHA CONTRA INCENDIOS

5.1 Medios de extinción

Medios de extinción apropiados
Usar agua pulverizada, espuma resistente al alcohol, polvo seco o dióxido de carbono.

5.2 Peligros específicos derivados de la sustancia o la mezcla
Óxidos de carbono, óxidos de nitrógeno (NOx), Óxidos de azufre

5.3 Recomendaciones para el personal de lucha contra incendios
Si es necesario, usar equipo de respiración autónomo para la lucha contra el fuego.

5.4 Otros datos
sin datos disponibles

6. MEDIDAS EN CASO DE VERTIDO ACCIDENTAL

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia
Utilícese equipo de protección individual. Evite la formación de polvo. Evitar respirar los vapores, la neblina o el gas. Asegúrese una ventilación apropiada. Evacuar el personal a zonas seguras. Evitar respirar el polvo.
Equipo de protección individual, ver sección 8.

6.2 Precauciones relativas al medio ambiente
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

6.3 Métodos y material de contención y de limpieza
Recoger y preparar la eliminación sin originar polvo. Limpiar y traspalar. Guardar en contenedores apropiados y cerrados para su eliminación.

6.4 Referencia a otras secciones
Para eliminación de desechos ver sección 13.

7. MANIPULACIÓN Y ALMACENAMIENTO

7.1 Precauciones para una manipulación segura
Evítese el contacto con los ojos y la piel. Evítese la formación de polvo y aerosoles.
Debe disponer de extracción adecuada en aquellos lugares en los que se forma polvo.
Ver precauciones en la sección 2.2

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades
Conservar el envase herméticamente cerrado en un lugar seco y bien ventilado.

7.3 Usos específicos finales
Aparte de los usos mencionados en la sección 1.2 no se estipulan otros usos específicos

8. CONTROLES DE EXPOSICIÓN/ PROTECCIÓN INDIVIDUAL

8.1 Parámetros de control

Componentes con valores límite ambientales de exposición profesional.
No contiene sustancias con valores límites de exposición profesional.

8.2 Controles de la exposición

Controles técnicos apropiados
Manipular con las precauciones de higiene industrial adecuadas, y respetar las prácticas de seguridad. Lávense las manos antes de los descansos y después de terminar la jornada laboral.

Protección personal

Protección de los ojos/ la cara
Caretas de protección y gafas de seguridad. Use equipo de protección para los ojos probado y aprobado según las normas gubernamentales correspondientes, tales como NIOSH (EE.UU.) o EN 166 (UE).

Protección de la piel
Manipular con guantes. Los guantes deben ser inspeccionados antes de su uso. Utilice la técnica correcta de quitarse los guantes (sin tocar la superficie exterior del guante) para evitar el contacto de la piel con este producto. Deseche los guantes contaminados después de su uso, de conformidad con las leyes aplicables y buenas prácticas de laboratorio. Lavar y secar las manos.

Sumerción
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

Salpicaduras
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

origen de datos: KCL GmbH, D-36124 Eichenzell, Teléfono +49 (0)6659 87300, e-mail sales@kcl.de, Método de prueba: EN374
Si es utilizado en solución, o mezclado con otras sustancias, y bajo condiciones diferentes de la EN 374, pornerse en contacto con el proveedor de los guantes aprobados CE. Esta recomendación es meramente aconsejable y deberá ser evaluada por un responsable de seguridad e higiene industrial familiarizado con la situación específica de uso previsto por nuestros clientes. No debe interpretarse como una aprobación de oferta para cualquier escenario de uso específico.

Protección Corporal
Traje de protección completo contra productos químicos, El tipo de equipamiento de protección debe ser elegido según la concentración y la cantidad de sustancia peligrosa al lugar específico de trabajo.

Protección respiratoria
Donde el asesoramiento de riesgo muestre que los respiradores purificadores de aire son apropiados, usar un respuirador que cubra toda la cara tipo N100 (EEUU) o tipo P3 (EN 143) y cartichos de respuesto para controles de ingieneria. Si el respirador es la unica protección, usar un respirador suministrado que cubra toda la cara Usar respiradores y componenetes testados y aprobados bajo los estandards gubernamentales apropiados como NIOSH (EEUU) o CEN (UE)

Control de exposición ambiental
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

9. PROPIEDADES FÍSICAS Y QUÍMICAS

9.1 Información sobre propiedades físicas y químicas básicas

a)	Aspecto	Forma: cristalino Color: amarillo claro
b)	Olor	sin datos disponibles
c)	Umbral olfativo	sin datos disponibles
d)	pH	sin datos disponibles
e)	Punto de fusión/ punto de congelación	Punto/intervalo de fusión: 154 - 158 °C (309 - 316 °F) - lit.

f)	Punto inicial de ebullición e intervalo de ebullición	sin datos disponibles
g)	Punto de inflamación	sin datos disponibles
h)	Tasa de evaporación	sin datos disponibles
i)	Inflamabilidad (sólido, gas)	sin datos disponibles
j)	Inflamabilidad superior/inferior o límites explosivos	sin datos disponibles
k)	Presión de vapor	sin datos disponibles
l)	Densidad de vapor	sin datos disponibles
m)	Densidad relativa	sin datos disponibles
n)	Solubilidad en agua	sin datos disponibles
o)	Coeficiente de reparto n-octanol/agua	sin datos disponibles
p)	Temperatura de auto-inflamación	sin datos disponibles
q)	Temperatura de descomposición	sin datos disponibles
r)	Viscosidad	sin datos disponibles
s)	Propiedades explosivas	sin datos disponibles
t)	Propiedades comburentes	sin datos disponibles

9.2 Otra información de seguridad
sin datos disponibles

10. ESTABILIDAD Y REACTIVIDAD

10.1 Reactividad
sin datos disponibles

10.2 Estabilidad química
Estable bajo las condiciones de almacenamiento recomendadas.

10.3 Posibilidad de reacciones peligrosas
sin datos disponibles

10.4 Condiciones que deben evitarse
sin datos disponibles

10.5 Materiales incompatibles
Agentes oxidantes fuertes

10.6 Productos de descomposición peligrosos
Otros productos de descomposición peligrosos - sin datos disponibles
En caso de incendio: véase sección 5

11. INFORMACIÓN TOXICOLÓGICA

11.1 Información sobre los efectos toxicológicos

Toxicidad aguda
DL50 Oral - rata - 1,020 mg/kg

Inhalación: sin datos disponibles

Cutáneo: sin datos disponibles

sin datos disponibles

Corrosión o irritación cutáneas
sin datos disponibles

Lesiones o irritación ocular graves
sin datos disponibles

Sensibilización respiratoria o cutánea
Mutagenicidad en células germinales
sin datos disponibles

Carcinogenicidad

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la ACGIH.

NTP: En este producto no se identifica ningún componente, que presente niveles mayores que o iguales a 0.1%, como agente carcinógeno conocido o anticipado por el (NTP) Programa Nacional de Toxicología.

OSHA: No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la (OSHA) Administración de Salud y Seguridad Ocupacional.

Toxicidad para la reproducción
sin datos disponibles

sin datos disponibles

Toxicidad específica en determinados órganos - exposición única
sin datos disponibles

Toxicidad específica en determinados órganos - exposiciones repetidas
sin datos disponibles

Peligro de aspiración
sin datos disponibles

Información Adicional
RTECS: DE4620000

Según nuestras informaciones, creemos que no se han investigado adecuadamente las propiedades químicas, físicas y toxicológicas.

12. INFORMACIÓN ECOLÓGICA

12.1 Toxicidad

Toxicidad para los peces	CL50 - Oncorhynchus mykiss (Trucha irisada) - 0.8 mg/l - 96.0 h
Toxicidad para las dafnias y otros invertebrados acuáticos	CE50 - Daphnia magna (Pulga de mar grande) - 4.4 mg/l - 48 h

12.2 Persistencia y degradabilidad
sin datos disponibles

12.3 Potencial de bioacumulación
sin datos disponibles

12.4 Movilidad en el suelo
sin datos disponibles

12.5 Resultados de la valoración PBT y mPmB
La valoración de PBT / mPmB no está disponible ya que la evaluación de la seguridad química no es necesaria / no se ha realizado

12.6 Otros efectos adversos
No se puede excluir un peligro para el medio ambiente en el caso de una manipulación o eliminación no profesional.
Muy tóxico para los organismos acuáticos.

13. CONSIDERACIONES RELATIVAS A LA ELIMINACIÓN

13.1 Métodos para el tratamiento de residuos

Producto
Ofertar el sobrante y las soluciones no-aprovechables a una compañia de vertidos acreditada. Para la eliminación de este producto, dirigirse a un servicio profesional autorizado.

Envases contaminados
Eliminar como producto no usado.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

DOT (US)
Mercancía no peligrosa

IMDG
Número ONU: 3077 Clase: 9 Grupo de embalaje: III EMS-No: F-A, S-F
Designación oficial de transporte de las Naciones Unidas: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Contaminante marino: MARINE POLUTANT

IATA
Número ONU: 3077 Clase: 9 Grupo de embalaje: III
Designación oficial de transporte de las Naciones Unidas: Sustancia sólida peligrosa para el medio ambiente, n.e.p. (1,2-Benzisothiazolin-3-one)

Otros datos
Marca-EHS requerida (códigos ADR 2.2.9.1.10 e IMDG 2.10.3) para embalajes únicos y embalajes combinados que contengan embalajes interiores con Mercancías Peligrosas > 5L para líquidos o > 5Kg para sólidos.

15. INFORMACIÓN REGLAMENTARIA

SARA 302 Componentes
SARA 302: Este material no contiene productos químicos sujetos a los requisitos reportados por SARA Titulo III, sección 302.

SARA 313 Componentes
SARA 313: Este material no contiene ningún componente químico con los conocidos números CAS que exceden el umbral de los niveles reportados (De Minimis) establecidos por SARA título III, sección 313.

SARA 311/312 Peligros
Peligro Agudo para la Salud

Massachusetts Right To Know Componentes
No hay componentes sujetos al Acta de Derecho a Saber de Massachussets.

Pennsylvania Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

Prop. 65 de California Componentes
Este producto no contiene ninguna sustancia química conocida para el de Estado de California que pueden causar cáncer, defectos de nacimiento, o cualquier otro daño reproductivo.

16. OTRA INFORMACIÓN

Texto íntegro de las Declaraciones-H referidas en las secciones 2 y 3.

Acute Tox.	Toxicidad aguda
Aquatic Acute	Toxicidad acuática aguda
Aquatic Chronic	Toxicidad acuática crónica
Eye Dam.	Lesiones oculares graves
H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H400	Muy tóxico para los organismos acuáticos.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Clasificación HMIS/NFPA

Peligro para la salud:	2
Peligro Crónico para la Salud:	
Inflamabilidad:	0
Peligro Físico	0

Clasificación NFPA

Peligro para la salud:	2
Peligro de Incendio:	0
Peligro de Reactividad:	0

Otros datos

La información indicada arriba se considera correcta pero no pretende ser exhaustiva y deberá utilizarse únicamente como orientación. La información contenida en este documento esta basada en el presente estado de nuestro conocimiento y es aplicable a las precauciones de seguridad apropiadas para el producto. No representa ninguna garantía de las propiedades del producto. La Corporación Sigma-Aldrich y sus Compañías Afiliadas, no responderán por ningún daño resultante de la manipulación o contacto con el producto indicado arriba. Dirijase a www.sigma-aldrich.com y/o a los términos y condiciones de venta en el reverso de la factura o de la nota de entrega.

Información suministrada por

Corporación Sigma-Aldrich
Product Safety – Americas Region
1-800-521-8956

Versión: 4.4	Fecha de revisión: 06/29/2014	Fecha de impresión: 02/02/2015

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 02/02/2015

MA1500939-0

APPROVED FOR USE
ONLY IN ITS ENTIRETY
SCHULMAN ASSOCIATES IRB
02/06/15

SE BUSCAN VOLUNTARIOS

Se buscan voluntarios para participar en un estudio de investigación que evalúa la exposición de la superficie de las manos a un producto antimicrobiano en pinturas. Se compensará a los voluntarios hasta $ 120 en total por su participación.

Para obtener más información, comuníquese con Megan Boatwright (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091.

Estudio patrocinado por Antimicrobial Exposure Assessment Task Force (AEATF); administrado por American Chemistry Council (ACC) y dirigido por Golden Pacific Laboratories (GPL) of Fresno, CA.
559-275-9091

APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the removal efficiency 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 removed from the palms of your hand when paint containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright or the Spanish speaking researcher.)

Guión de invitación a participar para sujetos

[Identifíquese e identifique la compañía para la que trabaja; pregunte si la llamada se relaciona con el estudio de eficiencia de la eliminación. Si la respuesta es "sí", pregunte cómo se enteraron del estudio y anote la respuesta. Pregunte al posible sujeto si le gustaría recibir más información sobre el estudio. Si la respuesta es "sí", continúe.]

Queremos averiguar cuánto producto químico se elimina de las palmas de las manos cuando se aplica una pintura con el producto químico BIT en las manos y se deja secar durante 45 minutos. Mediremos la cantidad de producto químico que queda en la solución para el lavado de manos que se empleará para que se limpie las manos.

El producto en estudio será la PINTURA LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

El estudio en sí tomará aproximadamente de una hora y media a dos horas de su tiempo. Le pediremos que acuda al laboratorio, se siente en una silla y apoye las manos sobre una mesa, con las palmas hacia arriba. Le pondremos pintura en las palmas de las manos. Permanecerá sentado allí durante 45 minutos mientras se seca el producto. Luego le limpiaremos las manos con alcohol para frotar y agua y las restregaremos con una esponja de gasa. Recogeremos el agua del lavado y la esponja de gasa. Luego le pagaremos y podrá retirarse.

¿Le gustaría obtener más información sobre este proyecto?

(Si la respuesta es "no", agradezca a la persona por su tiempo).

(Si la respuesta es "sí", comuníquele las siguientes instrucciones).

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del estudio. Deberá mostrar una identificación con fotografía para demostrar su edad y calificar para participar. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni en período de lactancia.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con la investigadora principal, Megan Boatwright. Si prefiere, podemos entrevistarlo en español. Esta entrevista se programará cuando sea mejor para usted, 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 fotografía emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

(Documentar la hora y fecha de la cita.)

(Nota: Si el posible sujeto hace preguntas que no se tratan en este guión telefónico, respóndale que Megan Boatwright o el investigador de habla hispana podrán responder las preguntas adicionales).

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.

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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Target BIT Concentration
AEA08-RE-01-PL	1	120 ppm
AEA08-RE-02-PL	2	120 ppm
AEA08-RE-03-PL	3	120 ppm
AEA08-RE-04-PL	4	120 ppm
AEA08-RE-05-PL	5	120 ppm
AEA08-RE-06-PL	6	120 ppm
AEA08-RE-07-PL	7	120 ppm
AEA08-RE-08-PL	8	120 ppm
AEA08-RE-09-PL	9	120 ppm
AEA08-RE-10-PL	10	120 ppm
AEA08-RE-11-PH	11	600 ppm
AEA08-RE-12-PH	12	600 ppm
AEA08-RE-13-PH	13	600 ppm
AEA08-RE-14-PH	14	600 ppm
AEA08-RE-15-PH	15	600 ppm
AEA08-RE-16-PH	16	600 ppm
AEA08-RE-17-PH	17	600 ppm
AEA08-RE-18-PH	18	600 ppm
AEA08-RE-18-PH	19	600 ppm
AEA08-RE-20-PH	20	600 ppm

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg

PROTOCOL AMENDMENT NO.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 6.A Risks to the Subjects**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

…The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than…

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

…The largest amount a subject will be exposed to in this study is 0.1 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.001 mg/Kg for a 70 Kg subject. This is much less than…

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

2. **Section 8.A Study Design Overview:**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

…
Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing

approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.
…

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

…
Each subject will be placed into one of two groups. Subjects assigned to group one will have their hands fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 7.9 µg per hand or 39 µg per hand.
…

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

3. **Section 8.B.6 Removal Efficiency Procedure**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. A 100 µL volume of the appropriate paint concentration will be applied to both hands, split as evenly as possible between the two hands (ca. 50 µL per hand). A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will

not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

4. **Section 8.C Assignment of Carrier and Amount of Active Ingredient**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

In this study, subjects will be assigned into two groups. The two groups are described below (total amount for both hands):

Group 1 100 µL of latex paint containing ca. 120 ppm BIT
Group 2 100 µL of latex paint containing ca. 600 ppm BIT

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

5. **Section 10.D Field Recovery Evaluation**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

…
An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.
…

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	100 µL	Approximately 120 ppm
Paint	100 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 500 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.
…

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The fortification level of the field recovery samples is being reduced to match subject samples. The volume of each field fortification sample is being adjusted to match subject samples.

6. **Section 9.A.iii Inclusion Criteria**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

Inclusion Criteria

…

- Resident of Fresno County

The section will now read:

Inclusion Criteria

…

- Resident of Fresno County and the surrounding area

Justification: The criteria is being updated to be consistent with Section 9.A.i Population Base which specified that Fresno County and the surrounding area should be included in the recruiting population. This is consistent with the circulation area of the newspapers used for study advertising and will not bias the study recruiting.

7. **Section 9.B Subject Sequence Number**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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.

The section will now read:

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and a number based on their enrollment position (subject 1, subject 2, 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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 subject sequence number. Study data will be recorded by assigning each removal event position a RE number. For example the first subject to be tested will represent RE-01, etc. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their subject sequence number and their removal event (RE) number if applicable, 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.

Justification: The procedure for assigning an initial subject number, randomization position number, and removal event (RE) number is being clarified.

8. **Section 8.D Random Selection and Assignment of Subject to Groups**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...

Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

...

The section will now read:

...

Within each group of fourteen, the subjects will be divided into two blocks of seven subjects for scheduling purposes (AM vs. PM). The first five subjects of each block of seven will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the block of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

...

Justification: The procedure for randomizing subjects into groups and scheduling times is being clarified and made consistent with section 9.B.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 03/27/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 3/27/15
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL AMENDMENT NO.: 2
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 12.B. Analytical Method**

Effective Date: March 30, 2015

Description of Amendment (including justification):

The section currently reads:

...The method (GPL-MTH-*079*) includes the use of isotopically labeled BIT internal standard to increase accuracy...

...Hand wipe samples will be analyzed following the method documented in 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)....

...The latex paint test substances will be analyzed following GPL-MTH-*079*....

The section is being amended to document the correct method number and title of the method. The method number and title are:

GPL Analytical Method GPL-MTH-*081* entitled, "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"

Justification: To correct typographical errors of the method number and analyte name in the method title.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 06/15/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Hasmukh Shah 06/15/15
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL Deviation No.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 9.A.ii. Recruitment of Surrogate Workers**

Effective Date: March 9, 2015

Description of Deviation (including justification):

The Protocol states, "SAIRB approved recruiting advertisements 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 recruitment period will be opened for 2 weeks following the first publication."

All three newspapers were contacted and sent the advertisement on March 5, 2015. The Fresno Bee and Vida en el Valle provided quotes, proofs, and ran the advertisements without any issues. California Advocate responded with a quote, size of space, and confirmation there was space available in the publications of March 9th and 16th, but never provided a proof. Although GPL attempted to contact the newspaper multiple times, the California Advocate staff did not follow up and the advertisement was not published in this newspaper.

Justification: Staff at the California Advocate did not respond to requests to publish the advertisement and GPL could not accomplish this task.

Effect on Study: Recruitment proceeded through the Fresno Bee and Vida en el Valle advertisements which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled during the initial two week period without using the California Advocate. This deviation is not expected to impact the results of the study.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 09/25/15
Megan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 09/22/2015
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL Deviation No.: 2
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Page 8 and 13 – Test Substance**

Dates of Occurrence: April 7, 2015 and April 9, 2015

Description of Deviation (including justification):

The Protocol states, "Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher (second) BIT concentration of approximately 600 ppm."

In preparing the BIT solution used to increase the concentration of BIT in the paint, diethylene glycol was used instead of dipropylene glycol.

Reason for Deviation: Chemist used wrong solvent when preparing solution of BIT.

Effect on Study: There is no expected effect on the study results since the chemical properties of dipropylene glycol and diethylene glycol are similar. In this fortification solution, BIT fully dissolved into the diethylene glycol solvent.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 02/28/17
Mégan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 02/27/17
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL Deviation No.: 3
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Page 25 and 105 and Amendment 1 Item 5 – Field Recovery Evaluation**

Dates of Occurrence: April 7, 2015 and April 9, 2015

Description of Deviation (including justification):

The Protocol states on page 25 and in Amendment 1 Item "Duplicate control matrix samples will also be prepared." However, on page 105 in Appendix I: Field Sample Identification Codes, only one code for a control matrix sample is provided. During the conduct of the study only one control matrix sample was prepared at each fortification event.

Reason for Deviation: Contradiction within the protocol text and list of Field Sample Identification Codes, which was unnoticed.

Effect on Study: There is no effect on the study since control samples showed no residues, therefore a duplicate control sample was not needed to verify any questionable results.

APPROVALS:

STUDY DIRECTOR: Mégan Boatwright 05/22/17
Mégan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 05/20/2017
Has Shah, Ph.D. Date
Sponsor Representative

APPENDIX B.

CERTIFICATES OF ANALYSIS

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 — Date: 14 March 2014

John MacLauchlan, Quality Assurance — Date: 14 March 2014

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

dentification

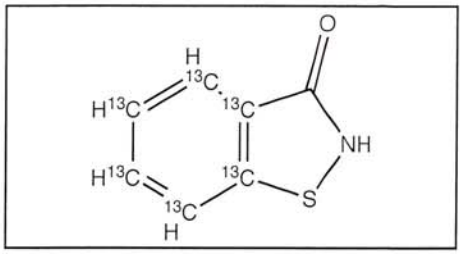
CAS Number:

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$_6$H$_5$NOS

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:
^{1}H 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.
^{1}H 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 C.

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 1)
Effective June 10, 2014

Reason for revision: Correct errors in extraction solvent for air sampling tubes and paint and to make minor editorial corrections.

Prepared by: _____ 04/28/16
Kimon P. Acedo, B.S. Date
Chemist
Golden Pacific Laboratories, LLC

Reviewed by: _____ 04/28/16
Robert J. Testman, MBA Date
President
Golden Pacific Laboratories, LLC

TABLE OF CONTENTS

APPENDICES

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:

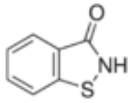
Matrix	LOQ
Face Wipes (Dressing Sponges)	100 ng/sample
Hand Washes	1 ng/mL
Outer Dosimeters	3 µg/sample
Inner Dosimeters	3 µg/sample
Painter's Hats	3 µg/sample
Air Sampling Tubes	10 ng/sample
Fiberglass Filters	10 ng/sample

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).

Solutions A, B, C, and D are fortification solutions used for fortifying air sampling tubes. The fortification solutions are stored in the refrigerator in amber bottles and renewed every 3 months or as needed.

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.

$$y = mx + b \qquad \text{[Eq. 1]}$$

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

$$\text{peak area ratio} = m(\text{analyte/IS ratio}) + b \qquad \text{[Eq. 2]}$$

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.

$$\text{ng BIT/mL} = \frac{[(\text{peak area BIT/peak area IS}) - b] * \text{ng IS/mL}}{m} \qquad \text{[Eq. 3]}$$

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:

$$\textit{ng/sample (ng/g, ng/mL)} = \frac{\textit{(ng/mL from curve) x (final vol in mL)}}{\textit{(1 sample)}} \qquad \text{[Eq. 4]}$$

$$\textit{\% Recovery} = \frac{\textit{measured residues}}{\textit{fortification amount}} \times 100 \qquad \text{[Eq. 5]}$$

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 $\geq$ 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

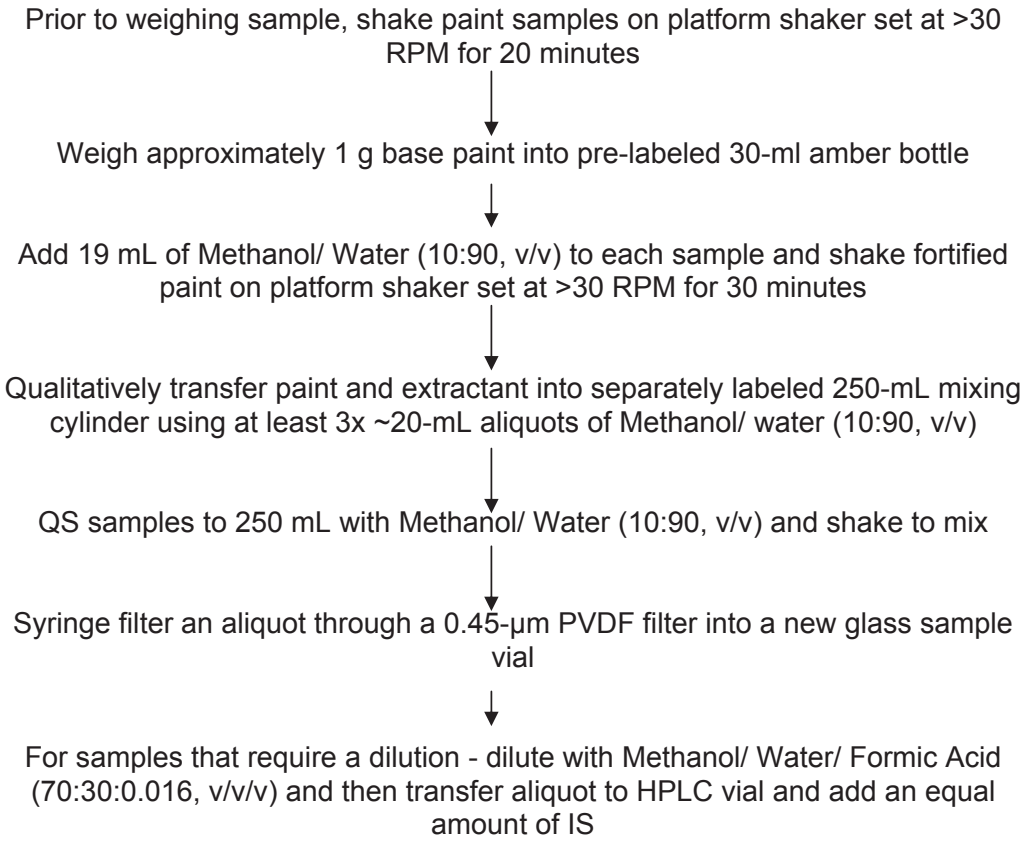
The limits of quantitation (LOQ) for this method for each matrix are listed below:

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



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

↓

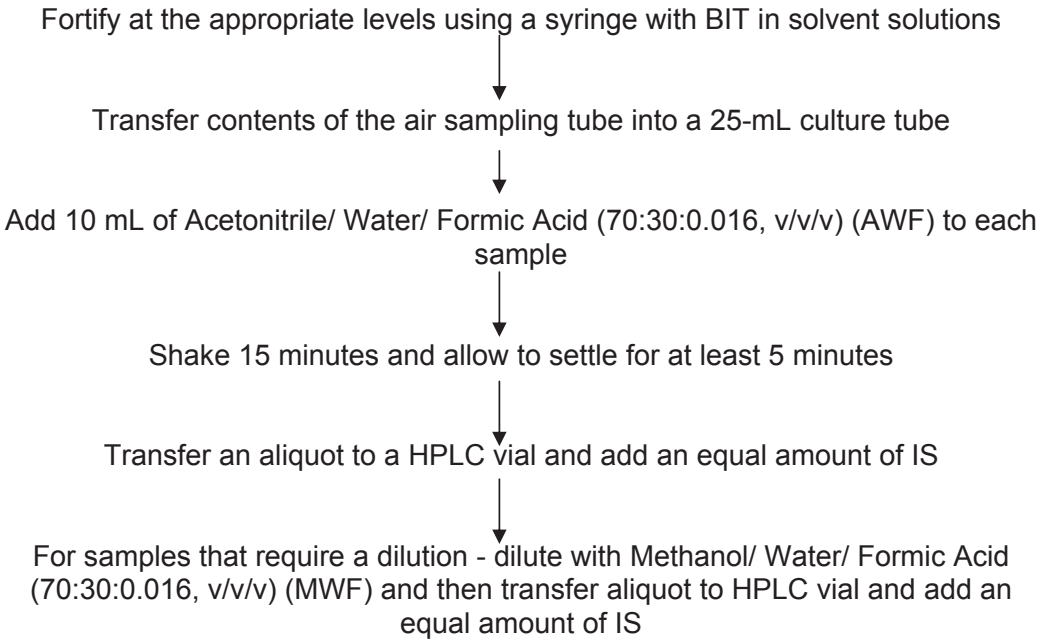
Transfer an aliquot to a HPLC vial and add an equal amount of IS

↓

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

Place one fiberglass filter into a 25-mL culture tube

↓

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.

↓

Allowed fortified samples to sit for at least 15 minutes at ambient temperature to ensure absorption of fortification solution or paint into matrix.

↓

Add 10 mL of Methanol/ Water/ Formic Acid (70: 30: 0.016, v/v/v) (MWF) to each sample

↓

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:

APPENDIX 2 CALIBRATION CURVE AND CHROMATOGRAMS

FIGURE 1

Example Chromatogram of a 0.250 ng/mL BIT LC-MS/MS Standard

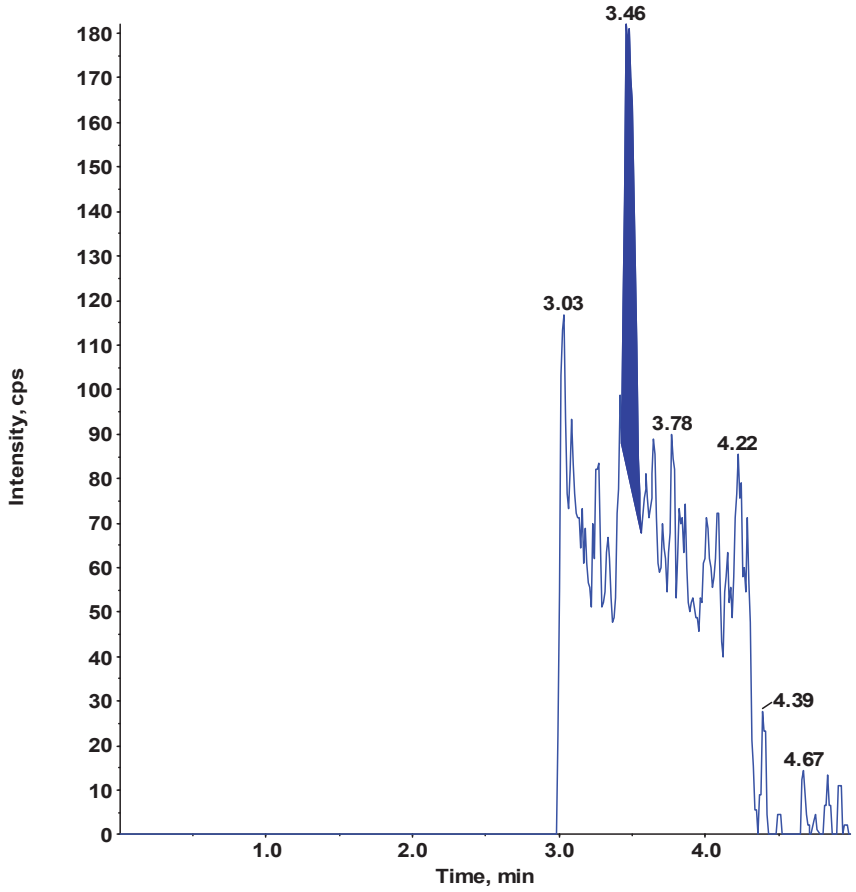


FIGURE 2

Example Chromatogram of a 25.0 ng/mL BIT Internal Standard LC-MS/MS Standard

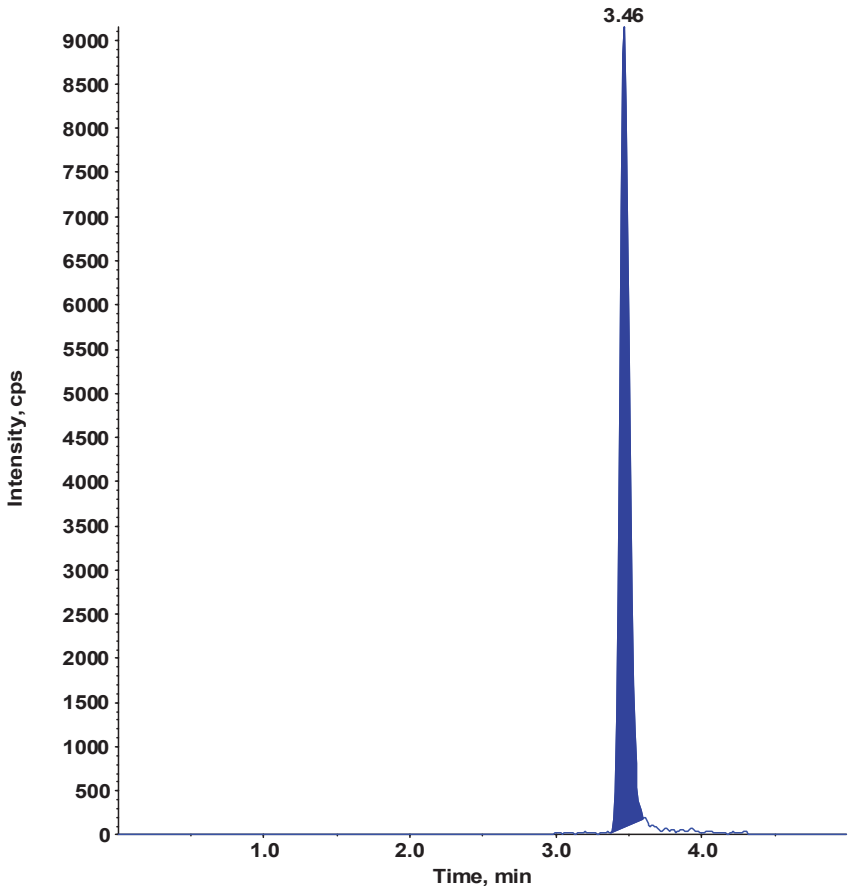


FIGURE 3

Example BIT Calibration Curve

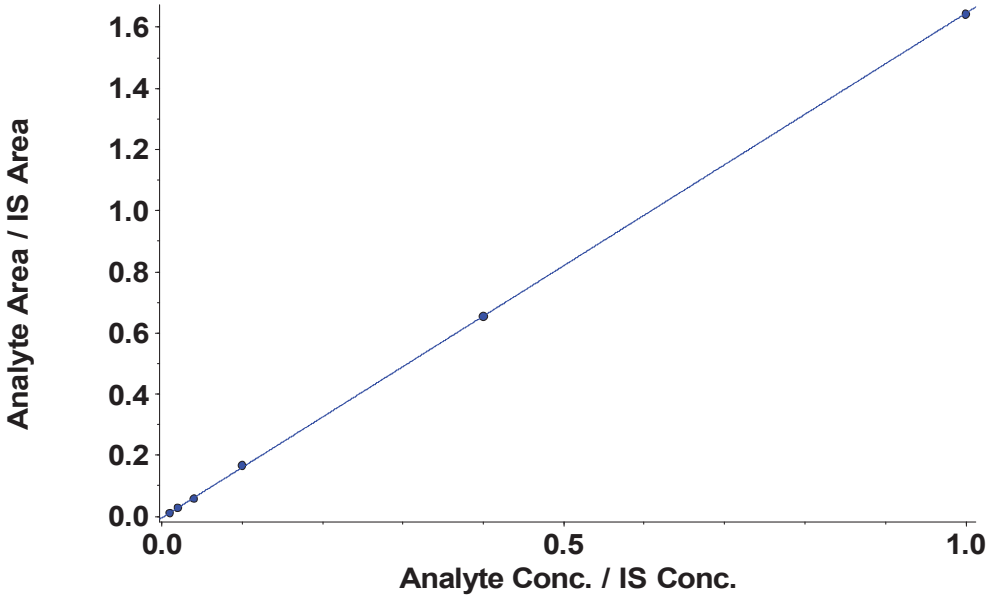


FIGURE 4

Example Chromatogram of Base Paint Fortified with an additional 300 ppm of BIT

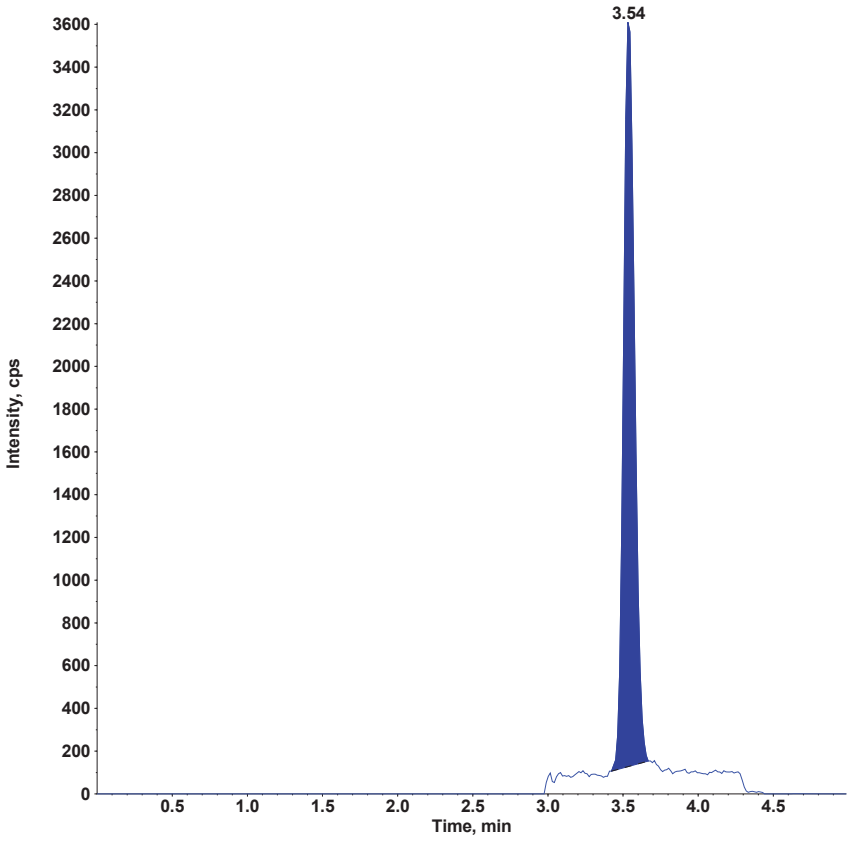


FIGURE 5

Example Chromatogram of a Dressing Sponge Sample Fortified with 0.100 µg/sample of BIT

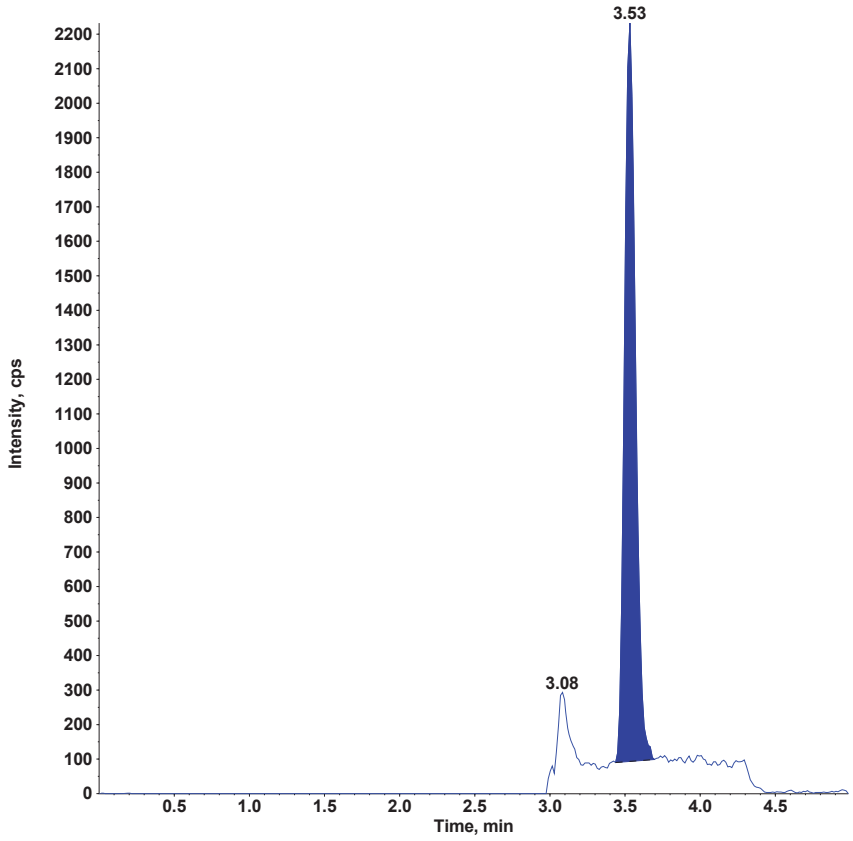


FIGURE 6

Example Chromatogram of a Hand Wash Sample Fortified with 1.00 ng/mL of BIT

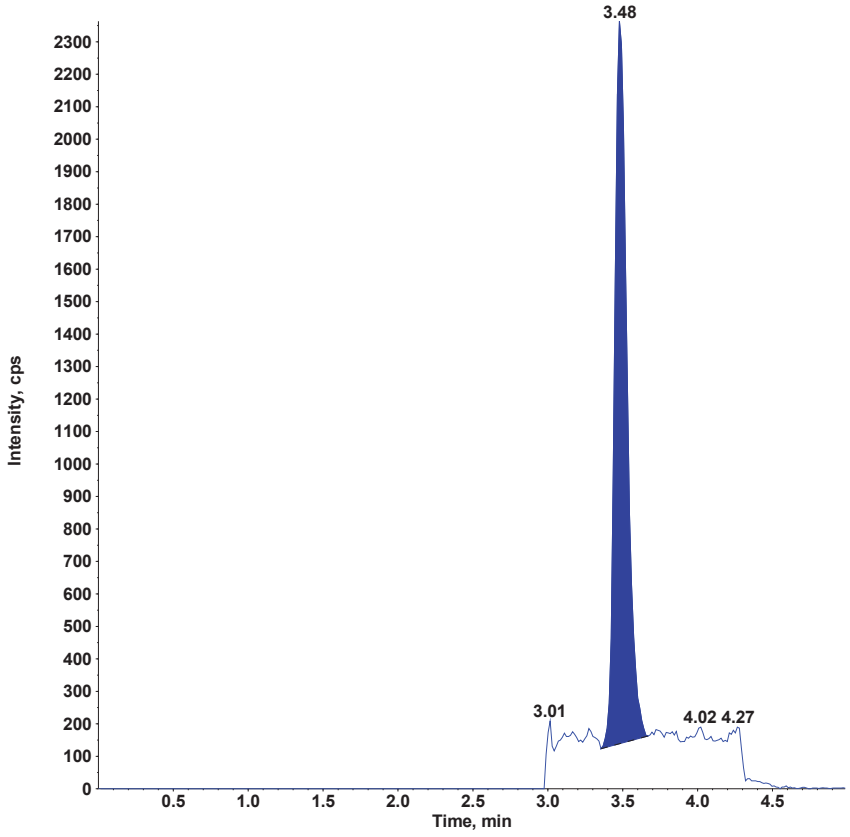


FIGURE 7

Example Chromatogram of an Inner Dosimeter Sample Fortified with 3.00 µg/sample of BIT

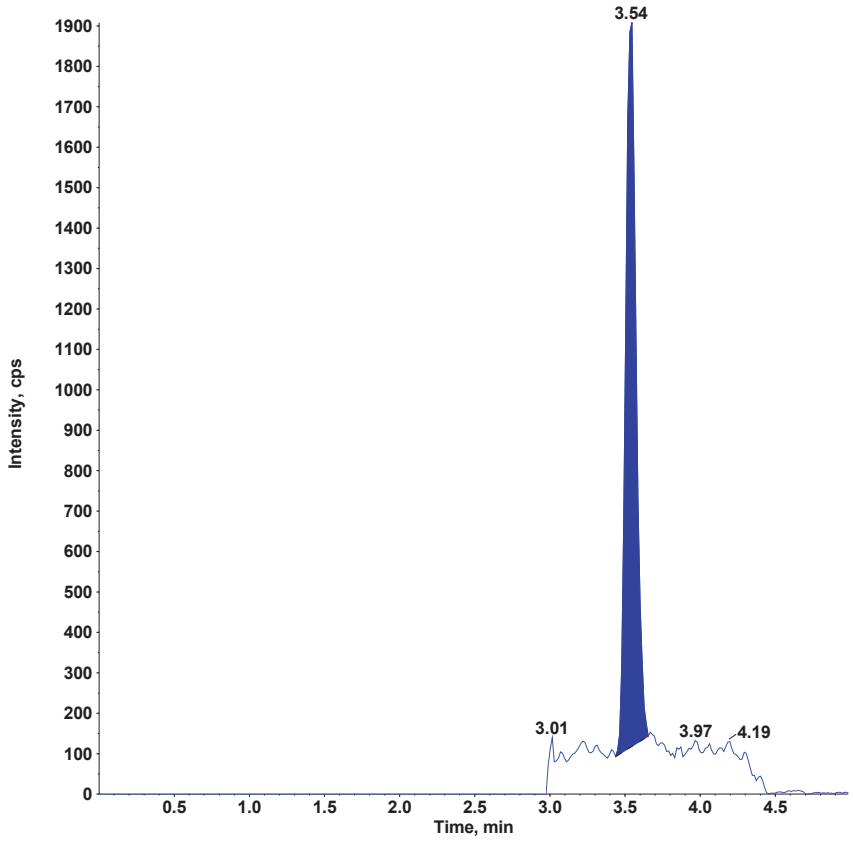


FIGURE 8

Example Chromatogram of an Outer Dosimeter Sample Fortified with 3.00 µg/sample of BIT

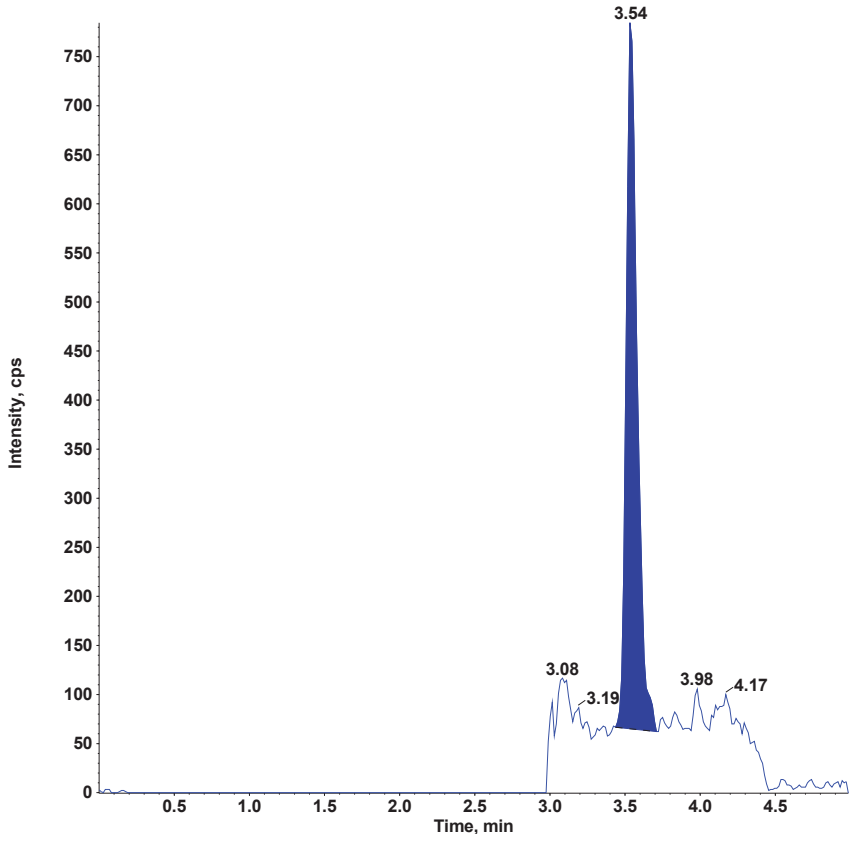


FIGURE 9

Example Chromatogram of a Painter's Hat Sample Fortified with 3.00 µg/sample of BIT

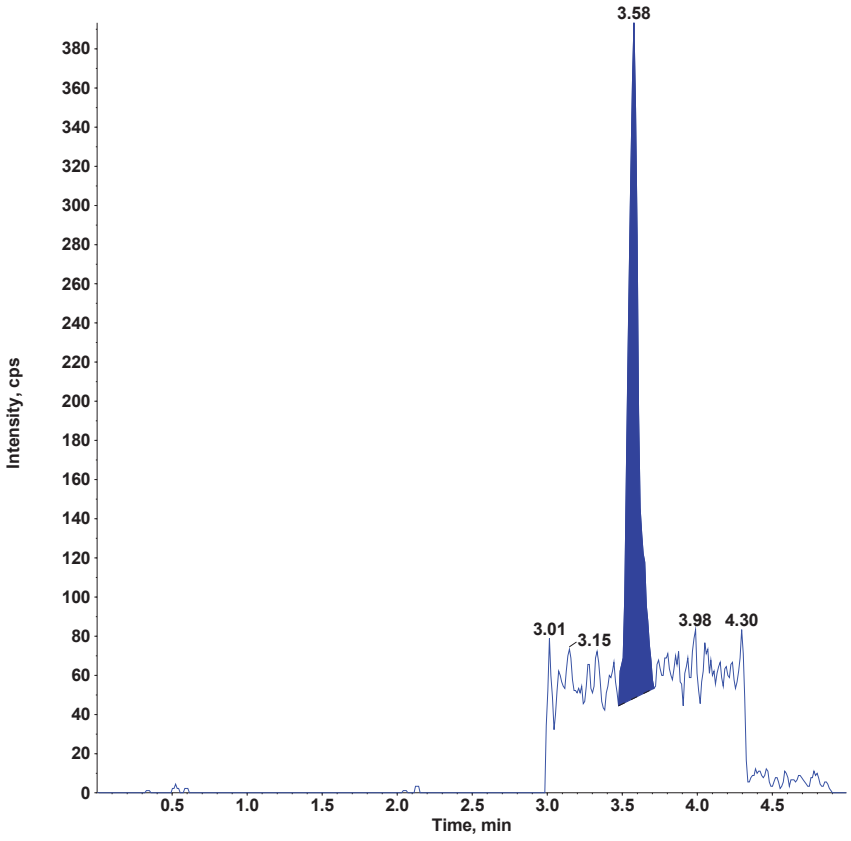


FIGURE 10

Example Chromatogram of an Air Sampling Tube Fortified with 0.0100 µg/sample of BIT

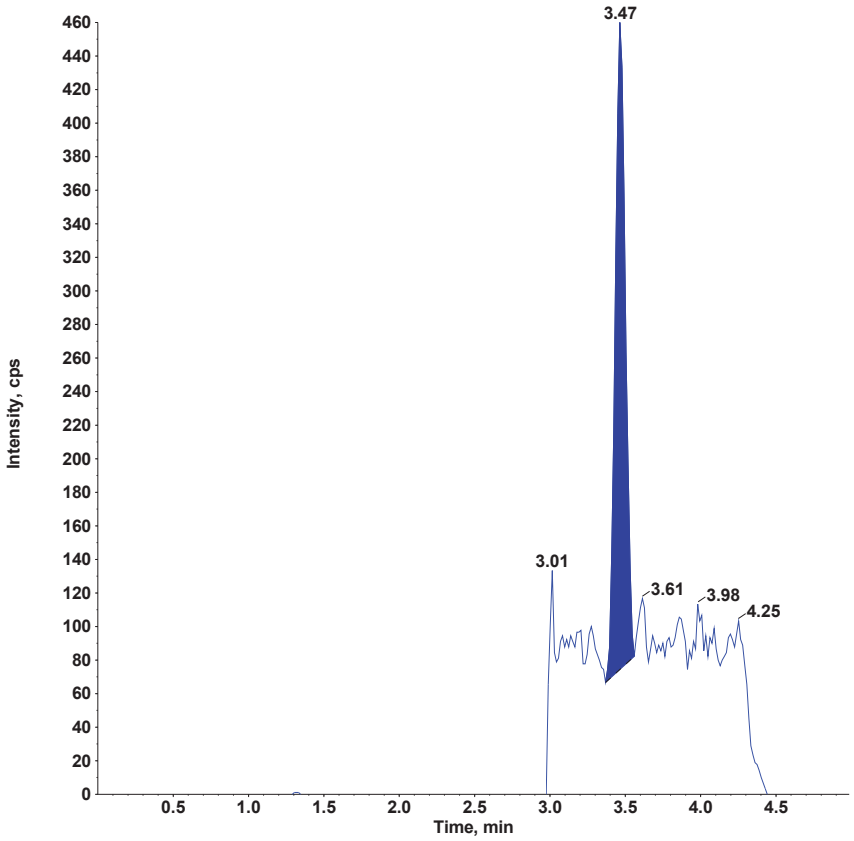
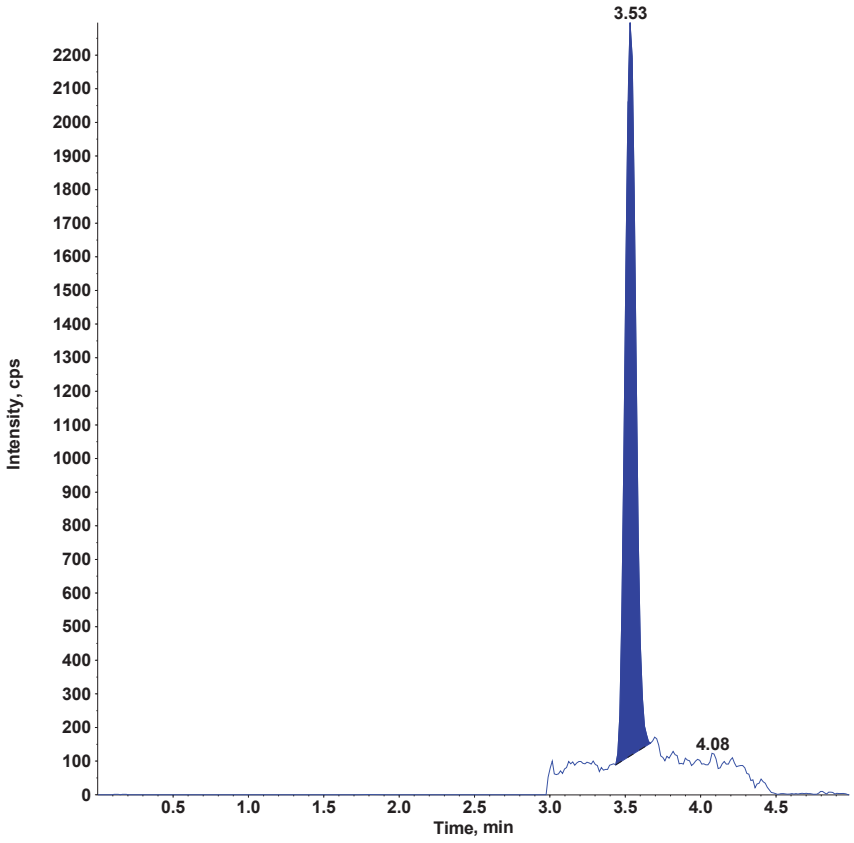


FIGURE 11

Example Chromatogram of a Fiberglass Filter Sample Fortified with 0.0100 µg/sample of BIT



APPENDIX D.

RAW DATA SUMMARY SPREADSHEETS

Summary of BIT Results in Base Paint

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET01
Analysis Set: 503SET01
Extraction Date: 3/31/2015
Analysis Date: 3/31/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.67
b= -0.000226

Coefficient of Determination (r^2): 0.9994
Correlation Coefficient (r): 0.9997

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	645.8	38806.4	0.252	0.797
1365-21	0.500	1299.8	40081.8	0.488	2.43
1365-22	1.00	2721.8	39250.2	1.04	3.92
1365-23	2.50	6608.4	39539.1	2.50	0.00
1365-24	10.0	26236.7	40595.7	9.66	3.46
1365-25	25.0	66147.8	39026.8	25.3	1.19

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc - Std Amount}| \times 2 \times 100}{(\text{Std Back calc + Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (g)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (ppm)	Average Concentration (ppm)
503SET01-1	TC-228 (base paint) Rep A	0.9916	50500	7736.0	38680.9	2.99	152	
503SET01-2	TC-228 (base paint) Rep B	0.9947	50500	8302.4	40365.3	3.08	156	154
503SET01-3	TC-228 (base paint) Rep C	0.9923	50500	8017.9	39509.9	3.03	154	

[1] Sample Conc. in ppm =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (g) x 1000 ng).
Note: Sample Concentration, Percent Recovery and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of BIT Results of Base Paint

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET02
Analysis Set: 503SET02
Extraction Date: 3/31/2015
Analysis Date: 3/31/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.63
b= -0.00283

Coefficient of Determination (r^2): 0.9994
Correlation Coefficient (r): 0.9997

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	501.6	38642.8	0.242	3.25
1365-21	0.500	1150.4	39162.0	0.493	1.41
1365-22	1.00	2285.1	37392.8	0.980	2.02
1365-23	2.50	6353.1	37525.5	2.64	5.45
1365-24	10.0	25165.6	37860.2	10.2	1.98
1365-25	25.0	62858.2	39111.5	24.7	1.21

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc} - \text{Std Amount}| \times 2 \times 100}{(\text{Std Back calc} + \text{Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (g)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (ppm)	Average Concentration (ppm)
503SET02-1	TC-228-1 (fortified paint) Rep A	1.0100	100500	13878.6	38074.9	5.63	560	
503SET02-2	TC-228-1 (fortified paint) Rep B	1.0038	100500	13465.9	37137.8	5.60	561	547
503SET02-3	TC-228-1 (fortified paint) Rep C	1.0067	100500	13278.6	39278.4	5.22	521	

[1] Sample Conc. in ppm =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (g) x 1000 ng).
Note: Sample Concentration, Percent Recovery and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT in Removal Efficiency Hand Washes

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET03
Analysis Set: 503SET03
Extraction Date: 5/18/2015
Analysis Date: 5/18/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.65
b= 0.00189

Coefficient of Determination (r^2): 0.9990
Correlation Coefficient (r): 0.9995

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	679.7	34944.5	0.267	6.58
1365-21	0.500	1054.6	36588.2	0.409	20.0
1365-22	1.00	2618.3	35672.3	1.09	8.61
1365-23	2.50	6468.5	36680.3	2.65	5.83
1365-24	10.0	25346.9	39070.4	9.82	1.82
1365-25	25.0	64246.2	38913.5	25.0	0.00
1365-22	1.00	2600.2	38823.8	0.988	1.21

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc - Std Amount}| \times 2 \times 100}{(\text{Std Back calc + Std Amount})}$

Sample Information:

Lab ID	Sample ID	Amount of Fortified Paint Added (g)	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)	Fortification Amount[2,3] (µg/sample)	Percent Recovery[4] (%)	
503SET03-1	Control	NA	1	1000	0.0	37193.1	<0.250	ND	NA	NA	
503SET03-2	Low Lab QC (~1 ng/mL)	NA	1	1000	1319.4	37292.0	0.508	0.508	0.521	97.5	
503SET03-3	High Lab QC (~150 ng/mL)	0.1424	1	51000	3582.8	36305.1	1.47	75.0	77.9	96.3	*
503SET03-4	AEA08-RE-01-PL	NA	1	10000	3495.3	36244.0	1.44	14.4	NA	NA	
503SET03-5	AEA08-RE-02-PL	NA	1	10000	3121.5	36759.5	1.26	12.6	NA	NA	
503SET03-6	AEA08-RE-03-PL	NA	1	10000	4575.0	35655.8	1.92	19.2	NA	NA	
503SET03-7	AEA08-RE-04-PL	NA	1	10000	4716.0	36551.5	1.93	19.3	NA	NA	
503SET03-8	AEA08-RE-05-PL	NA	1	10000	4329.6	36242.0	1.78	17.8	NA	NA	
503SET03-9	AEA08-RE-06-PL	NA	1	10000	3505.5	36670.5	1.42	14.2	NA	NA	
503SET03-10	AEA08-RE-07-PL	NA	1	10000	3762.4	37332.7	1.50	15.0	NA	NA	
503SET03-11	AEA08-RE-08-PL	NA	1	10000	3929.9	35789.8	1.64	16.4	NA	NA	
503SET03-12	AEA08-RE-09-PL	NA	1	10000	3419.8	38265.1	1.33	13.3	NA	NA	
503SET03-13	AEA08-RE-10-PL	NA	1	10000	4993.8	38083.0	1.96	19.6	NA	NA	
503SET03-14	AEA08-FF-P-01-C	NA	1	1000	0.0	37486.4	<0.250	ND	NA	NA	
503SET03-15	AEA08-FF-P-01-L1	0.1467	1	10000	5950.4	38435.9	2.32	23.2	22.6	103	**
503SET03-16	AEA08-FF-P-01-L2	0.1434	1	10000	5860.5	37923.2	2.32	23.2	22.1	105	**
503SET03-17	AEA08-FF-P-01-H1	0.1386	1	51000	4189.2	38332.0	1.63	83.1	75.8	110	*
503SET03-18	AEA08-FF-P-01-H2	0.1448	1	51000	3896.2	38834.8	1.49	76.0	79.2	96.0	*

* Sample fortified with TC-228-1 (547 ppm BIT in paint)
** Sample fortified with TC-228 (154 ppm BIT in paint)

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).

[2] Fortification Amount for samples fortified with 154 ppm paint = ((Amount Paint Added (g) x 154 µg/g) ÷ Sample Amount (sample)).

[3] Fortification Amount for samples fortified with 547 ppm paint = ((Amount Paint Added (g) x 547 µg/g) ÷ Sample Amount (sample)).

[4] Percent Recovery (%) = Sample Concentration in µg/sample ÷ Fortification Amount in µg/sample x 100.

LOQ = 1 ng/mL (0.500 µg/sample for 500-mL samples)

Note: Sample Concentration, Percent Recovery and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2. These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT in Removal Efficiency Hand Washes

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET04
Analysis Set: 503SET04
Extraction Date: 5/18/2015
Analysis Date: 5/18/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.71
b= 0.000879

Coefficient of Determination (r^2): 0.9978
Correlation Coefficient (r): 0.9989

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	772.3	38166.2	0.283	12.4
1365-21	0.500	1181.9	38218.3	0.439	13.0
1365-22	1.00	2969.1	39161.3	1.09	8.61
1365-23	2.50	6653.5	40536.9	2.39	4.50
1365-24	10.0	26574.3	41096.6	9.44	5.76
1365-25	25.0	68838.2	39207.6	25.6	2.37
1365-22	1.00	2688.1	39859.5	0.973	2.74

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc - Std Amount}| \times 2 \times 100}{(\text{Std Back calc + Std Amount})}$

Sample Information:

Lab ID	Sample ID	Amount of Fortified Paint Added (g)	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)	Fortification Amount[2,3] (µg/sample)	Percent Recovery[4] (%)	
503SET04-1	Control	NA	1	1000	0.0	40265.3	<0.250	ND	NA	NA	
503SET04-2	Low Lab QC (~1 ng/mL)	NA	1	1000	1378.6	38903.0	0.505	0.505	0.521	96.9	
503SET04-3	High Lab QC (~150 ng/mL)	0.1486	1	51000	3757.8	39618.6	1.37	69.9	81.3	86.0	*
503SET04-4	AEA08-RE-11-PH	NA	1	51000	2210.5	39140.5	0.812	41.4	NA	NA	
503SET04-5	AEA08-RE-12-PH	NA	1	51000	2613.1	39526.2	0.953	48.6	NA	NA	
503SET04-6	AEA08-RE-13-PH	NA	1	51000	1809.5	39763.8	0.652	33.3	NA	NA	
503SET04-7	AEA08-RE-14-PH	NA	1	51000	2596.4	39494.5	0.948	48.3	NA	NA	
503SET04-8	AEA08-RE-15-PH	NA	1	51000	2462.1	40640.0	0.872	44.5	NA	NA	
503SET04-9	AEA08-RE-16-PH	NA	1	51000	2330.1	38553.9	0.870	44.4	NA	NA	
503SET04-10	AEA08-RE-17-PH	NA	1	51000	2412.1	41457.3	0.837	42.7	NA	NA	
503SET04-11	AEA08-RE-18-PH	NA	1	51000	2980.1	39744.1	1.08	55.1	NA	NA	
503SET04-12	AEA08-RE-19-PH	NA	1	51000	2186.4	39150.3	0.803	41.0	NA	NA	
503SET04-13	AEA08-RE-20-PH	NA	1	51000	3233.0	39803.6	1.17	59.7	NA	NA	
503SET04-14	AEA08-FF-P-02-C	NA	1	1000	0.0	39569.3	<0.250	ND	NA	NA	
503SET04-15	AEA08-FF-P-02-L1	0.1439	1	10000	6197.4	39076.6	2.30	23.0	22.2	104	**
503SET04-16	AEA08-FF-P-02-L2	0.1432	1	10000	6043.2	38454.9	2.28	22.8	22.1	103	**
503SET04-17	AEA08-FF-P-02-H1	0.1403	1	51000	4210.4	40596.3	1.50	76.5	76.7	99.7	*
503SET04-18	AEA08-FF-P-02-H2	0.1412	1	51000	3883.4	39162.6	1.44	73.4	77.2	95.1	*

* Sample fortified with TC-228-1 (547 ppm BIT in paint)
** Sample fortified with TC-228 (154 ppm BIT in paint)

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).

[2] Fortification Amount for samples fortified with 154 ppm paint = ((Amount Paint Added (g) x 154 µg/g) ÷ Sample Amount (sample)).

[3] Fortification Amount for samples fortified with 547 ppm paint = ((Amount Paint Added (g) x 547 µg/g) ÷ Sample Amount (sample)).

[4] Percent Recovery (%) = Sample Concentration in µg/sample ÷ Fortification Amount in µg/sample x 100.

LOQ = 1 ng/mL (0.500 µg/sample for 500-mL samples)

Note: Sample Concentration, Percent Recovery and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2. These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT on Glass Stir Rods

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET05
Analysis Set: 503SET05
Extraction Date: 5/18/2015
Analysis Date: 5/18/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.64
b= 0.004820

Coefficient of Determination (r^2): 0.9990
Correlation Coefficient (r): 0.9995

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	759.0	39044.7	0.222	11.9
1365-21	0.500	1530.8	39279.0	0.520	3.92
1365-22	1.00	3127.7	39689.4	1.13	12.2
1365-23	2.50	6696.8	41043.6	2.41	3.67
1365-24	10.0	26835.1	41677.1	9.72	2.84
1365-25	25.0	69245.0	41600.7	25.3	1.19

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc - Std Amount}| \times 2 \times 100}{(\text{Std Back calc + Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)	
503SET05-1	AEA08-RE-01-PL (Test Tube)	1	400	287.0	40407.6	<0.250	ND	*
503SET05-2	AEA08-RE-02-PL (Test Tube)	1	400	1017.5	41303.6	0.301	0.120	
503SET05-3	AEA08-RE-03-PL (Test Tube)	1	400	2296.2	40341.7	0.793	0.317	
503SET05-4	AEA08-RE-04-PL (Test Tube)	1	400	223.5	41501.1	<0.250	ND	*
503SET05-5	AEA08-RE-05-PL (Test Tube)	1	400	500.2	39817.3	<0.250	ND	*
503SET05-6	AEA08-RE-06-PL (Test Tube)	1	400	646.6	39784.4	<0.250	ND	*
503SET05-7	AEA08-RE-07-PL (Test Tube)	1	400	828.6	39596.8	<0.250	ND	*
503SET05-8	AEA08-RE-08-PL (Test Tube)	1	400	373.4	40177.9	<0.250	ND	*
503SET05-9	AEA08-RE-09-PL (Test Tube)	1	400	868.4	41055.3	<0.250	ND	*
503SET05-10	AEA08-RE-10-PL (Test Tube)	1	400	861.1	41527.3	<0.250	ND	*

* Sample concentration below the calibration curve. Sample will be reanalyzed in 503SET05A without dilution.

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).

Note: Sample Concentration and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT on Glass Stir Rods

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET05
Analysis Set: 503SET05A
Extraction Date: 5/18/2015
Analysis Date: 5/20/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.63
b= -0.00151

Coefficient of Determination (r^2): 0.9996
Correlation Coefficient (r): 0.9998

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	301.4	22075.8	0.232	7.47
1365-21	0.500	694.9	22135.3	0.504	0.797
1365-22	1.00	1427.5	22175.6	1.01	0.995
1365-23	2.50	3698.3	21662.7	2.64	5.45
1365-24	10.0	15427.0	23591.1	10.0	0.00
1365-25	25.0	39010.8	24106.1	24.8	0.803

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc} - \text{Std Amount}| \times 2 \times 100}{(\text{Std Back calc} + \text{Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)
503SET05-1	AEA08-RE-01-PL (Test Tube)	1	80	538.2	21535.4	0.406	0.0325
503SET05-4	AEA08-RE-04-PL (Test Tube)	1	80	611.0	22061.4	0.448	0.0358
503SET05-5	AEA08-RE-05-PL (Test Tube)	1	80	680.7	21610.2	0.506	0.0405
503SET05-6	AEA08-RE-06-PL (Test Tube)	1	80	1259.4	22240.7	0.891	0.0713
503SET05-7	AEA08-RE-07-PL (Test Tube)	1	80	2024.7	21906.4	1.44	0.115
503SET05-8	AEA08-RE-08-PL (Test Tube)	1	80	768.8	22271.9	0.552	0.0442
503SET05-9	AEA08-RE-09-PL (Test Tube)	1	80	2127.6	22155.2	1.49	0.119
503SET05-10	AEA08-RE-10-PL (Test Tube)	1	80	1978.5	22932.7	1.35	0.108

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).
Note: Sample Concentration and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT on Glass Stir Rods

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET06
Analysis Set: 503SET06
Extraction Date: 5/18/2015
Analysis Date: 5/19/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.69
b= 0.00488

Coefficient of Determination (r^2): 0.9990
Correlation Coefficient (r): 0.9995

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	1017.0	41108.3	0.293	15.8
1365-21	0.500	1412.7	40415.1	0.444	11.9
1365-22	1.00	3005.3	41326.1	1.00	0.00
1365-23	2.50	6845.1	41539.2	2.36	5.76
1365-24	10.0	27439.4	41376.7	9.73	2.74
1365-25	25.0	71387.7	41389.7	25.4	1.59

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc - Std Amount}| \times 2 \times 100}{(\text{Std Back calc + Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)	
503SET06-1	AEA08-RE-11-PH (Test Tube)	1	1680	700.2	40749.6	<0.250	ND	*
503SET06-2	AEA08-RE-12-PH (Test Tube)	1	1680	531.5	42736.3	<0.250	ND	*
503SET06-3	AEA08-RE-13-PH (Test Tube)	1	1680	0.0	40882.4	<0.250	ND	*
503SET06-4	AEA08-RE-14-PH (Test Tube)	1	1680	323.6	41797.9	<0.250	ND	*
503SET06-5	AEA08-RE-15-PH (Test Tube)	1	1680	519.7	40741.7	<0.250	ND	*
503SET06-6	AEA08-RE-16-PH (Test Tube)	1	1680	0.0	41443.0	<0.250	ND	*
503SET06-7	AEA08-RE-17-PH (Test Tube)	1	1680	340.4	41439.2	<0.250	ND	*
503SET06-8	AEA08-RE-18-PH (Test Tube)	1	1680	274.4	42532.6	<0.250	ND	*
503SET06-9	AEA08-RE-19-PH (Test Tube)	1	1680	1868.6	41540.0	0.593	0.996	
503SET06-10	AEA08-RE-20-PH (Test Tube)	1	1680	766.7	42585.8	<0.250	ND	*

* Sample concentration below the calibration curve. Sample will be reanalyzed in 503SET06A without dilution.

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).
Note: Sample Concentration and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

Summary of Analytical Results of BIT on Glass Stir Rods

GPL Study #130503, Sponsor Study #AEA08

Extraction Set: 503SET06
Analysis Set: 503SET06A
Extraction Date: 5/18/2015
Analysis Date: 5/20/2015
Injection Volume: 10 µL

Curve Equation: y= ax + b
where y is peak area response ratio (analyte peak area/ IS peak area)
and x is the ratio of analyte concentration/ IS concentration (ng/mL) (1/x weighting)
IS concentration: 25.0 ng/mL (for all samples and standards)
a= 1.63
b= 0.00667

Coefficient of Determination (r^2): 0.9994
Correlation Coefficient (r): 0.9997

Standard Injections: **BIT**

Standard ID	Standard Amount (ng/mL)	BIT Peak Area	IS Peak Area	Back Calc of Standard (ng/mL)	RPD
1365-20	0.250	553.7	24380.5	0.246	1.61
1365-21	0.500	967.7	22785.4	0.550	9.52
1365-22	1.00	1612.7	24979.7	0.890	11.6
1365-23	2.50	4213.5	24348.4	2.56	2.37
1365-24	10.0	16375.0	24850.9	10.0	0.00
1365-25	25.0	41631.0	25502.2	25.0	0.00

NA = Not applicable
ND = Not detected
LOQ = Limit of Quantitation

RPD = Relative Percent Difference
where, RPD = $\frac{|\text{Std Back calc} - \text{Std Amount}| \times 2 \times 100}{(\text{Std Back calc} + \text{Std Amount})}$

Sample Information:

Lab ID	Sample ID	Sample Amount (sample)	Final Volume (mL)	BIT Peak Area	IS Peak Area	Concentration from Curve (ng/mL)	Sample Concentration[1] (µg/sample)
503SET06-1	AEA08-RE-11-PH (Test Tube)	1	80	7369.9	23909.4	4.63	0.370
503SET06-2	AEA08-RE-12-PH (Test Tube)	1	80	5568.3	23623.4	3.52	0.282
503SET06-3	AEA08-RE-13-PH (Test Tube)	1	80	1194.9	23419.0	0.682	0.0546
503SET06-4	AEA08-RE-14-PH (Test Tube)	1	80	4860.4	24479.0	2.95	0.236
503SET06-5	AEA08-RE-15-PH (Test Tube)	1	80	6227.3	24474.2	3.81	0.305
503SET06-6	AEA08-RE-16-PH (Test Tube)	1	80	1622.2	23497.3	0.958	0.0766
503SET06-7	AEA08-RE-17-PH (Test Tube)	1	80	3506.2	23696.2	2.17	0.174
503SET06-8	AEA08-RE-18-PH (Test Tube)	1	80	3800.8	23722.1	2.36	0.189
503SET06-10	AEA08-RE-20-PH (Test Tube)	1	80	5319.5	24965.4	3.17	0.254

[1] Sample Conc. in µg/sample =(Conc. from curve (ng/mL) x Final Volume (mL) x 1 µg) ÷ (Sample Amount (sample) x 1000 ng).
Note: Sample Concentration and RPD values are calculated by Excel. All other calculations are performed by Analyst 1.5.2.
These values are rounded to three significant figures and transcribed to the Excel spreadsheet.

APPENDIX E.

REPRESENTATIVE CHROMATOGRAMS

Figure 1. Representative Chromatogram of a 0.250 ng/mL BIT Standard (503SET03)

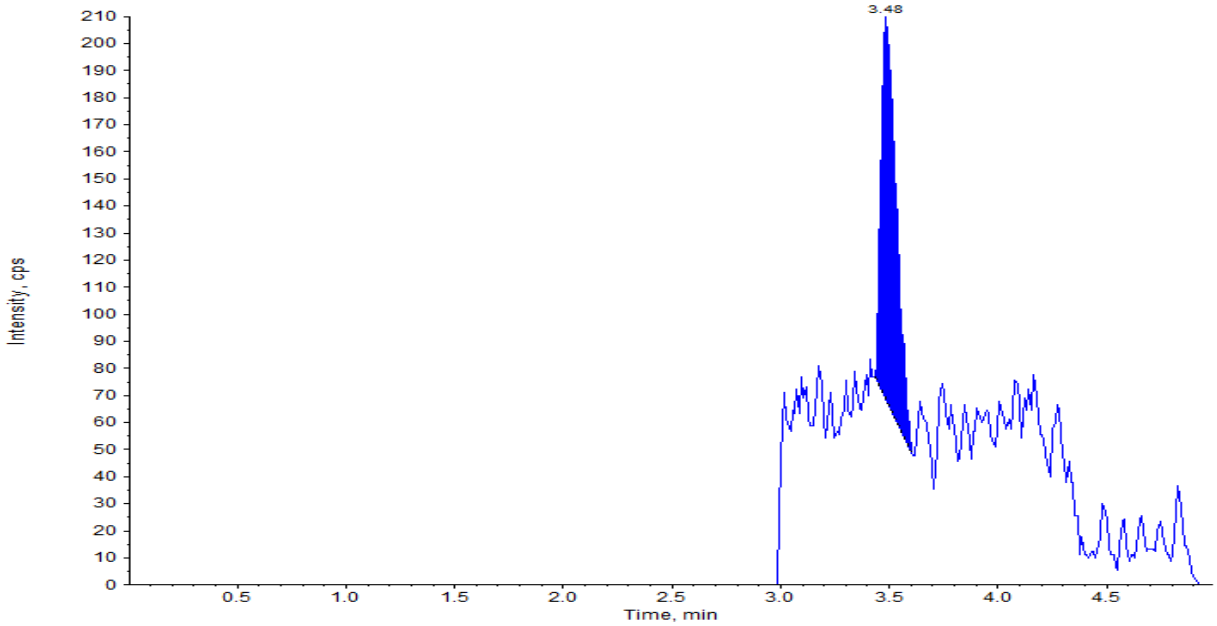


Figure 2. Representative Chromatogram of a 0.500 ng/mL BIT Standard (503SET03)

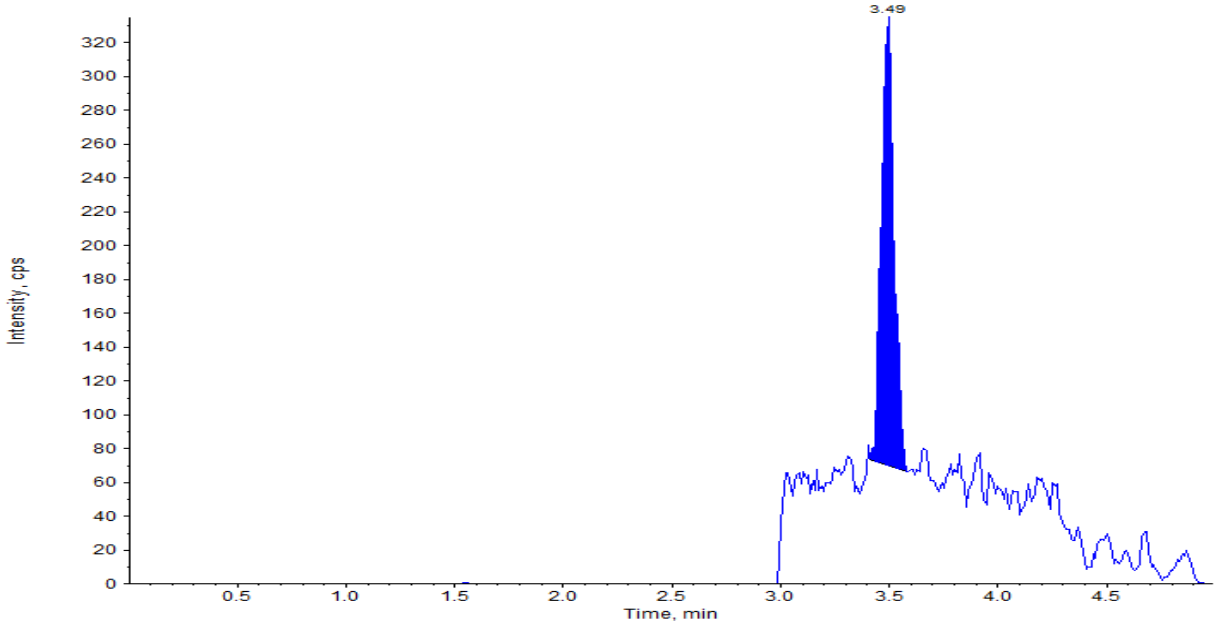


Figure 3. Representative Chromatogram of a 1.00 ng/mL BIT Standard (503SET03)

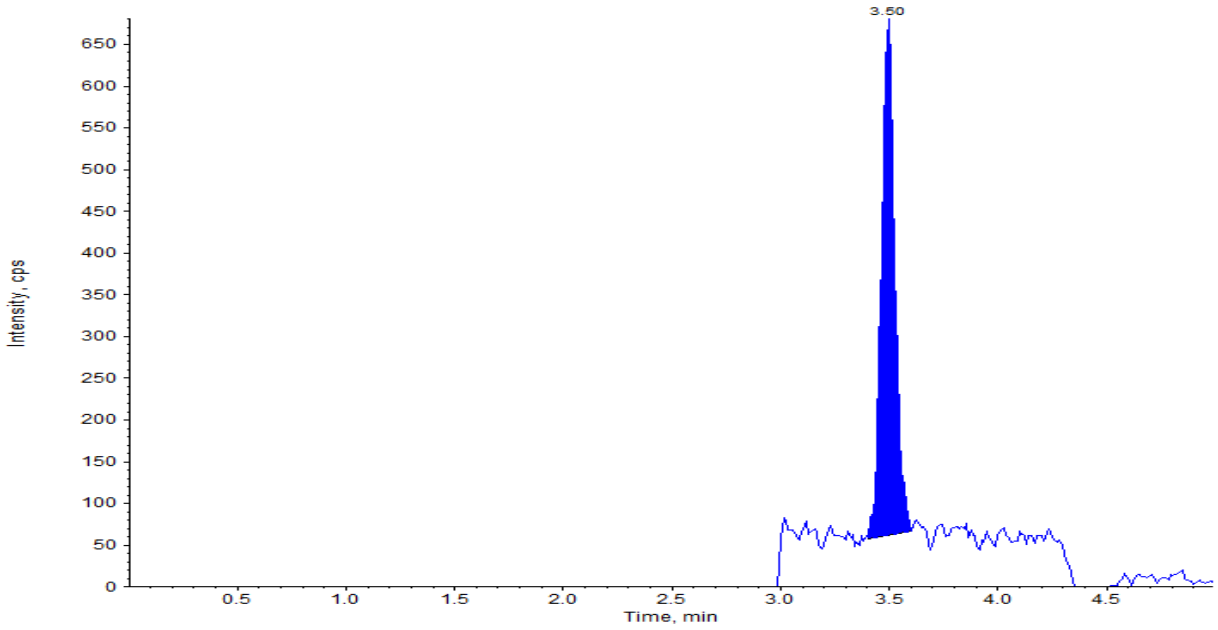


Figure 4. Representative Chromatogram of a 2.50 ng/mL BIT Standard (503SET03)

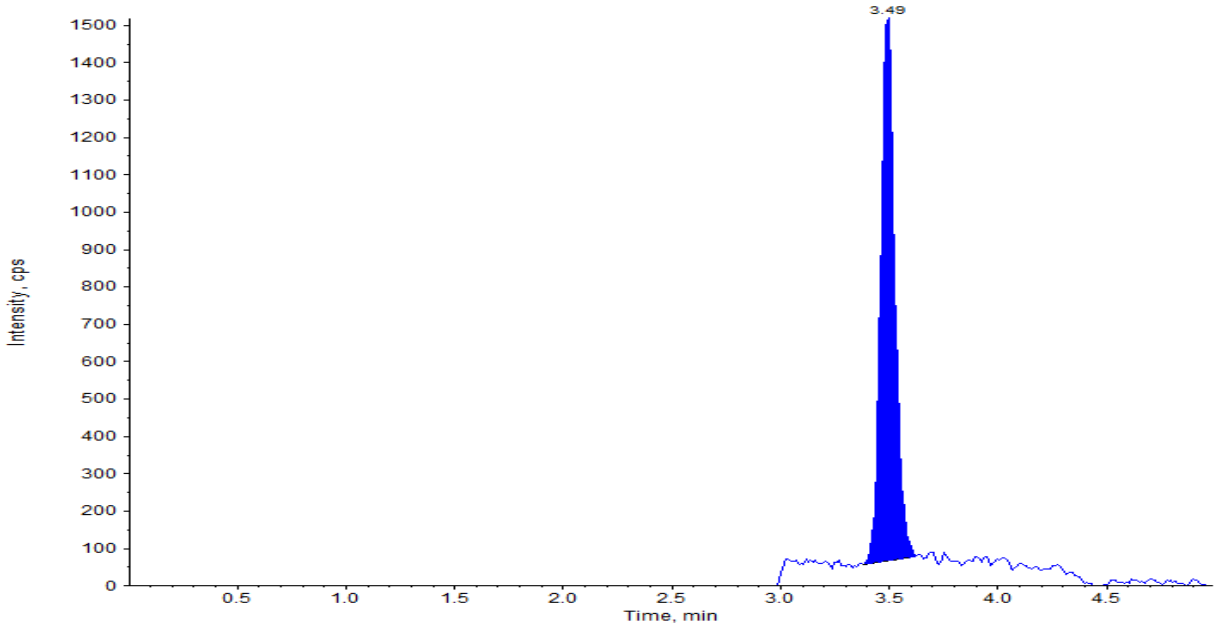


Figure 5. Representative Chromatogram of a 10.0 ng/mL BIT Standard (503SET03)

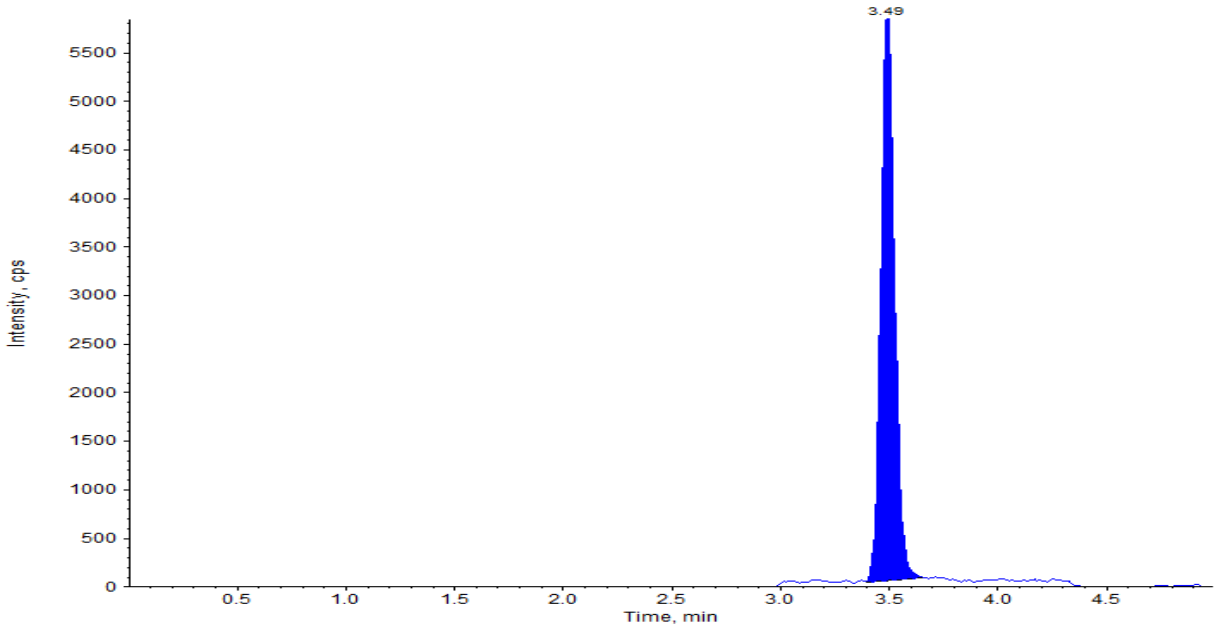


Figure 6. Representative Chromatogram of a 25.0 ng/mL BIT Standard (503SET03)

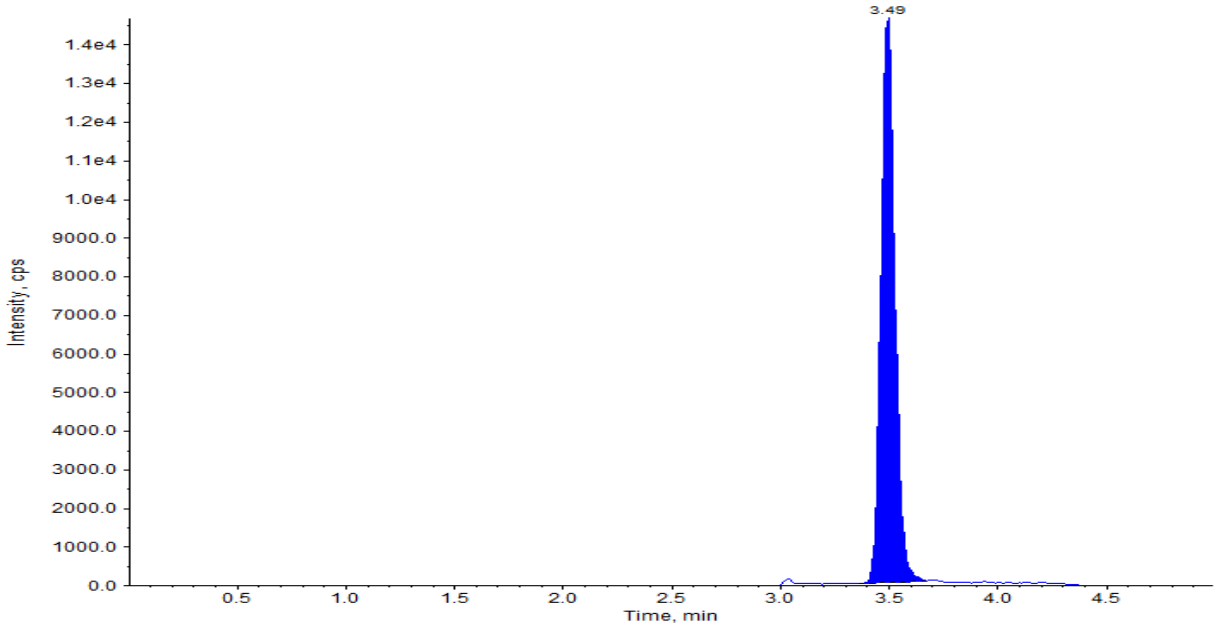


Figure 7. Representative Chromatogram of a 25.0 ng/mL BIT Internal Standard (503SET03)

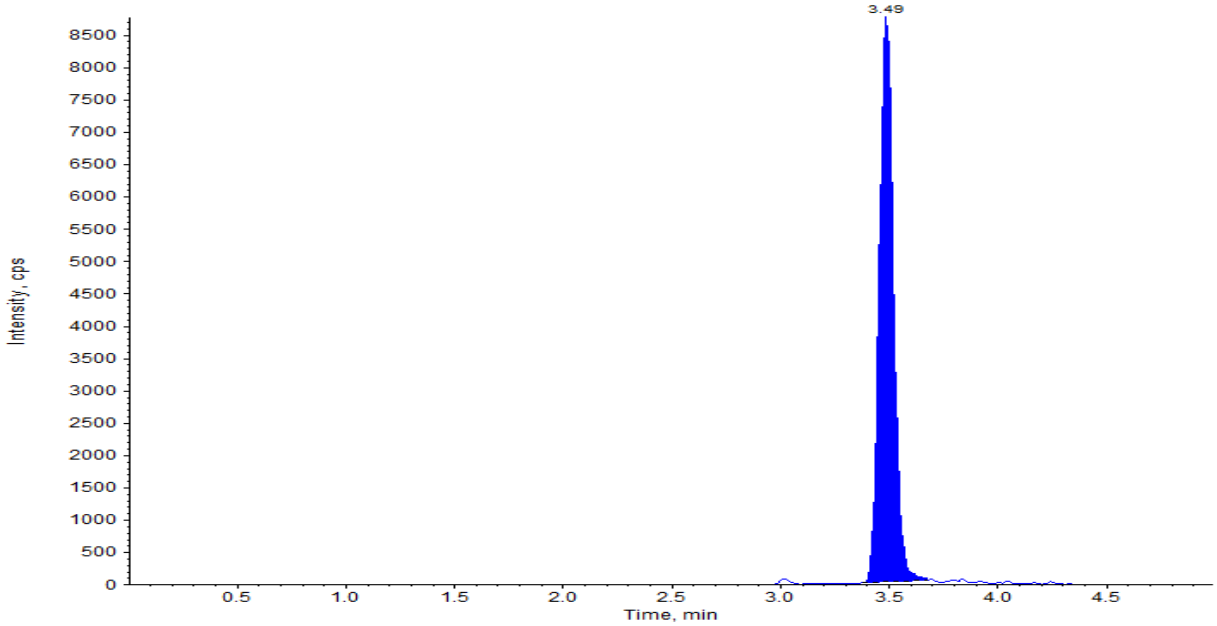


Figure 8. Representative BIT Standard Curve (503SET03)

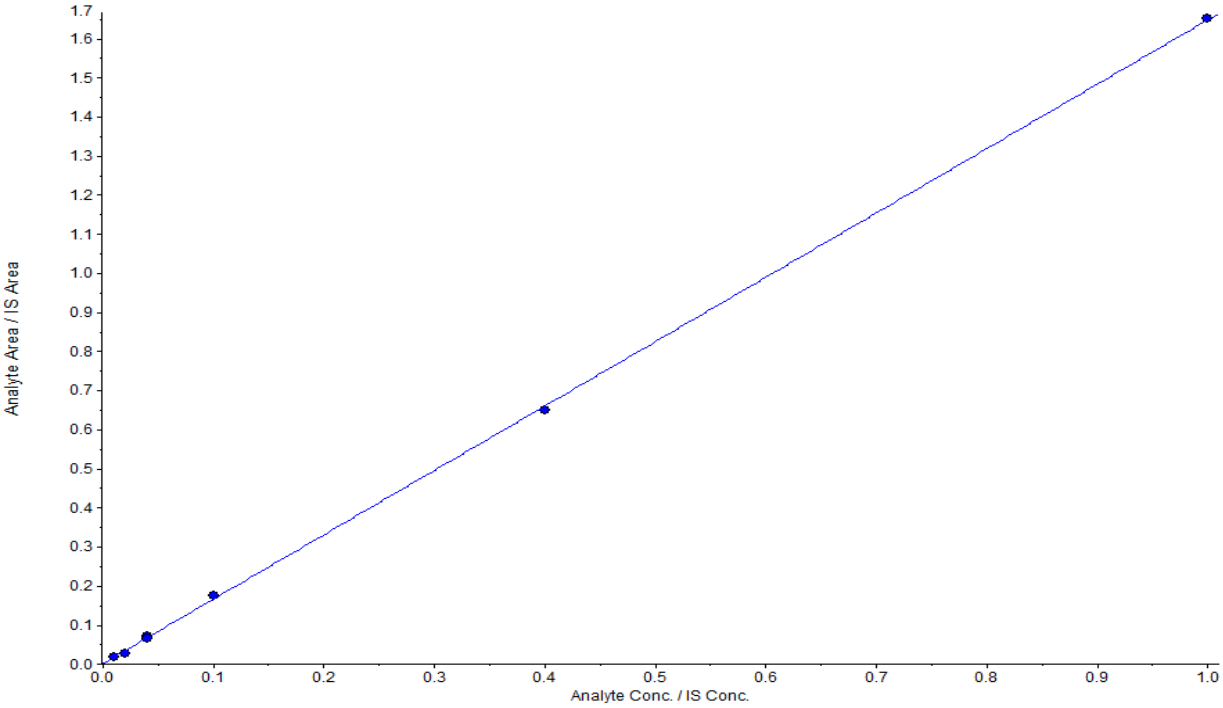


Figure 9. Representative Chromatogram of a Laboratory Control Hand Wash Sample

(503SET03-1)

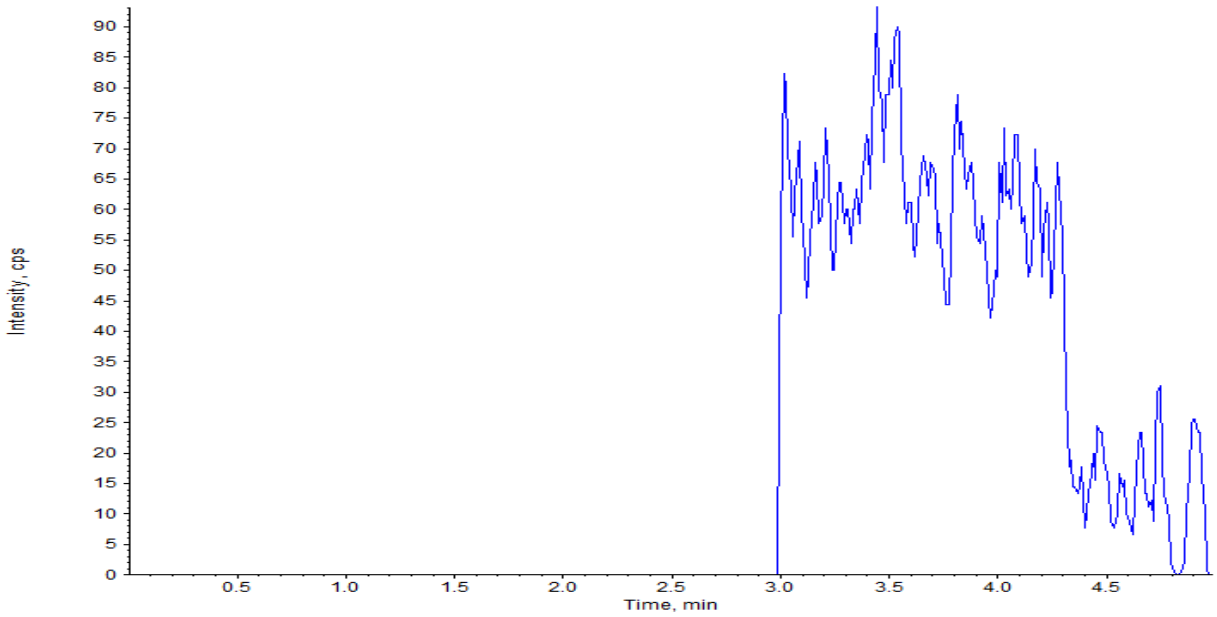


Figure 10. Representative Chromatogram of a Low Laboratory Fortified Hand Wash Sample at 0.521 µg/sample

(503SET03-2)

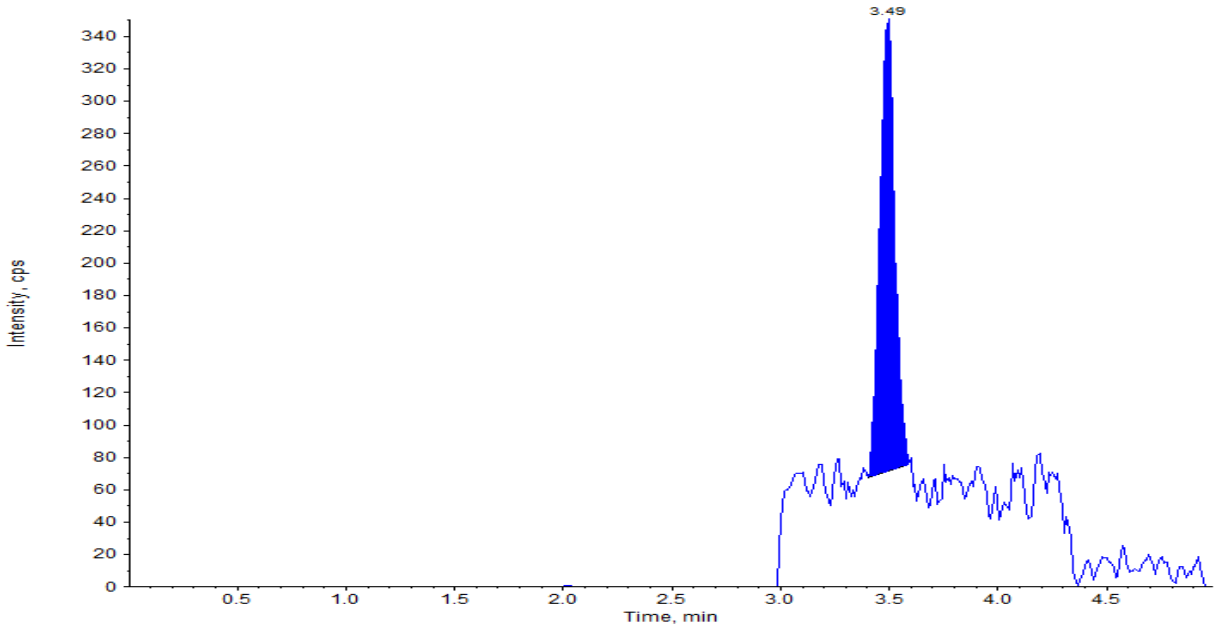


Figure 11. Representative Chromatogram of a High Laboratory Fortified Hand Wash Sample at 77.9 µg/sample

(503SET03-3)

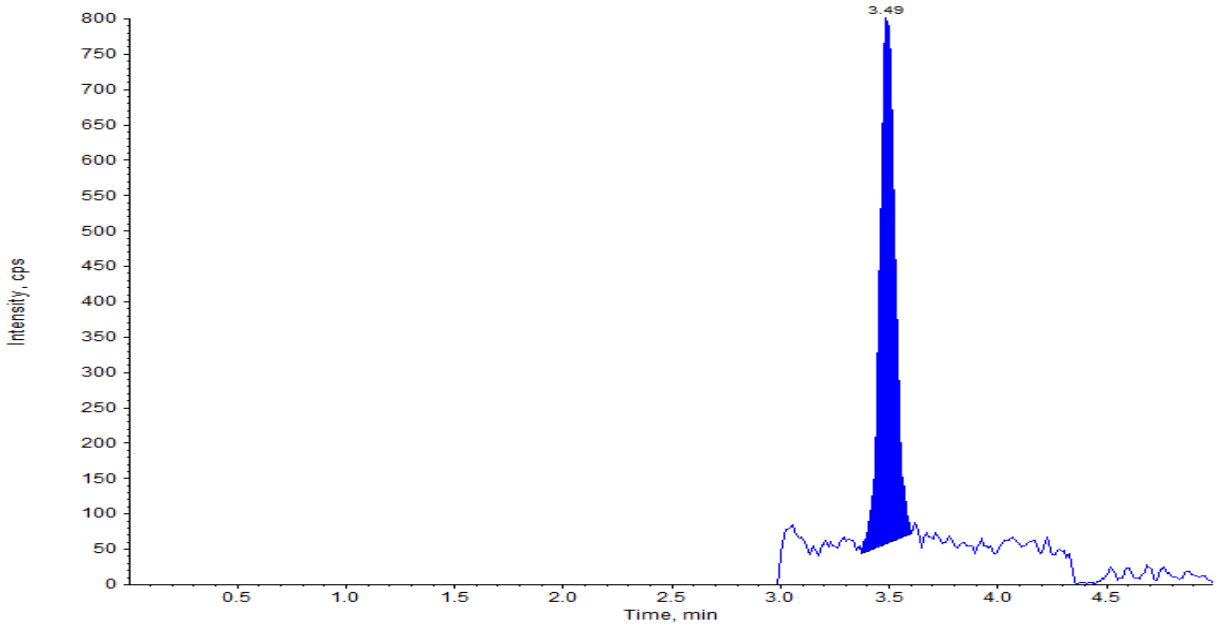


Figure 12. Representative Chromatogram of a Field Control Hand Wash Sample

(503SET03-14)

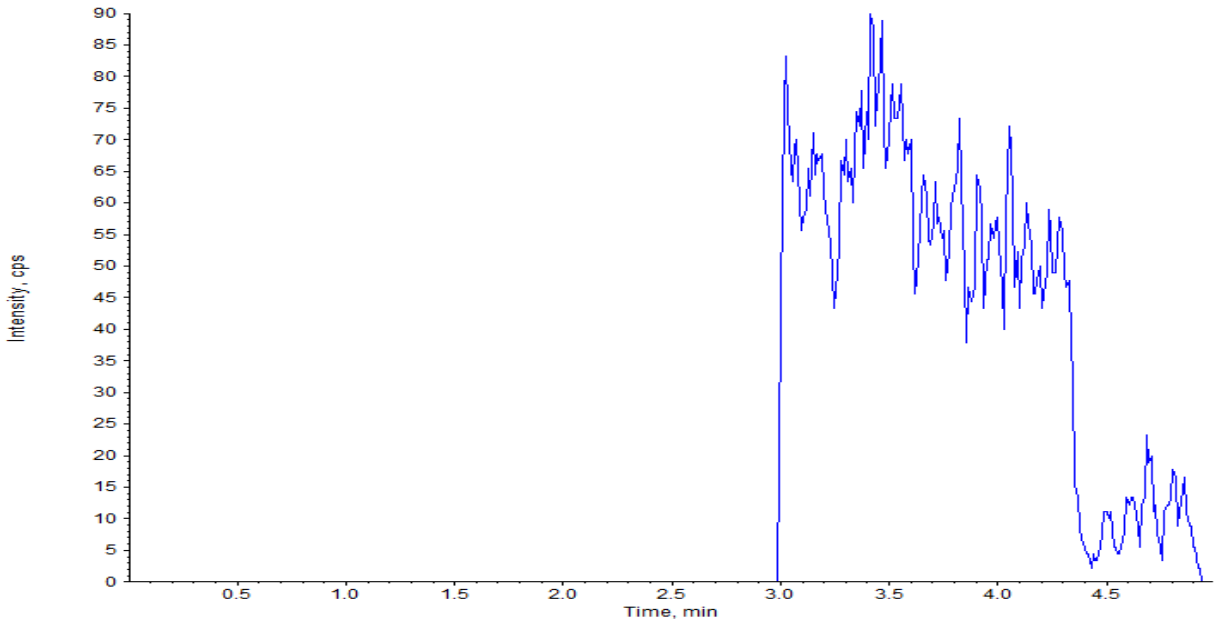


Figure 13. Representative Chromatogram of a Low Field Fortified Hand Wash Sample at 22.6 µg/sample

(503SET03-15)

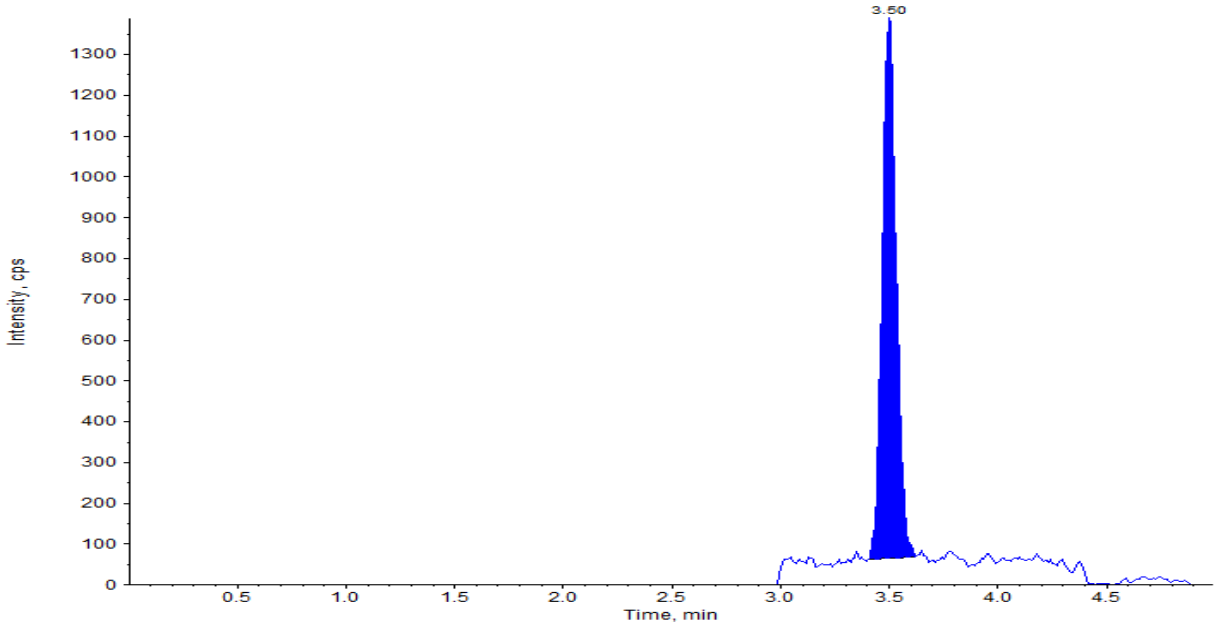


Figure 14. Representative Chromatogram of a High Field Fortified Hand Wash Sample at 79.2 µg/sample

(503SET03-18)

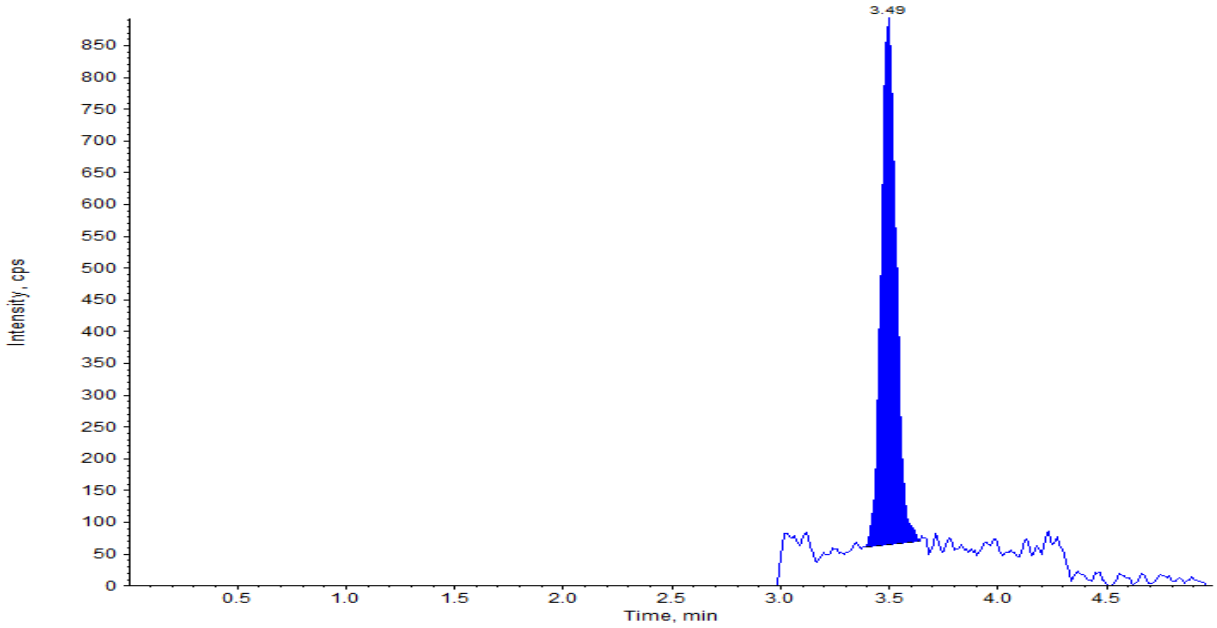


Figure 15. Representative Chromatogram of a Hand Wash Sample Applying Paint Containing 154 ppm of BIT to Subjects Hands

(503SET03-7)

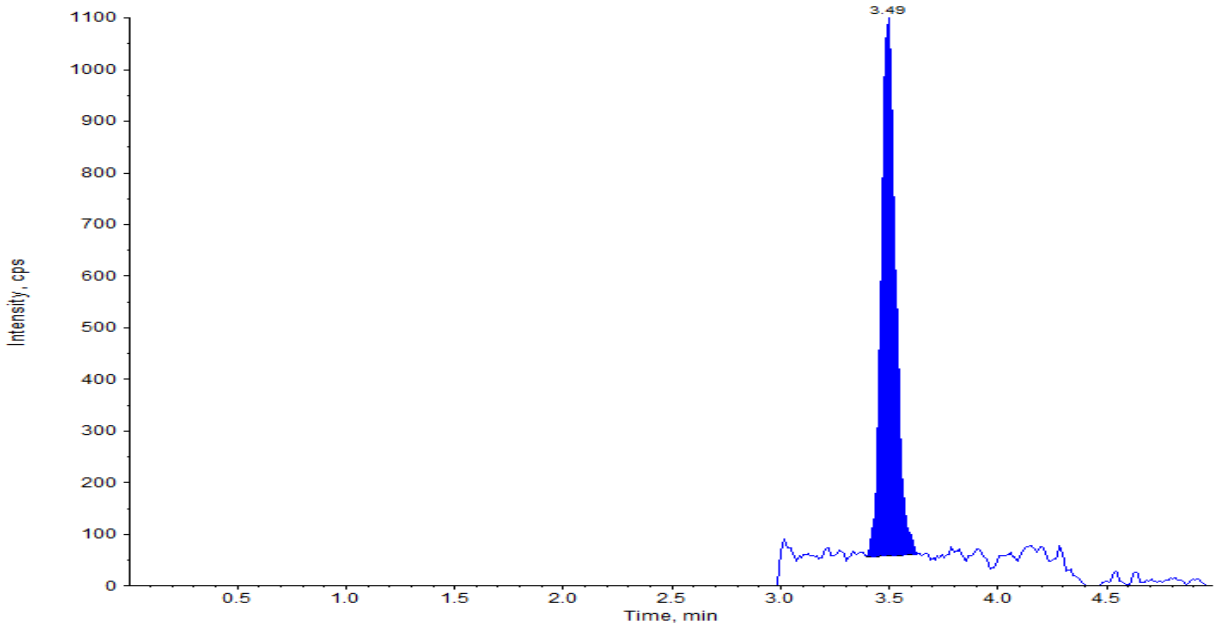


Figure 16. Representative Chromatogram of a Hand Wash Sample Applying Paint Containing 154 ppm of BIT to Subjects Hands

(503SET03-11)

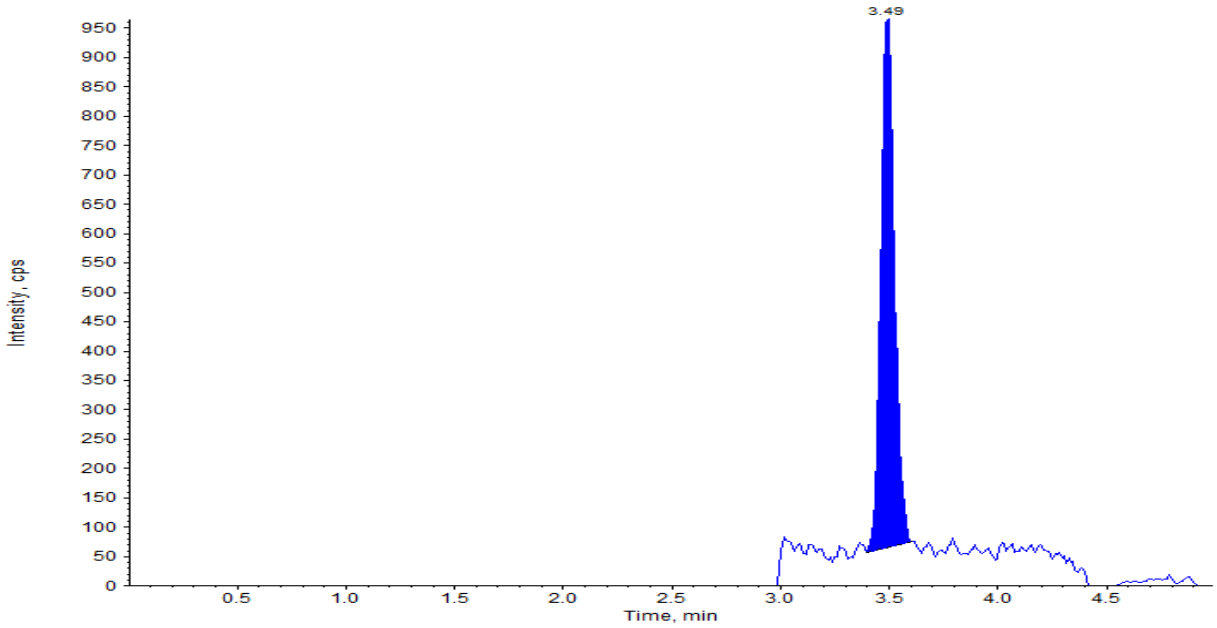


Figure 17. Representative Chromatogram of a Hand Wash Sample Applying Paint Containing 547 ppm of BIT to Subjects Hands

(503SET04-5)

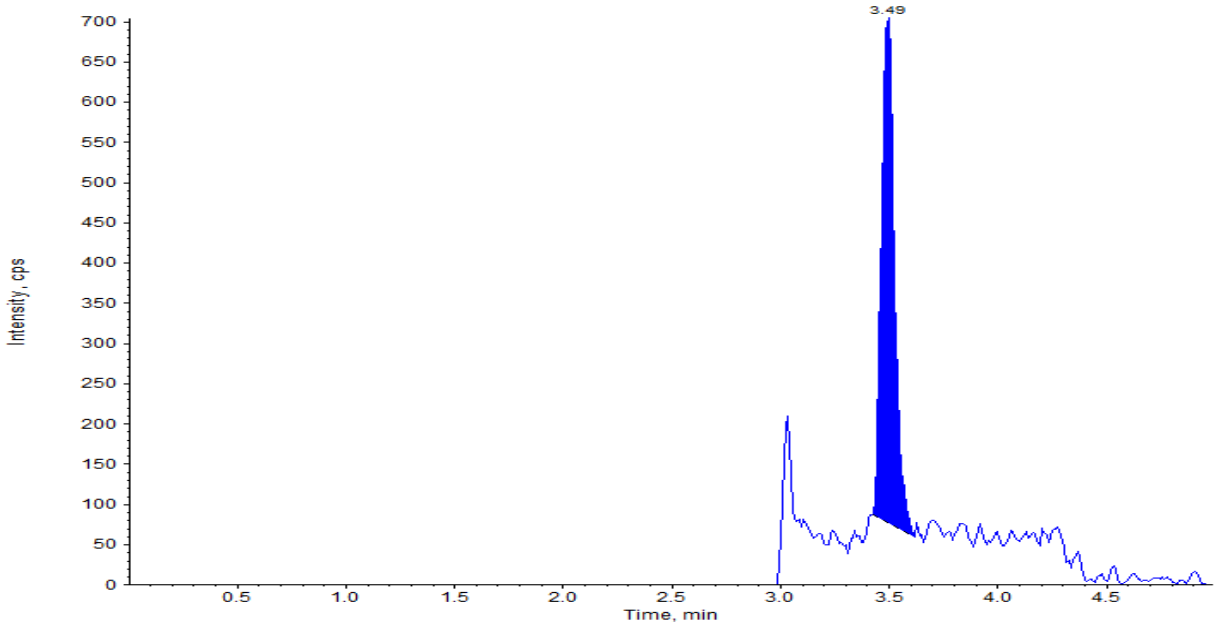
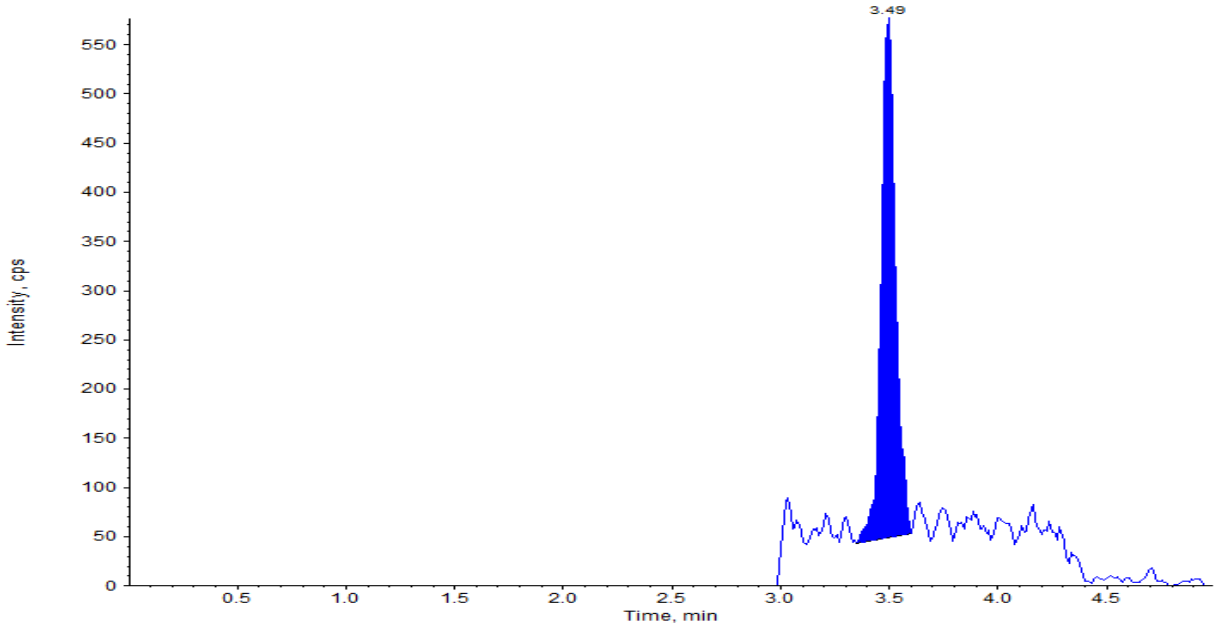


Figure 18. Representative Chromatogram of a Hand Wash Sample Applying Paint Containing 547 ppm of BIT to Subjects Hands

(503SET04-10)



APPENDIX F.

CORRESPONDENCE WITH IIRB AND IIRB MEETING MINUTES

Table of Content

Date	Page Range	Document(s)
4 Feb 14	380-381	JAtlas→MBoatwright responding to Item 6 of Check List with Letter from Operations Manager as an attachment
	382	Letter from Operations Manager
11 Mar 14	383	JAtlas→MBoatwright inquiring of progress of study
11 Mar 14	384	RTestman→JAtlas responding with schedule for HSRB meeting on April 8 and expected timelines for process
17 June 14	385-388	JAtlas↔RTestman exchanging request and response of status of EPA/HSRB review and final written approval
4 Sept 14	389-391	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
	392-395	Single Site Study Periodic and Continuing Review Report From Version: September 2013
13 Oct 14	396-398	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	399	JAtlas→RTestman reminding of expiration date and providing form to be completed for continued review
	400-403	Single Site Study Periodic and Continuing Review Report From Version: September 2013
6 Nov 14	404-405	JAtlas→RTestman reminding of timeline to get form submitted and again providing form
	406-409	Single Site Study Periodic and Continuing Review Report From Version: September 2013
6 Nov 14	410-411	MBoatwright→JAtlas transmittal of Single Site Study Periodic and Continuing Review Report Form and letter from PI explaining delay in providing final protocol
	412	Letter from PI
	413-416	Single Site Study Periodic and Continuing Review Report From
11 Nov 14	417-422	DMartz↔MBoatwright exchanging request and response of CV for W Harkey, RN
	423	CV for W Harkey
	424	Nurses License
17 Nov 14	425	Schulman Technical Support→MBoatwright informing of Re-Approval Letter available via SiteAccess
	426	Re-approval Letter Dated November 13, 2014
9 Dec 14	427	Memorandum notifying of language mistakes in Re-Approval Letter issued November 13, 2014 and issue of corrected letter
	428	Corrected letter dated 12/09/14
2 Feb 15	429-430	RTestman→JAtlas transmittal of final Protocol 130503 dated 02 February 2015 along with protocol in tracked changes
	431-533	Protocol 130503 dated 02 February 2015 (Final)
	534-627	Protocol 130503 dated 02 February 2015 (Tracked Changes)

Date	Page Range	Document(s)
2 Feb 15	628-631	JAtlas↔RTestman exchanging request and response to expediting review and need for word versions of Appendices to be translated
	632	English Newspaper Advertisement
	633	English Subject Invitation to Participate Script
	634	English Qualification Worksheet
2 Feb 15	635-638	JAtlas→RTestman request for documents from CDPR and HSRB indicating review and approval
2 Feb 15	639-643	RTestman→JAtlas providing EPA Letter of Review, CDPR Letter of Review, Letter and response summary for CDPR Review, CDPR e-mail confirming and acceptance of GPL changes and response
	644-686	EPA Letter dated March 18, 2014
	687-692	CDPR Letter dated December 19, 2013
	693	Letter to CDPR from GPL dated January 23, 2014
	694-705	Summary of CDPR Comments, GPL Response, and Protocol Modifications
5 Feb 15	706	DGuzman→RTestman notification of outcome of Board expedited review of response to final condition of approval and providing Study Status Notification III which communicates status remains conditionally approved pending response to listed findings
	707-708	Study Status Notification III – Conditionally Approved
5 Feb 15	709-710	RTestman→DGuzman responding to video recording finding
6 Feb 15	711-712	DGuzman→RTestman confirming language for video recording section in protocol and adding recommended wording to add
6 Feb 15	713	RTestman→DGuzman transmittal of response letter from PI, revised protocol in tracked changes and protocol without tracked changes
	714	Cover Letter to SAIRB from PI responding to Study Status Notification III
	715-808	Protocol 130503 in tracked changes dated 05 February 2015
	809-912	Protocol 130503 dated 05 February 2015 (changes accepted)
6 Feb 15	913-914	DGuzman→RTestman acknowledgement of receipt
9 Feb 15	915	DGuzman→RTestman notification of expedited review accepting responses fulfilling conditions of approval
	916	Study Status Notification IV
9 Feb 15	917	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	918-919	Initial Approval Documents dated February 9, 2015
	920-928	Informed Consent Form (English) in tracked changes
	929-938	Informed Consent Form (English) SCHULMAN APPROVED, IRB # 201307366, Date: 02/06/15

Date	Page Range	Document(s)
10 Feb 15	939	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	940	Certification Letter of Translated Recruitment/Study –Related Materials Appendix G: Subject Invitation to Participate Script
	941-942	Spanish Subject Invitation to Participate Script dated 02/06/15
	943	Certification Letter of Translated Recruitment/Study –Related Materials Appendix F: Newspaper Advertisement
	944-945	Spanish Newspaper Advertisement dated 02/06/15
	946	Certification Letter of Translated Recruitment/Study –Related Materials Appendix D: Subject Self Reporting Demographic Form
	947-948	Spanish Subject Self Reporting Demographic Form dated 02/06/15
12 Feb 15	949	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	950	Certification Letter of Translated Approved Documents Spanish Informed Consent
	951-961	Spanish Informed Consent dated 02/06/15
12 Feb 15	962	RTestman→DGuzman acknowledgement of receipt of all translated material and request for change to Spanish Informed Consent
13 Feb 15	963-964	DGuzman→RTestman acknowledgement of request and change in Schulman contact to Jeff Atlas for this study
13 Feb 15	965-966	JAtlas→RTestman informing the revised consent for was received and being issued
13 Feb 15	967	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	968	Memorandum Corrected Spanish Informed Consent
	969-979	Spanish Informed Consent dated 02/06/15 Corrected Spanish Document 02-13-15
27 Mar 15	980	MBoatwright→JAtlas transmittal of Protocol Amendment 1
	981-987	Protocol Amendment 1
27 Mar 15	988	JAtlas→MBoatwright acknowledgement of receipt and request to complete attached form
	989-990	Protocol/Informed Consent Change Submission Form
27 Mar 15	991	MBoatwright→submissions@sairb.com transmittal of Protocol/Informed Consent Change Submission Form and Protocol Amendment 1
	992-993	Protocol/Informed Consent Change Submission Form dated March 27, 2015
	994-1000	Protocol Amendment 1

Date	Page Range	Document(s)
27 Mar 15	1001	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	1002	Letter dated March 27, 2015 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 1
29 April 15	1003	Site Reminder→MBoatwright transmittal of Events to Report Reminder
14 July 15	1004	MBoatwright→submissions@sairb.com transmittal of Protocol/Informed Consent Change Submission Form and Protocol Amendment 2
	1005-1006	Protocol/Informed Consent Change Submission Form dated July 14, 2015
	1007	Protocol Amendment 2
15 July 15	1008	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	1009	Letter dated July 15, 2015 Updated Approval Documents documenting expedited review and approval of Protocol Amendment 2
14 Sept 15	1010-1011	Site Reminder→MBoatwright transmittal that periodic review is due in 8 weeks 1st reminder
30 Sept 15	1012-1013	Site Reminder→MBoatwright transmittal that periodic review is due in 6 weeks 2nd reminder
12 Oct 15	1014-1015	Site Reminder→MBoatwright transmittal that periodic review is due in 4 weeks 3rd reminder
12 Oct 15	1016	MBoatwright→submissions@sairb.com and JAtlas transmittal of Protocol/Informed Consent Change Form and Protocol Deviation 1
	1017-1018	Protocol/Informed Consent Change Form dated October 12, 2015
	1019	Protocol Deviation 1
12 Oct 15	1020-1021	JAtlas→MBoatwright acknowledgement of receipt and reminder to submit through eSubmission portal
12 Oct 15	1022-1026	Single Site Study Periodic and Continuing Review Report (submitted via eSubmission portal)
12 Oct 15	1027	Schulman Technical Support→MBoatwright acknowledgement of receipt of Protocol/Informed Consent Change Form dated October 12, 2015 and Protocol Deviation 1
12 Oct 15	1028	Schulman Technical Support→MBoatwright acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report and supporting material
15 Oct 15	1029	Schulman Ongoing Review→MBoatwright requesting additional information to support submitted Single Site Study Periodic and Continuing Review Report

Date	Page Range	Document(s)
15 Oct 15	1030-1031	MBoatwright→ OngoingReviewFollowup providing requested material and response to findings
	1032-1041	Spanish Informed Consent Form Redacted
22 Oct 15	1042	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	1043	Re-Approval Letter dated October 15, 2015
6 April 6	1044	Site Reminder→MBoatwright transmittal of Events to Report Reminder
26 Aug 16	1045	Site Reminder→MBoatwright transmittal that periodic review is due in 8 weeks 1st reminder
9 Sept 16	1046	Site Reminder→MBoatwright transmittal that periodic review is due in 6 weeks 2nd reminder
12 Sept 16	1047-1051	Single Site Study Periodic and Continuing Review Report (submitted via eSubmission portal)
12 Sept 16	1052-1053	Single Site Study Periodic and Continuing Review Report Form Submission Receipt (submitted via eSubmission portal)
12 Sept 16	1054	Schulman Technical Support→MBoatwright acknowledgement of receipt of Single Site Study Periodic and Continuing Review Report and supporting materials
12 Sept 16	1055	MBoatwright→ OngoingReviewFollowup notifying committee of correction needed to Single Site Study Periodic and Continuing Review Report submitted on September 12, 2016
12 Sept 16	1056	MGoodwin→MBoatwright acknowledging receipt of clarification and confirming matching to report for explanation of discreancy
27 Sept 16	1057	Schulman Technical Support→MBoatwright notification of IRB documents available via SAIRB SiteAccess
	1058	Re-Approval Letter dated September 27, 2016
14 Mar 17	1059-1060	Protocol/Informed Consent Change Form (submitted via eSubmission portal) for Protocol Deviation 2
14 Mar 17	1061-1062	Study Change Form – Form Summary
14 Mar 17	1063	Schulman Technical Support→MBoatwright acknowledgement of receipt of Protocol/Informed Consent Change Form and supporting material
23 May 17	1064-1065	Schulman Technical Support→MBoatwright acknowledgement of receipt of Noncompliance Issue/Deviation Submission (submitted via eSubmission portal)
23 May 17	1066	Schulman Technical Support→MBoatwright acknowledged receipt of Closeout Report dated May 23, 2017 (submitted via eSubmission portal)
25 May 17	1067	MHoltman→MBoatwright notification of incorrect entry of date for the consent of the first subject on the closeout report.

Date	Page Range	Document(s)
25 May 17	1068	Schulman Technical Support→MBoatwright informing that Study Closure letter dated May 25 2017 was posted and available via Schulman IRB SiteAccess.
	1069	Study Closure letter dated May 25 2017

SCHULMAN
ASSOCIATES IRB

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:** 130503 **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): Megan T. Boatwright, B.S.
Office Phone Number to appear on IC (Optional): 559-275-9091
24-Hour Phone Number to appear on IC (Required): 559-917-1736

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:	mboatwright@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): _____

b. Please specify which of these additional locations are to be listed on the Informed Consent (attach additional sheets if necessary): _____

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:	_____

SCHULMAN
ASSOCIATES IRB

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.

Single Site Study Submission Form

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)

Single Site Study Submission Form

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: Golden Pacific Laboratories' conference room	

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

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

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

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: Megan T. Boatwright, B.S.	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: _____
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:

Single Site Study Submission Form

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

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.

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.

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

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;

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

Megan Boatwright
Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature

11/08/2013
Signature Date (mm/dd/yyyy)

Megan T. Boatwright, Laboratory Manager
Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

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.

Natan R. Chavez, Laboratory Technician — Date 8/2/2012

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 TFM 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
Robert J. Testman

TITLE
President

PREPARED BY:
Omer 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)
Elmer Griffin

TITLE OF COLLECTOR
Compliance Officer

SIGNATURE OF COLLECTOR
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	FIRM ADDRESS (NUMBER, STREET, CITY, STATE AND ZIP CODE)
Golden Pacific Laboratories	4720 West Jennifer Ave Suite 105 Fresno, CA 93722
NAME OF OWNER OR AGENT IN CHARGE: Thomas Maita	
SIGNATURE OF OWNER OR AGENT IN CHARGE (SIGNATURE GRANTS CONSENT TO INSPECTION): Thomas Maita	SIGNATURE OF EPA EMPLOYEE: Elmer Fullam
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

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Megan Boatwright** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 05/25/2011

Certification Number: 686633

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

Principal Investigator:
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:

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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint or rubbing (isopropyl) alcohol containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. 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) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 BIT in rubbing alcohol. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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; 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. 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 your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze pads wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe sample, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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. 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 have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

***DRAFT* PROTOCOL**

01 November 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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

April 2014

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 77

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1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	April 2014
Proposed Experimental Termination Date:	June 2014
Proposed Final Report Issue Date:	August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
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8C.2	Dermal Face/Neck Wipe Samples	10.0
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10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.1	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

Sponsor:

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:

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

Field Research Associates:	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
Quality Assurance Unit:	Margaret A. Hamelin Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mhamelin@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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated by testing BIT in solvent will better enable extrapolation of the BIT in paint data to other antimicrobial active ingredients. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. 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.

The test substances in this study are latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 µg/mL and 3.9 mg/mL. The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection, therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 10 subjects at one of two concentrations (5 subjects each). A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. Hand exposure will be measured by scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs their hands together. The gauze pads will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in IPA or latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The data generated by testing BIT in solvent will better enable extrapolation of the paint data to other antimicrobial active ingredients. The primary objective of this study is to determine the removal efficiency of BIT in latex paint, and in IPA from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to extrapolate data from existing human hand removal efficiency studies. In this study, at least 20 subjects (5 for each scenario) will be monitored in order to capture the expected variation in skin differences, concentration, and paint or solvent as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions

(Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT. Even if all of the applied BIT were absorbed this would represent about 0.009 mg/Kg for a 50 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorbtion.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used on the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 30 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is

quite low. 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint or solvent from human skin is not available. Removal efficiency studies which have been conducted with other actives do not provide for interpretation of BIT removal, or the removal of any actives in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substances for this study are the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT) and BIT prepared in isopropyl alcohol (IPA). BIT is the active ingredient selected for measurement in the proposed paint

applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

B. Test Substance Identification – BIT in Solvent

The reference substance 1,2-Benzisothiazol-3(2H)-one (BIT) will be prepared at approximately 786 µg/mL and 3.9 mg/mL using isopropyl alcohol (HPLC grade) as the dilution solvent.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be recorded in the raw data
Purity:	to be recorded in the raw data
Date Received:	to be recorded in the raw data
Expiration Date:	to be recorded in the raw data

C. 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.

BIT in solvent will be used as a second test substance in order to provide comparative removal efficiency information between a paint matrix and solvent. This information will be used to improve extrapolation of data for other actives which may have removal efficiency data in solvent to a paint matrix.

The analytical method for the determination of BIT in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

D. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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.

E. Calibration of Application Equipment

BIT in paint or solvent will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

F. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint or IPA.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of four groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 786 µg/mL in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/mL in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tube. The glass capillary tube will be placed into a glass test tube and retained for analysis.

The paint or solution will be left on the hands to dry for 45 minutes. Each hand will then be washed by scrubbing with a gauze wipe soaked in 50% IPA / 50% distilled water solution and rinsed with the same solution. The solution and gauze wipe will be collected as a single sample for each hand, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. Either a 500 µL volume of the appropriate paint concentration or a 100 µL volume of the appropriate solvent concentration will be applied. A glass capillary tube will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread

closer than 2 cm from any edge of the palmar surface. The capillary tube from each subject will be placed into a glass test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects 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.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into four groups. Two groups will receive BIT applied in paint, and two groups will receive BIT applied in IPA. The four groups are described below:

Group 1	500 µL of latex paint containing ca. 120 ppm BIT
Group 2	500 µL of latex paint containing ca. 600 ppm BIT
Group 3	100 µL of ~ 786 µg/mL fortification solution of BIT in IPA
Group 4	100 µL of ~ 3.9 mg/mL fortification solution of BIT in IPA

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four groups, each corresponding to one of the four test substance/concentration combinations. The first set of seven subjects will be placed into Group 1, the second set of seven subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4.

Within each group of seven, the first five subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the group of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into four groups, subjects from the first group will be scheduled into the study. No more than two groups will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., five subjects for each of four groups). As described above, an additional eight subjects (two per cluster) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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 ask the subject if he/she is taking any medication and 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects

have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- Consider their self to be in good health

- 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

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 or sensitivities 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)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer an 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. If a monitoring event is terminated early due to medical reasons any samples from the subject will not be analyzed.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with

water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

B. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

C. 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 (hand wipe/wash solutions containing gauze wipes) will take place on each day of the study. Field fortification solutions of BIT in latex paint or in solvent will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the hand wash samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm
IPA	100 µL	Approximately 786 µg/mL
IPA	100 µL	Approximately 3.9 mg/mL

On each study day, samples will be fortified as shown above in duplicate. Duplicate control hand wash samples will also be prepared.

Hand wash samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL-LH:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
LH = Left Hand
Additional designations are as follows:
S = Solvent
H = High Concentration Level
RH = Right Hand

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at $\leq$ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze wipes is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The IPA test substances will be analyzed by diluting to an appropriate concentration with 50% acetonitrile /50% water, vialing with internal standard, and analyzing by HPLC/MS/MS. The capillary pipets used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the capillary tubes used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the QAU. The QAU will report to the President of

Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.
3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.

13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

_____

Has Shah, Ph.D. Date
Sponsor's Representative

_____

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

_____

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

_____

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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 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 Finishes 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% by weight 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 of 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 –	Simicides (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 product weight or 1.5-4.5 on the dry polysaccharide weight. Subsurface injection waters such as polysaccharides-0.015-0.15% on solution weight. Thickeners such as xanthan gum and

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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:

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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint or rubbing (isopropyl) alcohol containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. 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) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 BIT in rubbing alcohol. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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; 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. 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 your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze pads wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe sample, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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. 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 have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*	
6. Name	
7. Address	
8. City, ST, Zip	
9. Telephone(s)	

10. Age in years =	11. DOB:	12. Sex M F	
13. Resident in Fresno County? Yes No			
14. Preferred Language: English Spanish		15. Reads: English Spanish	
16. Are you pregnant? NA Yes No		17. Are you nursing a baby? NA Yes No	
18. Do you consider your general health good? Yes No			
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? Yes No			
20. 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 AND BIT REFERENCE SUBSTANCE

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

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.

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.

SIGMA-ALDRICH

sigma-aldrich.com

Material Safety Data Sheet

Version 4.2
Revision Date 10/05/2012
Print Date 05/30/2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Supplier	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052
Emergency Phone # (For both supplier and manufacturer)	:	(314) 776-6555
Preparation Information	:	Sigma-Aldrich Corporation Product Safety - Americas Region 1-800-521-8956

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

GHS Classification
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Serious eye damage (Category 1)
Skin sensitization (Category 1)
Acute aquatic toxicity (Category 1)

GHS Label elements, including precautionary statements

Pictogram

Signal word: Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary statement(s)

P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

HMIS Classification

Health hazard:	2
Flammability:	0
Physical hazards:	0

NFPA Rating

Health hazard:	2
Fire:	0
Reactivity Hazard:	0

Potential Health Effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.
Ingestion	Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula	: C_7H_5NOS
Molecular Weight	: 151.19 g/mol

Component		Concentration
1,2-Benzisothiazolin-3-one		
CAS-No.	2634-33-5	-
EC-No.	220-120-9	
Index-No.	613-088-00-6	

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	crystalline
Colour	light yellow

Safety data

pH	no data available
Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Autoignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Vapour pressure	no data available
Density	no data available
Water solubility	no data available

Partition coefficient: n-octanol/water	no data available
Relative vapour density	no data available
Odour	no data available
Odour Threshold	no data available
Evaporation rate	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
no data available

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides
Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50
LD50 Oral - rat - 1,020 mg/kg

Inhalation LC50
no data available

Dermal LD50
no data available

Other information on acute toxicity
no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
May cause allergic skin reaction.

Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects
no data available

Additional Information
RTECS: DE4620000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint or rubbing alcohol on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 5/30/2013

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 removal efficiency 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 removed from the palms of your hand when paint or rubbing alcohol containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint or rubbing alcohol on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze wipe. We will collect the wash water and gauze wipe. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Hand	Target BIT Concentration
AEA08-RE-01-PL-LH	1	Left	120 ppm
AEA08-RE-01-PL-RH	1	Right	120 ppm
AEA08-RE-02-PL-LH	2	Left	120 ppm
AEA08-RE-02-PL-RH	2	Right	120 ppm
AEA08-RE-03-PL-LH	3	Left	120 ppm
AEA08-RE-03-PL-RH	3	Right	120 ppm
AEA08-RE-04-PL-LH	4	Left	120 ppm
AEA08-RE-04-PL-RH	4	Right	120 ppm
AEA08-RE-05-PL-LH	5	Left	120 ppm
AEA08-RE-05-PL-RH	5	Right	120 ppm
AEA08-RE-06-PH-LH	6	Left	600 ppm
AEA08-RE-06-PH-RH	6	Right	600 ppm
AEA08-RE-07-PH-LH	7	Left	600 ppm
AEA08-RE-07-PH-RH	7	Right	600 ppm
AEA08-RE-08-PH-LH	8	Left	600 ppm
AEA08-RE-08-PH-RH	8	Right	600 ppm
AEA08-RE-09-PH-LH	9	Left	600 ppm
AEA08-RE-09-PH-RH	9	Right	600 ppm
AEA08-RE-10-PH-LH	10	Left	600 ppm
AEA08-RE-10-PH-RH	10	Right	600 ppm
AEA08-RE-11-SL-LH	11	Left	786 µg/mL
AEA08-RE-11-SL-RH	11	Right	786 µg/mL
AEA08-RE-12-SL-LH	12	Left	786 µg/mL
AEA08-RE-12-SL-RH	12	Right	786 µg/mL
AEA08-RE-13-SL-LH	13	Left	786 µg/mL
AEA08-RE-13-SL-RH	13	Right	786 µg/mL
AEA08-RE-14-SL-LH	14	Left	786 µg/mL
AEA08-RE-14-SL-RH	14	Right	786 µg/mL
AEA08-RE-15-SL-LH	15	Left	786 µg/mL
AEA08-RE-15-SL-RH	15	Right	786 µg/mL
AEA08-RE-16-SH-LH	16	Left	3.9 mg/mL
AEA08-RE-16-SH-RH	16	Right	3.9 mg/mL
AEA08-RE-17-SH-LH	17	Left	3.9 mg/mL
AEA08-RE-17-SH-RH	17	Right	3.9 mg/mL
AEA08-RE-18-SH-LH	18	Left	3.9 mg/mL
AEA08-RE-18-SH-RH	18	Right	3.9 mg/mL
AEA08-RE-19-SH-LH	19	Left	3.9 mg/mL
AEA08-RE-19-PH-RH	19	Right	3.9 mg/mL
AEA08-RE-20-PH-LH	20	Left	3.9 mg/mL
AEA08-RE-20-PH-RH	20	Right	3.9 mg/mL

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-S-01-C	Control	None
AEA08-FF-S-01-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-01-H2	High Fortified with Solvent	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg
AEA08-FF-S-02-C	Control	None
AEA08-FF-S-02-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-02-H2	High Fortified with Solvent	390 µg

SCHULMAN ASSOCIATES IRB

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Secure electronic submission system
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eSubmission Summary

Thank you for your secure eSubmission to Schulman Associates IRB.

You will receive a confirmation e-mail within 15 minutes. If you do not receive this e-mail confirmation, please contact Technical Support.

The following items have been submitted on Friday November 08, 2013 6:04 PM:

Checked Document Type
☑ Site Submission Form
☑ CVs (PI/QI and Sub-Investigators)
☑ Protocol
☑ Informed Consent (Unlocked Word Version)
☑ Other

Additional documents:
Documents for EPA Audits and Certificate from NIH for PI;
Files Uploaded:

1. CV PI AND SUBI (3).pdf (1084.7 KB) - upload successful.
2. EPA INSPECTION.pdf (1384.7 KB) - upload successful.
3. NIH CERT - MEGAN BOATWRIGHT.pdf (115.6 KB) - upload successful.
4. INFORMED CONSENT FORM Nov0813.docx (32.0 KB) - upload successful.
5. Protocol 130503 BIT Removal Effeciency 01Nov2013 Draft.docx (4595.2 KB) - upload successful.
6. submission form.pdf (1221.9 KB) - upload successful.

Print Summary | Submit More | Logout

4445 Lake Forest Drive, Suite 300
Cincinnati, Ohio 45242
513.761.4100

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Friday, November 08, 2013 2:39 PM
To: Megan Boatwright
Subject: eSubmission System - Document Submission Confirmation

Importance: High

Megan,

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: Documents for EPA Audits and Certificate from NIH for PI
Additional Instructions:

List of Uploaded Files
(1) CV PI AND SUBI (3).pdf (1084.7 KB)
(2) EPA INSPECTION.pdf (1384.7 KB)
(3) NIH CERT - MEGAN BOATWRIGHT.pdf (115.6 KB)
(4) INFORMED CONSENT FORM Nov0813.docx (32.0 KB)
(5) Protocol 130503 BIT Removal Effeciency 01Nov2013 Draft.docx (4595.2 KB)
(6) submission form.pdf (1221.9 KB)

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone 5592759091
Email: mboatwright@gplabs.com

SCHULMAN Associates IRB, Inc.
www.sairb.com

Megan Boatwright

From: Nina Chinery-Hesse <NChinery-Hesse@sairb.com>
Sent: Wednesday, November 13, 2013 5:44 AM
To: Megan Boatwright
Cc: Jeffrey Atlas; Denisse Guzman
Subject: Protocol 130503 for Board review 11/14/2013

Dear Megan,

Thank you for submitting your new study. The screening process for 130503 is complete and the study and has been scheduled for review at the Board meeting on 130503.

The following items were identified during the screening process and will require clarification:

1. It was noted that the protocol indicates that it is a "draft" version. Please provide us with a final version of the protocol or a rationale for why the protocol must be reviewed in draft form.

2. Item 3 on page 16 of the protocol indicates that the Principal Investigator (PI) or on-site health professional will check subject's hands for any cracking, bleeding , sores or other disqualifying skin problems. Item 10 on page 17 indicates that the PI or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. The protocol also makes several other references to the role of the on-site health professional in assessing skin reactions or adverse events. Please clarify whether the on-site health professional is part of the study staff and if so, please provide their CV and credentials as well as an updated Single Site Study Submission Form which lists the on-site health professional as a Sub-Investigator.

Please note that the Screening Process is separate from Board Review and may not reflect the opinions of the Board. This process is designed to identify regulatory concerns, protocol and IC inconsistencies and errors and to obtain all information to support the Board in their review of your study.

Failure to provide responses to these items in a timely manner may result in a delay in review of your study by the Full Board.

Any changes made to the protocol will require authenticated documentation to support the chan or a signed Administrative Letter. Some clarifications may be provided by Sponsor or Site email.

Thank you for your prompt attention to this matter.

Nina

Nina Chinery-Hesse, MS | Board Liaison
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
nchinery-hesse@iirb.com | Visit us at http://www.iirb.com

P Please consider the environment before printing this e-mail.

Megan Boatwright

From: Megan Boatwright
Sent: Thursday, November 14, 2013 11:27 AM
To: 'Nina Chinery-Hesse'
Cc: Jeffrey Atlas; Denisse Guzman
Subject: RE: Protocol 130503 for Board review 11/14/2013
Attachments: Willa H.pdf

Hi Nina,

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 after it is signed.
2. The on-site health professional will be a RN 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. I have added the nurse we will ask to work with us RN card and NIH certificarte.

Feel free to give me a call to discuss either of these items.

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

From: Nina Chinery-Hesse [mailto:NChinery-Hesse@sairb.com]
Sent: Wednesday, November 13, 2013 5:44 AM
To: Megan Boatwright
Cc: Jeffrey Atlas; Denisse Guzman
Subject: Protocol 130503 for Board review 11/14/2013

Dear Megan,

Thank you for submitting your new study. The screening process for 130503 is complete and the study and has been scheduled for review at the Board meeting on 130503.

The following items were identified during the screening process and will require clarification:

1. It was noted that the protocol indicates that it is a "draft" version. Please provide us with a final version of the protocol or a rationale for why the protocol must be reviewed in draft form.

2. Item 3 on page 16 of the protocol indicates that the Principal Investigator (PI) or on-site health professional will check subject's hands for any cracking, bleeding , sores or other disqualifying skin problems. Item 10 on page 17 indicates that the PI or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. The protocol also makes several other references to the role of the on-site health professional in assessing skin reactions or adverse events. Please clarify whether the on-site health professional is part of the study staff and if so, please provide their CV and credentials as well as an updated Single Site Study Submission Form which lists the on-site health professional as a Sub-Investigator.

Please note that the Screening Process is separate from Board Review and may not reflect the opinions of the Board. This process is designed to identify regulatory concerns, protocol and IC inconsistencies and errors and to obtain all information to support the Board in their review of your study.

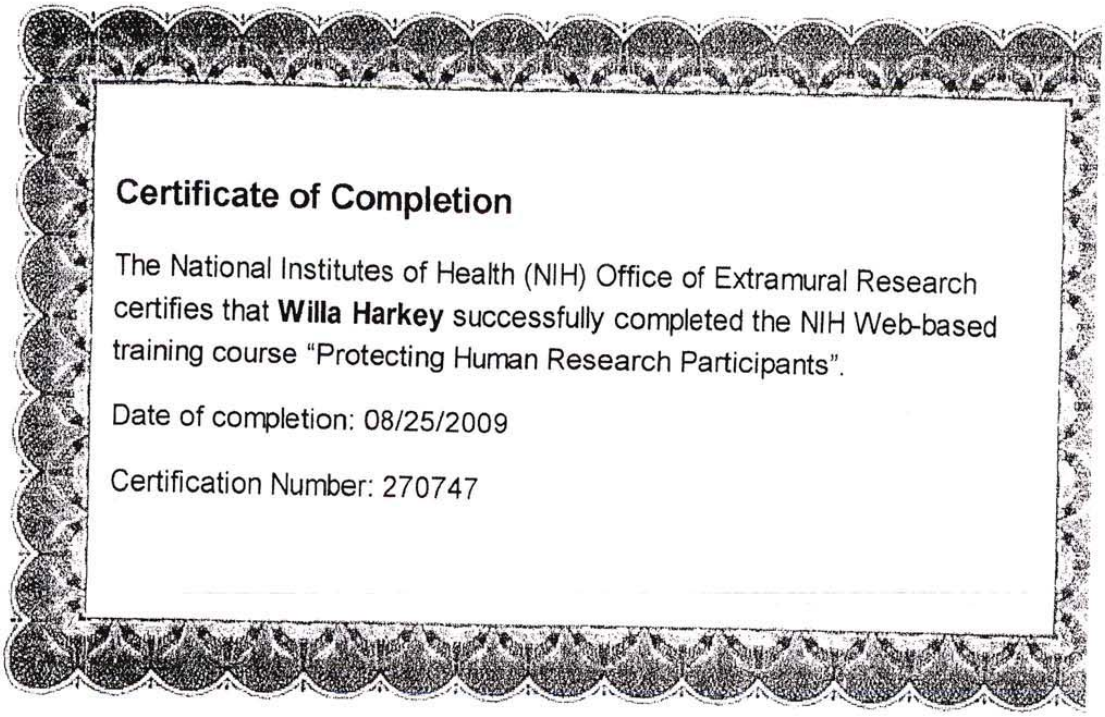
Failure to provide responses to these items in a timely manner may result in a delay in review of your study by the Full Board.

Any changes made to the protocol will require authenticated documentation to support the chan or a signed Administrative Letter. Some clarifications may be provided by Sponsor or Site email.

Thank you for your prompt attention to this matter.

Nina

Nina Chinery-Hesse, MS | Board Liaison
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
nchinery-hesse@iirb.com | Visit us at http://www.iirb.com



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

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Thursday, November 14, 2013 1:29 PM
To: Megan Boatwright; Nina Chinery-Hesse
Cc: Denisse Guzman
Subject: RE: Protocol 130503 for Board review 11/14/2013
Attachments: SSN - Conditionally Approved 130503.pdf

Hi Megan,

The attached document is Study Status Notification I, which communicates to you the outcome of the review of the above-noted submission at today's board meeting.

For any questions or assistance regarding this submission, please feel free to contact myself or Nina Chinery-Hesse (**nchinery-hesse@sairb.com)**.

Thank you.

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

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Thursday, November 14, 2013 2:28 PM
To: Nina Chinery-Hesse
Cc: Jeffrey Atlas; Denisse Guzman
Subject: RE: Protocol 130503 for Board review 11/14/2013

Hi Nina,

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 after it is signed.
2. The on-site health professional will be a RN 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. I have added the nurse we will ask to work with us RN card and NIH certificarte.

Feel free to give me a call to discuss either of these items.

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

From: Nina Chinery-Hesse [mailto:NChinery-Hesse@sairb.com]
Sent: Wednesday, November 13, 2013 5:44 AM
To: Megan Boatwright
Cc: Jeffrey Atlas; Denisse Guzman
Subject: Protocol 130503 for Board review 11/14/2013

Dear Megan,

Thank you for submitting your new study. The screening process for 130503 is complete and the study and has been scheduled for review at the Board meeting on 130503.

The following items were identified during the screening process and will require clarification:

1. It was noted that the protocol indicates that it is a "draft" version. Please provide us with a final version of the protocol or a rationale for why the protocol must be reviewed in draft form.

2. Item 3 on page 16 of the protocol indicates that the Principal Investigator (PI) or on-site health professional will check subject's hands for any cracking, bleeding , sores or other disqualifying skin problems. Item 10 on page 17 indicates that the PI or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. The protocol also makes several other references to the role of the on-site health professional in assessing skin reactions or adverse events. Please clarify whether the on-site health professional is part of the study staff and if so, please provide their CV and credentials as well as an updated Single Site Study Submission Form which lists the on-site health professional as a Sub-Investigator.

Please note that the Screening Process is separate from Board Review and may not reflect the opinions of the Board. This process is designed to identify regulatory concerns, protocol and IC inconsistencies and errors and to obtain all information to support the Board in their review of your study.

Failure to provide responses to these items in a timely manner may result in a delay in review of your study by the Full Board.

Any changes made to the protocol will require authenticated documentation to support the chan or a signed Administrative Letter. Some clarifications may be provided by Sponsor or Site email.

Thank you for your prompt attention to this matter.

Nina

Nina Chinery-Hesse, MS | Board Liaison
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
Office: 954-327-0778 | FAX: 866-258-6674
nchinery-hesse@iirb.com | Visit us at http://www.iirb.com

Study Status Notification

DATE: 11/14/2013

TO: Megan T. Boatwright

FROM: **Jeff Atlas**, Operation Specialist
Schulman Associates IRB, Inc.

RE: **Protocol#:** 130503
Sponsor: American Chemistry Council
IRB#: 201307365
Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The Board reviewed the above-referenced protocol (11/1/2013) 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 ***conditions of approval:***

1. The Board noted that the version of the protocol submitted for review is in draft form. 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 item 4 on page 16 of 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 page 22 of the protocol indicates that pregnancy is an exclusion.

3. The Board noted that item 3 on page 16 of the protocol indicates that the Principal Investigator (PI) or on-site health professional will check subject's hands for any cracking, bleeding, sores or other disqualifying skin problems and item 10 on page 17 indicates that the PI or on-site health professional will check subjects' hands before they leave for redness or other signs of irritation. The Board requested review of the credentials for the on-site

health professional who will be delegated the task of assessing skin reactions or adverse events.

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 Nina Chinery-Hesse, Board Liaison:

- FAX: 866-258-6774
- E-mail: **nchinery-hesse**@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: Megan Boatwright
Sent: Wednesday, December 04, 2013 9:38 AM
To: Jeffrey Atlas (JAtlas@sairb.com)
Subject: Protocol 130503 - Pregnancy Response

Dear Jeff,

I would like to address the board's pregnancy test question now before submitting the document protocol 130503 for HSRB review. (This response coincides with that of protocol 120463.)

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.

Thank you,

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, December 10, 2013 7:38 AM
To: Megan Boatwright
Subject: RE: Protocol 130503 - Pregnancy Response
Attachments: SSN - Conditions Met (partially).pdf

Hi Megan,

Please see the attached SSN communicating the last remaining condition needing to be met.

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.
Our Holiday Season Submission Deadlines and Board Meeting Schedule is now available on our website here:

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Wednesday, December 04, 2013 12:38 PM
To: Jeffrey Atlas
Subject: Protocol 130503 - Pregnancy Response

Dear Jeff,

I would like to address the board's pregnancy test question now before submitting the document protocol 130503 for HSRB review. (This response coincides with that of protocol 120463.)

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.

Thank you,

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

Study Status Notification II

DATE: 12/10/2013

TO: Megan T. Boatwright

FROM: **Jeff Atlas**, Operation Specialist
Schulman Associates IRB, Inc.

RE: **Protocol#:** 130503
IRB#: 201307365
Sponsor: American Chemistry Council
Title: Determination of Removal Efficiency of 1, 2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The above-referenced item was *Conditionally Approved* at the 11/14/2013 Board meeting. On 12/6/2013, the Board reviewed in an expedited manner, the documentation 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 two 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: Megan Boatwright
Sent: Monday, January 20, 2014 4:14 PM
To: Jeffrey Atlas (JAtlas@sairb.com)
Cc: Rob Testman (rtestman@gplabs.com)
Subject: Meeting Minutes and Rosster (130503)

Dear Jeff,

Can you please provide me with the minutes and member roster for the meeting or meetings in which our study protocol 130503 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: Meeting Minutes and Rosster (130503)
Attachments: 130503 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
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: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, January 20, 2014 7:14 PM
To: Jeffrey Atlas
Cc: Robert Testman
Subject: Meeting Minutes and Rosster (130503)

Dear Jeff,

Can you please provide me with the minutes and member roster for the meeting or meetings in which our study protocol 130503 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
2.	201307365	130503		*Protocol*			US	Antimicrobial Exposure Assessment Task Force II (AEATF II)	Status: Conditionally Approved For: 5 Against: 0 Unanimous: Abstain: 0

DESCRIPTION: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

DISCUSSION: Protocol DRAFT dated 01 November 2013

This study seeks to determine the removal efficiency of 1, 2-Benzisothiazol-3(2(H)-one (BIT) from hands due to dermal exposure associated with the use of latex paint containing BIT. The Board noted that this study plans to enroll 28 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 the protocol indicates that the Principal Investigator or on-site health professional will inspect subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems or other signs of irritation. The Board noted that the credentials for the on-site health professional were not provided.

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.
(3) Provide the credentials for the on-site health professional who will be delegated the task of assessing skin reactions or adverse events.

The ICD can be finalized and released when the issues related to the conditions for approval are satisfied.

2.	201307366	130503 [Pesticide;]	Boatwright, Megan T., B.S.		Fresno	CA	US	Antimicrobial Exposure Assessment Task Force II (AEATF II)	201307365	Status: Conditionally Approved For: 5 Against: 0 Unanimous: Abstain: 0
Description: Single site study listed in Section 3 of the agenda;										
Discussion: The Board noted that the protocol indicates that the Principal Investigator or on-site health professional will inspect subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems or other signs of irritation. The Board noted that the credentials for the on-site health professional were not provided. 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 credentials for the on-site health professional who will be delegated the task of assessing skin reactions or adverse events.										

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

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.

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		
		(2) The measures proposed to minimize risks to the human subjects;		
		(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue		
		(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and		
		(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,

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Sincerely,

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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
Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com
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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

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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

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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

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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,

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To: Jeffrey Atlas; Megan Boatwright
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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.

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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
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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: _____

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)?

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?

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

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

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
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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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

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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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

Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

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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

Jeff Atlas, BS-HSA | Operations Coordinator 1
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Office: 954-327-0778 | FAX: 866-258-6674
jatlas@sairb.com |Visit us at http://www.sairb.com

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: _____

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)?

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?

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

SCHULMAN
ASSOCIATES IRB

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

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

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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.

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
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Office: 954-327-0778 | FAX: 866-258-6674
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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)?

SCHULMAN
ASSOCIATES IRB

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.

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?

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

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

Megan Boatwright

From: Megan Boatwright
Sent: Thursday, November 06, 2014 11:55 AM
To: 'Jeffrey Atlas'
Subject: RE: Conditionally Approved Studies
Attachments: 130503 letter.pdf; 130503 irb report.pdf

Dear Jeff,

Please find attached the "Single Site Periodic and Continuing Review Report Form" and explanation letter per the discussion.

Best Regards,

Megan

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Thursday, November 06, 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.

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Thank you.

Best Regards,

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**

From: Jeffrey Atlas
Sent: Monday, November 03, 2014 11:45 AM
To: 'Robert Testman'
Cc: Megan Boatwright; Danielle Martz
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Thank you again!

Best Regards,

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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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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 130503, Schulman IRB number 201307365. 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,

Megan T. Boatwright
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: 201307365

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: Megan T. Boatwright

2. Sponsor: AEATF II **3. Protocol Number:** 130503

4. Contact information for this Study Status Report:

Name: Megan T. Boatwright Email: mboatwright@gplabs.com

Phone: (559) 275-9091 Fax: (559) 275-1810

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 improved for enrollment.

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)?

SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307365

☒ 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:

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Single Site Study Periodic and Continuing Review Report Form

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- Had a hospital/healthcare facility take an adverse action against his/her clinical privileges/medical staff membership, e.g. suspension, revocation, or restriction?
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☒ 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? _____

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SCHULMAN
ASSOCIATES IRB

Single Site Study Periodic and Continuing Review Report Form

Please enter the Schulman IRB number: 201307365

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☒ 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.

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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.

Megan Boatwright

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Signature

11/06/2014

Signature Date (mm/dd/yyyy)

Megan T. Boatwright, Priciple Investigator

Principal Investigator [US] / Qualified Investigator [CAN] or Designee Name & Title

Megan Boatwright

From: Danielle Martz <DMartz@sairb.com>
Sent: Tuesday, November 11, 2014 10:46 AM
To: Megan Boatwright
Cc: Jeffrey Atlas
Subject: RE: Conditionally Approved Studies

Hi Megan,

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: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Thursday, November 06, 2014 2:57 PM
To: Jeffrey Atlas
Subject: RE: Conditionally Approved Studies

Dear Jeff,

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Best Regards,

Megan

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Sent: Thursday, November 06, 2014 6:26 AM
To: Robert Testman; Megan Boatwright
Cc: Danielle Martz
Subject: FW: Conditionally Approved Studies
Importance: High

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Thank you.

Best Regards,

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Cc: Jeffrey Atlas
Subject: RE: Conditionally Approved Studies
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
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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

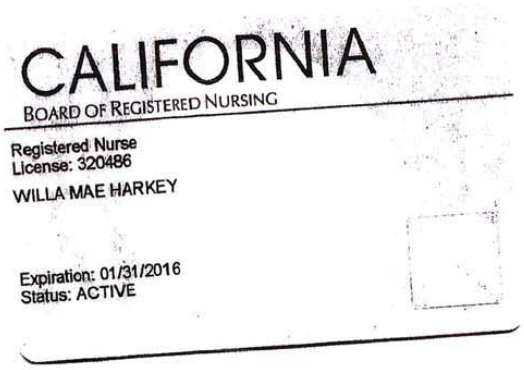
PROFESSIONAL MEMBERSHIPS:
Member, National Nurses Assn.
Member, Neonatal Nursing Assn.

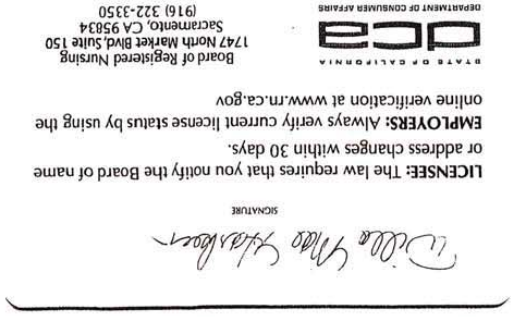
STATEMENT:

For purposes of GLP compliance, I acknowledge this to be a true and correct curriculum vitae.

W Harkey 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
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
Board of Registered Nursing
1747 North Market Blvd, Suite 150
Sacramento, CA 95834
(916) 322-3350

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, November 17, 2014 1:59 PM
To: Megan Boatwright
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol 130503 [Country:US]

Importance: High

Megan,

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:	**130503 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Boatwright, Megan T., B.S.	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.
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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:	Megan T. Boatwright, BS
SUBJECT:	Reapproval
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	130503
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

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 #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yy format.

Memorandum

December 09, 2014

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, BS
SUBJECT:	Corrected Reapproval Letter
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	130503
IRB NO:	201307366

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 #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

Corrected Letter dated 12/09/14

CONDITIONAL REAPPROVALED: 11/13/14
EXPIRATION DATE: 11/12/15

November 13, 2014

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") — Board #3
TO:	Megan T. Boatwright, BS
SUBJECT:	Reapproval
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	130503
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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 #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yy format.

Megan Boatwright

From: Robert Testman
Sent: Tuesday, April 18, 2017 8:56 AM
To: Megan Boatwright
Subject: FW: Invoicing for 120463 and 130503
Attachments: Protocol 130503 BIT Removal Effeciency 02Feb2015 tracked.docx; Protocol 130503 BIT Removal Effeciency 02Feb2015.docx

From: Robert Testman
Sent: Monday, February 2, 2015 8:52 AM
To: Jeffrey Atlas <JAtlas@sairb.com>
Subject: RE: Invoicing for 120463 and 130503

Hi Jeff,

Attached are the revised protocol as well as a "tracked" version showing changes from the prior version. The "tracked" version does not include updates made to the product label and MSDS appendices (updating to newest English and Spanish versions). The documents needing Spanish translation are contained in appendices C, D, F, and G. Let me know if you would like us to provide stand-alone Word versions of these. Also, do you need any submission documents, or do the initial submission documents cover us?

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Monday, February 2, 2015 8:40 AM
To: Robert Testman
Subject: RE: Invoicing for 120463 and 130503

Hi Rob,

Please submit the final protocol to me and I can proceed with sending for review today. You can pay for a RUSH fee on the protocol review, which will include the initial approval documents and all subject/recruitment materials. It is a fee per item. As for Spanish translation, I will get an estimate for you which will contain multiple turnaround times, ranging from 2-3 business days up to a week.

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

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Monday, February 02, 2015 11:32 AM
To: Jeffrey Atlas
Subject: RE: Invoicing for 120463 and 130503

Hi Jeff,

The revised protocol for 130503 is ready for final review. Unfortunately after all the delays EPA and sponsor are requesting we proceed as urgently as possible. I don't know the timeline or if we can pay to expedite the review (and Spanish translation of informed consent, subject self-reporting form, newspaper ad, and subject interview script). They are hoping to be able to submit to EPA at the end of the week or shortly after. The larger study revisions are in progress, but are less urgent as it will run after this one. Please advise how best to proceed. You can give me a call to discuss at (949)939-3585 if that is easier.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Monday, December 8, 2014 7:58 AM
To: Robert Testman; Megan Boatwright
Cc: Rhonda Hensley
Subject: Invoicing for 120463 and 130503

Hi Robert and Megan,

Typically SAIRB will invoice a new study at the time of full approval, and then each subsequent submission will receive its own, separate invoice. As both studies never received full approval, SAIRB has yet to invoice for the initial review nor the annual review which recently took place. I have been asked to inform you that you will be receiving an invoice in the amount of $3535.00 for each study, which includes the initial review and annual review. Please let me know if you have any questions about the forthcoming invoice.

If I can be of any assistance, 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

PROTOCOL

02 February 2015

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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

March 2015

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 103

TABLE OF CONTENTS

List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	March 2015
Proposed Experimental Termination Date:	June 2015
Proposed Final Report Issue Date:	October 2015

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8F.1	Sample Identification	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.2	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

Sponsor:

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:

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

Field Research Associates:	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
Quality Assurance Unit:	Margaret A. Hamelin Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mhamelin@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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

The test substance in this study is latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5The latex paint will be

tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 20 subjects at one of two concentrations (10 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to interpret data from painter exposure monitoring studies. In this study, at least 20 subjects (10 for each concentration) will be monitored in order to capture the expected variation in skin differences, and BIT concentration using paint as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used for cleaning the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint from human skin is not available. Removal efficiency studies which have been conducted with other active ingredients do not provide for interpretation of BIT removal, or the removal of any active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substance for this study is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT). BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT

Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

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 in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

C. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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

BIT in paint will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

E. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass stirring rod with rounded annealed ends. The glass stirring rod will be placed into a test tube and retained for analysis.

The paint will be left on the hands to dry for 45 minutes. The hands will then be washed. The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their

hands together. The gauze sponges will be added to the rinse solvent for extraction. The solution and gauze sponge will be collected as a single sample for both hands of each subject, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold both hands over a stainless steel bowl while researchers scrub the hand with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into two groups, each corresponding to one of the two test substance/concentration combinations. The first set of fourteen subjects will be placed into Group 1, and the second set of fourteen subjects will be placed into Group 2,.

Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into two groups, subjects from the first group will be scheduled into the study. No more than one group will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., ten subjects for each of two groups). As described above, an additional eight subjects (four per group) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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. 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified

by a government issued photo ID

- 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

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 or sensitivities to latex paint, soaps. isopropyl alcohol, BIT 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)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

B. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

C. 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 (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
Additional designations are as follows:
H = High Concentration Level

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The glass stir rods used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the glass stir rods used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear

regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.

3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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.

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.

APPENDIX A: 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 suitable for use in product formulations, including products and systems, including industrial and institutional products to control growth of bacteria, fungi and yeasts at levels of 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 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 21CFR 177.2600 (d)(1)(ii).

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. 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

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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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	Sí	LEED® 09 CI	Sí
SCAQMD	Sí	LEED® 09 NC	Sí
CARB	Sí	LEED® 09 CS	Sí
CARB SCM 2007	Sí	LEED® 09 H	Sí
MPI N.°	53	NGBS	Sí

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

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.
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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:
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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. We will measure how much chemical can be removed from your hands by rinsing and scrubbing your hands with a gauze sponge soaked with a solution of rubbing alcohol (also called isopropyl alcohol or IPA) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your palms facing up. We will place a small amount of paint on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe samples, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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 might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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 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. We may take photographs or video of the study, but we will edit these so that you cannot be identified.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*			
6. Name			
7. Address			
8. City, ST, Zip			
9. Telephone(s)			
10. Age in years =	11. DOB:	12. Sex ☐ M ☐ F	
13. Resident in Fresno County? ☐ Yes ☐ No			
14. Preferred Language: ☐ English ☐ Spanish	15. Reads: ☐ English ☐ Spanish		
16. Are you pregnant? ☐ NA ☐Yes ☐ No	17. Are you nursing a baby? ☐ NA ☐Yes ☐ No		
18. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No			
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐ No			
20. 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 AND BIT REFERENCE SUBSTANCE

MATERIAL SAFETY DATA SHEET

A86W151
12 00

DATE OF PREPARATION
Oct 27, 2014

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A86W151
PRODUCT NAME
SUPERPAINT® Interior Flat 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
15	14808-60-7	Quartz		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.1 mg/m3 as Resp. Dust	
1	14464-46-1	Cristobalite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
2	1332-58-7	Kaolin		
		ACGIH TLV	Not Available	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	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	12.05 lb/gal	1443 g/l
SPECIFIC GRAVITY	1.45	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	57%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.3	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.35 lb/gal	42 g/l	Less Water and Federally Exempt Solvents
0.16 lb/gal	19 g/l	Emitted VOC

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0.41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

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			
14808-60-7	Quartz			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
1332-58-7	Kaolin			
		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.

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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 sílice 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.

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SIGMA-ALDRICH

sigma-aldrich.com

SAFETY DATA SHEET

Version 4.4
Revision Date 06/30/2014
Print Date 02/02/2015

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : 1,2-Benzisothiazol-3(2*H*)-one

Product Number : 561487
Brand : Aldrich
Index-No. : 613-088-00-6

CAS-No. : 2634-33-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

Telephone : +1 800-325-5832
Fax : +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone # : (314) 776-6555

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Acute toxicity, Oral (Category 4), H302
Skin irritation (Category 2), H315
Serious eye damage (Category 1), H318
Skin sensitisation (Category 1), H317
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word Danger

Hazard statement(s)
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.

P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P321	Specific treatment (see supplemental first aid instructions on this label).
P330	Rinse mouth.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula	:	C_7H_5NOS
Molecular Weight	:	151.19 g/mol
CAS-No.	:	2634-33-5
EC-No.	:	220-120-9
Index-No.	:	613-088-00-6

Hazardous components

Component	Classification	Concentration
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

5.3 Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information
no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: crystalline Colour: light yellow
b)	Odour	no data available
c)	Odour Threshold	no data available
d)	pH	no data available
e)	Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
f)	Initial boiling point and boiling range	no data available
g)	Flash point	no data available
h)	Evapouration rate	no data available
i)	Flammability (solid, gas)	no data available
j)	Upper/lower flammability or explosive limits	no data available
k)	Vapour pressure	no data available
l)	Vapour density	no data available

m)	Relative density	no data available
n)	Water solubility	no data available
o)	Partition coefficient: n-octanol/water	no data available
p)	Auto-ignition temperature	no data available
q)	Decomposition temperature	no data available
r)	Viscosity	no data available
s)	Explosive properties	no data available
t)	Oxidizing properties	no data available

9.2 Other safety information
no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
no data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
no data available

10.4 Conditions to avoid
no data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - no data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - 1,020 mg/kg

Inhalation: no data available

Dermal: no data available

no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitisation
Germ cell mutagenicity
no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
no data available

no data available

Specific target organ toxicity - single exposure
no data available

Specific target organ toxicity - repeated exposure
no data available

Aspiration hazard
no data available

Additional Information
RTECS: DE4620000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

12.2 Persistence and degradability
no data available

12.3 Bioaccumulative potential
no data available

12.4 Mobility in soil
no data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Dam.	Serious eye damage
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

HMIS Rating

Health hazard:	2
Chronic Health Hazard:	
Flammability:	0
Physical Hazard	0

NFPA Rating
Health hazard: 2

Fire Hazard:	0
Reactivity Hazard:	0

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Preparation Information

Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956

Version: 4.4 Revision Date: 06/30/2014 Print Date: 02/02/2015

SIGMA-ALDRICH

sigma-aldrich.com

FICHA DE DATOS DE SEGURIDAD

Versión 4.4
Fecha de revisión 06/29/2014
Fecha de impresión 02/02/2015

1. IDENTIFICACIÓN DEL PRODUCTO Y DE LA COMPAÑÍA

1.1 Identificadores del producto

Nombre del producto : 1,2-Benzisothiazol-3(2*H*)-one

Referencia : 561487
Marca : Aldrich
No. Indice : 613-088-00-6

No. CAS : 2634-33-5

1.2 Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados

Usos identificados : Reactivos para laboratorio, Fabricación de sustancias

1.3 Datos del proveedor de la ficha de datos de seguridad

Compañía : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

Teléfono : +1 800-325-5832
Fax : +1 800-325-5052

1.4 Teléfono de emergencia

Teléfono de Urgencia : (314) 776-6555

2. IDENTIFICACIÓN DE LOS PELIGROS

2.1 Clasificación de la sustancia o de la mezcla

Clasificación SGA de acuerdo con 29 CFR 1910 (OSHA HCS).
Toxicidad aguda, Oral (Categoría 4), H302
Irritación cutáneas (Categoría 2), H315
Lesiones oculares graves (Categoría 1), H318
Sensibilización cutánea (Categoría 1), H317
Toxicidad acuática aguda (Categoría 1), H400
Toxicidad acuática crónica (Categoría 1), H410

Para el texto íntegro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

2.2 Elementos de las etiquetas del SGA, incluidos los consejos de prudencia

Pictograma

Palabra de advertencia: Peligro

Indicación(es) de peligro

H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Declaración(es) de prudencia

P261	Evitar respirar el polvo/ el humo/ el gas/ la niebla/ los vapores/ el aerosol.

P264	Lavarse la piel concienzudamente tras la manipulación.
P270	No comer, beber ni fumar durante su utilización.
P272	Las prendas de trabajo contaminadas no podrán sacarse del lugar de trabajo.
P273	Evitar su liberación al medio ambiente.
P280	Llevar guantes de protección/ gafas de protección/ máscara de protección.
P301 + P312	EN CASO DE INGESTIÓN: Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico si se encuentra mal.
P302 + P352	EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes.
P305 + P351 + P338	EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado.
P310	Llamar inmediatamente a un CENTRO DE INFORMACION TOXICOLOGICA o a un médico.
P321	Se necesita un tratamiento específico (véase las instrucciones suplementarias de primeros auxilios en esta etiqueta).
P330	Enjuagarse la boca.
P333 + P313	En caso de irritación o erupción cutánea: Consultar a un médico.
P362	Quitarse las prendas contaminadas y lavarlas antes de volver a usarlas.
P391	Recoger el vertido.
P501	Eliminar el contenido/ el recipiente en una planta de eliminación de residuos aprobada.

2.3 Peligros no clasificados de otra manera - ninguno(a)

3. COMPOSICIÓN/INFORMACIÓN SOBRE LOS COMPONENTES

3.1 Sustancias

Formula	:	C_7H_5NOS
Peso molecular	:	151.19 g/mol
No. CAS	:	2634-33-5
No. CE	:	220-120-9
No. Indice	:	613-088-00-6

Componentes peligrosos

Componente	Clasificación	Concentración
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

4. PRIMEROS AUXILIOS

4.1 Descripción de los primeros auxilios

Recomendaciones generales
Consultar a un médico. Mostrar esta ficha de seguridad al doctor que esté de servicio.Retire a la persona de la zona peligrosa.

Si es inhalado
Si aspiró, mueva la persona al aire fresco. Si ha parado de respirar, hacer la respiración artificial. Consultar a un médico.

En caso de contacto con la piel
Eliminar lavando con jabón y mucha agua. Consultar a un médico.

En caso de contacto con los ojos
Lávese a fondo con agua abundante durante 15 minutos por lo menos y consulte al médico.

Si es tragado
Nunca debe administrarse nada por la boca a una persona inconsciente. Enjuague la boca con agua. Consultar a un médico.

4.2 Principales síntomas y efectos, agudos y retardados
Los síntomas y efectos más importantes conocidos se describen en la etiqueta (ver sección 2.2) y / o en la sección 11

4.3 Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente
sin datos disponibles

5. MEDIDAS DE LUCHA CONTRA INCENDIOS

5.1 Medios de extinción

Medios de extinción apropiados
Usar agua pulverizada, espuma resistente al alcohol, polvo seco o dióxido de carbono.

5.2 Peligros específicos derivados de la sustancia o la mezcla
Óxidos de carbono, óxidos de nitrógeno (NOx), Óxidos de azufre

5.3 Recomendaciones para el personal de lucha contra incendios
Si es necesario, usar equipo de respiración autónomo para la lucha contra el fuego.

5.4 Otros datos
sin datos disponibles

6. MEDIDAS EN CASO DE VERTIDO ACCIDENTAL

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia
Utilícese equipo de protección individual. Evite la formación de polvo. Evitar respirar los vapores, la neblina o el gas. Asegúrese una ventilación apropiada. Evacuar el personal a zonas seguras. Evitar respirar el polvo.
Equipo de protección individual, ver sección 8.

6.2 Precauciones relativas al medio ambiente
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

6.3 Métodos y material de contención y de limpieza
Recoger y preparar la eliminación sin originar polvo. Limpiar y traspalar. Guardar en contenedores apropiados y cerrados para su eliminación.

6.4 Referencia a otras secciones
Para eliminación de desechos ver sección 13.

7. MANIPULACIÓN Y ALMACENAMIENTO

7.1 Precauciones para una manipulación segura
Evítese el contacto con los ojos y la piel. Evítese la formación de polvo y aerosoles.
Debe disponer de extracción adecuada en aquellos lugares en los que se forma polvo.
Ver precauciones en la sección 2.2

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades
Conservar el envase herméticamente cerrado en un lugar seco y bien ventilado.

7.3 Usos específicos finales
Aparte de los usos mencionados en la sección 1.2 no se estipulan otros usos específicos

8. CONTROLES DE EXPOSICIÓN/ PROTECCIÓN INDIVIDUAL

8.1 Parámetros de control

Componentes con valores límite ambientales de exposición profesional.
No contiene sustancias con valores límites de exposición profesional.

8.2 Controles de la exposición

Controles técnicos apropiados
Manipular con las precauciones de higiene industrial adecuadas, y respetar las prácticas de seguridad. Lávense las manos antes de los descansos y después de terminar la jornada laboral.

Protección personal

Protección de los ojos/ la cara
Caretas de protección y gafas de seguridad. Use equipo de protección para los ojos probado y aprobado según las normas gubernamentales correspondientes, tales como NIOSH (EE.UU.) o EN 166 (UE).

Protección de la piel
Manipular con guantes. Los guantes deben ser inspeccionados antes de su uso. Utilice la técnica correcta de quitarse los guantes (sin tocar la superficie exterior del guante) para evitar el contacto de la piel con este producto. Deseche los guantes contaminados después de su uso, de conformidad con las leyes aplicables y buenas prácticas de laboratorio. Lavar y secar las manos.

Sumerción
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

Salpicaduras
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

origen de datos: KCL GmbH, D-36124 Eichenzell, Teléfono +49 (0)6659 87300, e-mail sales@kcl.de, Método de prueba: EN374
Si es utilizado en solución, o mezclado con otras sustancias, y bajo condiciones diferentes de la EN 374, pornerse en contacto con el proveedor de los guantes aprobados CE. Esta recomendación es meramente aconsejable y deberá ser evaluada por un responsable de seguridad e higiene industrial familiarizado con la situación específica de uso previsto por nuestros clientes. No debe interpretarse como una aprobación de oferta para cualquier escenario de uso específico.

Protección Corporal
Traje de protección completo contra productos químicos, El tipo de equipamiento de protección debe ser elegido según la concentración y la cantidad de sustancia peligrosa al lugar específico de trabajo.

Protección respiratoria
Donde el asesoramiento de riesgo muestre que los respiradores purificadores de aire son apropiados, usar un respuirador que cubra toda la cara tipo N100 (EEUU) o tipo P3 (EN 143) y cartichos de respuesto para controles de ingieneria. Si el respirador es la unica protección, usar un respirador suministrado que cubra toda la cara Usar respiradores y componenetes testados y aprobados bajo los estandards gubernamentales apropiados como NIOSH (EEUU) o CEN (UE)

Control de exposición ambiental
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

9. PROPIEDADES FÍSICAS Y QUÍMICAS

9.1 Información sobre propiedades físicas y químicas básicas

a)	Aspecto	Forma: cristalino Color: amarillo claro
b)	Olor	sin datos disponibles
c)	Umbral olfativo	sin datos disponibles
d)	pH	sin datos disponibles
e)	Punto de fusión/ punto de congelación	Punto/intervalo de fusión: 154 - 158 °C (309 - 316 °F) - lit.

f)	Punto inicial de ebullición e intervalo de ebullición	sin datos disponibles
g)	Punto de inflamación	sin datos disponibles
h)	Tasa de evaporación	sin datos disponibles
i)	Inflamabilidad (sólido, gas)	sin datos disponibles
j)	Inflamabilidad superior/inferior o límites explosivos	sin datos disponibles
k)	Presión de vapor	sin datos disponibles
l)	Densidad de vapor	sin datos disponibles
m)	Densidad relativa	sin datos disponibles
n)	Solubilidad en agua	sin datos disponibles
o)	Coeficiente de reparto n-octanol/agua	sin datos disponibles
p)	Temperatura de auto-inflamación	sin datos disponibles
q)	Temperatura de descomposición	sin datos disponibles
r)	Viscosidad	sin datos disponibles
s)	Propiedades explosivas	sin datos disponibles
t)	Propiedades comburentes	sin datos disponibles

9.2 Otra información de seguridad
sin datos disponibles

10. ESTABILIDAD Y REACTIVIDAD

10.1 Reactividad
sin datos disponibles

10.2 Estabilidad química
Estable bajo las condiciones de almacenamiento recomendadas.

10.3 Posibilidad de reacciones peligrosas
sin datos disponibles

10.4 Condiciones que deben evitarse
sin datos disponibles

10.5 Materiales incompatibles
Agentes oxidantes fuertes

10.6 Productos de descomposición peligrosos
Otros productos de descomposición peligrosos - sin datos disponibles
En caso de incendio: véase sección 5

11. INFORMACIÓN TOXICOLÓGICA

11.1 Información sobre los efectos toxicológicos

Toxicidad aguda
DL50 Oral - rata - 1,020 mg/kg

Inhalación: sin datos disponibles

Cutáneo: sin datos disponibles

sin datos disponibles

Corrosión o irritación cutáneas
sin datos disponibles

Lesiones o irritación ocular graves
sin datos disponibles

Sensibilización respiratoria o cutánea
Mutagenicidad en células germinales
sin datos disponibles

Carcinogenicidad

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la ACGIH.

NTP: En este producto no se identifica ningún componente, que presente niveles mayores que o iguales a 0.1%, como agente carcinógeno conocido o anticipado por el (NTP) Programa Nacional de Toxicología.

OSHA: No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la (OSHA) Administración de Salud y Seguridad Ocupacional.

Toxicidad para la reproducción
sin datos disponibles

sin datos disponibles

Toxicidad específica en determinados órganos - exposición única
sin datos disponibles

Toxicidad específica en determinados órganos - exposiciones repetidas
sin datos disponibles

Peligro de aspiración
sin datos disponibles

Información Adicional
RTECS: DE4620000

Según nuestras informaciones, creemos que no se han investigado adecuadamente las propiedades químicas, físicas y toxicológicas.

12. INFORMACIÓN ECOLÓGICA

12.1 Toxicidad

Toxicidad para los peces	CL50 - Oncorhynchus mykiss (Trucha irisada) - 0.8 mg/l - 96.0 h
Toxicidad para las dafnias y otros invertebrados acuáticos	CE50 - Daphnia magna (Pulga de mar grande) - 4.4 mg/l - 48 h

12.2 Persistencia y degradabilidad
sin datos disponibles

12.3 Potencial de bioacumulación
sin datos disponibles

12.4 Movilidad en el suelo
sin datos disponibles

12.5 Resultados de la valoración PBT y mPmB
La valoración de PBT / mPmB no está disponible ya que la evaluación de la seguridad química no es necesaria / no se ha realizado

12.6 Otros efectos adversos
No se puede excluir un peligro para el medio ambiente en el caso de una manipulación o eliminación no profesional.
Muy tóxico para los organismos acuáticos.

13. CONSIDERACIONES RELATIVAS A LA ELIMINACIÓN

13.1 Métodos para el tratamiento de residuos

Producto
Ofertar el sobrante y las soluciones no-aprovechables a una compañia de vertidos acreditada. Para la eliminación de este producto, dirigirse a un servicio profesional autorizado.

Envases contaminados
Eliminar como producto no usado.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

DOT (US)
Mercancía no peligrosa

IMDG
Número ONU: 3077 Clase: 9 Grupo de embalaje: III EMS-No: F-A, S-F
Designación oficial de transporte de las Naciones Unidas: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Contaminante marino: MARINE POLUTANT

IATA
Número ONU: 3077 Clase: 9 Grupo de embalaje: III
Designación oficial de transporte de las Naciones Unidas: Sustancia sólida peligrosa para el medio ambiente, n.e.p. (1,2-Benzisothiazolin-3-one)

Otros datos
Marca-EHS requerida (códigos ADR 2.2.9.1.10 e IMDG 2.10.3) para embalajes únicos y embalajes combinados que contengan embalajes interiores con Mercancías Peligrosas > 5L para líquidos o > 5Kg para sólidos.

15. INFORMACIÓN REGLAMENTARIA

SARA 302 Componentes
SARA 302: Este material no contiene productos químicos sujetos a los requisitos reportados por SARA Titulo III, sección 302.

SARA 313 Componentes
SARA 313: Este material no contiene ningún componente químico con los conocidos números CAS que exceden el umbral de los niveles reportados (De Minimis) establecidos por SARA título III, sección 313.

SARA 311/312 Peligros
Peligro Agudo para la Salud

Massachusetts Right To Know Componentes
No hay componentes sujetos al Acta de Derecho a Saber de Massachussets.

Pennsylvania Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

Prop. 65 de California Componentes
Este producto no contiene ninguna sustancia química conocida para el de Estado de California que pueden causar cáncer, defectos de nacimiento, o cualquier otro daño reproductivo.

16. OTRA INFORMACIÓN

Texto íntegro de las Declaraciones-H referidas en las secciones 2 y 3.

Acute Tox.	Toxicidad aguda
Aquatic Acute	Toxicidad acuática aguda
Aquatic Chronic	Toxicidad acuática crónica
Eye Dam.	Lesiones oculares graves
H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H400	Muy tóxico para los organismos acuáticos.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Clasificación HMIS/NFPA

Peligro para la salud:	2
Peligro Crónico para la Salud:	
Inflamabilidad:	0
Peligro Físico	0

Clasificación NFPA

Peligro para la salud:	2
Peligro de Incendio:	0
Peligro de Reactividad:	0

Otros datos

La información indicada arriba se considera correcta pero no pretende ser exhaustiva y deberá utilizarse únicamente como orientación. La información contenida en este documento esta basada en el presente estado de nuestro conocimiento y es aplicable a las precauciones de seguridad apropiadas para el producto. No representa ninguna garantía de las propiedades del producto. La Corporación Sigma-Aldrich y sus Compañías Afiliadas, no responderán por ningún daño resultante de la manipulación o contacto con el producto indicado arriba. Dirijase a www.sigma-aldrich.com y/o a los términos y condiciones de venta en el reverso de la factura o de la nota de entrega.

Información suministrada por

Corporación Sigma-Aldrich
Product Safety – Americas Region
1-800-521-8956

Versión: 4.4	Fecha de revisión: 06/29/2014	Fecha de impresión: 02/02/2015

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 02/02/2015

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 removal efficiency 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 removed from the palms of your hand when paint containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Target BIT Concentration
AEA08-RE-01-PL	1	120 ppm
AEA08-RE-02-PL	2	120 ppm
AEA08-RE-03-PL	3	120 ppm
AEA08-RE-04-PL	4	120 ppm
AEA08-RE-05-PL	5	120 ppm
AEA08-RE-06-PL	6	120 ppm
AEA08-RE-07-PL	7	120 ppm
AEA08-RE-08-PL	8	120 ppm
AEA08-RE-09-PL	9	120 ppm
AEA08-RE-10-PL	10	120 ppm
AEA08-RE-11-PH	11	600 ppm
AEA08-RE-12-PH	12	600 ppm
AEA08-RE-13-PH	13	600 ppm
AEA08-RE-14-PH	14	600 ppm
AEA08-RE-15-PH	15	600 ppm
AEA08-RE-16-PH	16	600 ppm
AEA08-RE-17-PH	17	600 ppm
AEA08-RE-18-PH	18	600 ppm
AEA08-RE-18-PH	19	600 ppm
AEA08-RE-20-PH	20	600 ppm

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg

~~*DRAFT*~~ **PROTOCOL**

~~23~~ 02 ~~January~~ February ~~2014~~2015

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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

~~April~~ March ~~2014~~2015

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: : ~~83~~

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List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	~~April~~ March ~~2014~~2015
Proposed Experimental Termination Date:	June ~~2014~~2015
Proposed Final Report Issue Date:	~~August~~ October ~~2014~~2015

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8F.1	Sample Identification	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.2	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

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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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. ~~The data generated by testing BIT in solvent will better enable extrapolation of the BIT in paint data to other antimicrobial active ingredients.~~ The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. 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.

The test substance~~s~~ in this study ~~are~~ is latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5~~, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 µg/mL and 3.9 mg/mL.~~ The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of ~~10~~ 20 subjects at one of two concentrations (~~5~~ 10 subjects each). ~~A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each).~~ After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. ~~Hand exposure will be measured by~~ The researchers ~~scrubbing~~ will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then ~~rinsing with~~ the researchers will pour the same solvent over the hands while the subject rubs their ~~fingers to their palm~~hands together. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in ~~IPA or~~ latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. ~~The data generated by testing BIT in solvent will better enable extrapolation of the paint data to other antimicrobial active ingredients.~~ The primary objective of this study is to determine the removal efficiency of BIT in latex paint ~~and in IPA~~ from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to ~~extrapolate~~ interpret data from ~~existing human hand removal efficiency studies~~painter exposure monitoring studies. In this study, at least 20 subjects (~~5~~ 10 for each ~~scenario~~concentration) will be monitored in order to capture the expected variation in skin differences, and BIT concentration~~, and~~ using paint ~~or solvent~~ as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used ~~on~~ for cleaning the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces

risk to low levels. 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint ~~or solvent~~ from human skin is not available. Removal efficiency studies which have been conducted with other active ~~ingrediaents~~ingredients do not provide for interpretation of BIT removal, or the removal of any active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substance~~s~~ for this study ~~are~~ is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT)~~ and BIT prepared in isopropyl alcohol (IPA)~~.

BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

~~**B. Test Substance Identification – BIT in Solvent**~~

~~The reference substance 1,2-Benzisothiazol-3(2H)-one (BIT) will be prepared at approximately 786 µg/mL and 3.9 mg/mL using isopropyl alcohol (HPLC grade) as the dilution solvent.~~

~~Name: 1,2-Benzisothiazol-3(2H)-one (BIT)~~
~~CAS Number: [2634-33-5]~~
~~Active Ingredient: BIT~~
~~Lot Number: to be recorded in the raw data~~
~~Purity: to be recorded in the raw data~~
~~Date Received: to be recorded in the raw data~~
~~Expiration Date: to be recorded in the raw data~~

~~M.~~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.

~~BIT in solvent will be used as a second test substance in order to provide comparative removal efficiency information between a paint matrix and solvent. This information will be used to improve extrapolation of data for other active ingredients which may have removal efficiency data in solvent to a paint matrix.~~

The analytical method for the determination of BIT in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

~~N.~~C. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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.

~~O.~~D. Calibration of Application Equipment

BIT in paint ~~or solvent~~ will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

~~P.~~E. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint ~~or IPA~~.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of ~~four~~ two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. ~~Subjects assigned to group three will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 786 µg/mL in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/mL in isopropyl alcohol (IPA).~~ Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned ~~carrier and~~ test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass ~~capillary tube~~stirring rod with rounded annealed ends. The glass ~~capillary tube~~stirring rod will be placed into a ~~glass~~ test tube and retained for analysis.

The paint ~~or solution~~ will be left on the hands to dry for 45 minutes. ~~Each~~ The hands will then be washed~~ by~~. The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. ~~scrubbing with a gauze sponge soaked in 50% IPA / 50% distilled water solution and rinsed with the same solution.~~ The solution and gauze sponge will be collected as a single sample for ~~each hand~~both hands of each subject, extracted and analyzed.

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Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection,

compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, ~~either~~ a 500 µL volume of the appropriate paint concentration ~~or a~~

~~100 µL volume of the appropriate solvent concentration~~ will be applied. A glass ~~capillary tube~~stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The ~~capillary tube~~stirring rod from each subject will be placed into a ~~glass~~ test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold ~~their hand~~both hands over a stainless steel bowl while researchers scrub the hand with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their ~~fingers and palm~~hands together. The total volume of IPA/water solution used will be ~~250~~ 500 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis. ~~The procedure will then be repeated for the second hand producing a second sample.~~

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into ~~four~~ two groups. ~~Two groups will receive BIT applied in paint, and two groups will receive BIT applied in IPA.~~ The ~~four~~ two groups are described below (amounts per hand):

Group 1	500 µL of latex paint containing ca. 120 ppm BIT
Group 2	500 µL of latex paint containing ca. 600 ppm BIT
~~Group 3~~	~~100 µL of ~ 786 µg/mL fortification solution of BIT in IPA~~
~~Group 4~~	~~100 µL of ~ 3.9 mg/mL fortification solution of BIT in IPA~~

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into ~~four~~ two groups, each corresponding to one of the ~~four~~ two test substance/concentration combinations. The first set of ~~seven~~ fourteen subjects will be placed into Group 1, and the second set of ~~seven~~ fourteen subjects will be placed into Group 2, ~~the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4~~.

Within each group of ~~seven~~fourteen, the first ~~five~~ ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last ~~two~~ four subjects in the group of ~~seven~~ fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ~~five~~ ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into ~~four~~ two groups, subjects from the first group will be scheduled into the study. No more than ~~two~~ one group~~s~~ will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., ~~five~~ ten subjects for each of ~~four~~ two groups). As described above, an additional eight subjects (~~two~~ four per ~~cluster~~group) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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. 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- Consider their own health sufficient to conduct the described activities
- ~~Consider their self to be in good health~~
- 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

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 or sensitivities to latex paint, soaps, ~~or~~ isopropyl alcohol, BIT 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)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

B. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

C. 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 (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex

paint ~~or in solvent~~ will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm
~~IPA~~	~~100 µL~~	~~Approximately 786 µg/mL~~
~~IPA~~	~~100 µL~~	~~Approximately 3.9 mg/mL~~

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL-~~LH~~:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
~~LH = Left Hand~~
Additional designations are as follows:
~~S = Solvent~~
H = High Concentration Level
~~RH = Right Hand~~

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. ~~The IPA test substances will be analyzed by diluting to an appropriate concentration with 50% acetonitrile /50% water, vialing with internal standard, and analyzing by HPLC/MS/MS.~~ The ~~capillary pipets~~glass stir rods used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the ~~capillary tubes~~glass stir rods used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.

3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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.

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.

APPENDIX A: 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, 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
- 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. Maintain adequate cardiac and circulatory status, respiratory support, and consultation 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 Sizes, Leather Processing, Building And Construction Compositions, Inks, Latex Coatings, Building Solutions, Car Care Products Including Car Washes, Car Waxes, Air Fresheners, Floor Waxes, Floor Polishes And Floor Cleaners, Household Cleaning Products Including Laundry Additives Including Liquid Laundry Detergents, Fabric Softeners And Stain Removers, Oil Recovery Systems, Pesticide Formulations

EPA Reg. No.	6383-121
EPA Establishment Number	6383-NJ-1

ACTIVE INGREDIENT:
1,2-Benzisothiazolin-3(2H)-One ..... % Weight 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 emulsion polymers, latex paints and coatings, adhesives, and paper coatings, at a use level of 0.05% to 0.25% w/w of Mergal® BIT 20 on the finished product. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 100 gallons of finished product.

ADHERES 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/in² (0.0326 mg/cm²) of finished paper and paperboard intended for contact with aqueous and fatty foods.

Mergal® BIT 20 complies with the following FDA regulations when used under 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 177.1200 - Cellophane (use in accordance with the limitations and the provisions of paper and paperboard in contact with dry food)
21 CFR 177.2600 - Rubber articles intended for repeated use (follow instructions in contact food)

OIL RECOVERY SYSTEMS: Drilling fluids, packer fluids, completion fluids. Polysaccharide fluid loss control agents and modifiers such as starch, guar, and xanthan gum 0.05-0.15% on solution weight. Thickeners such as polyacrylamide, polyacrylic acid, polyacrylate copolymer and modified 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 1/4 full with water. Replace and tighten closures. Shake container vigorously for 10 seconds. Pour 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012 Complies with:			
GTC	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 SCR/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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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 03/29/2013 A86W00151 09 47

~~Spanish product label here after translation of approved English version~~

101.02

SHERWIN WILLIAMS.

SUPERPAINT®
Interior Latex
Flat
A86-1100 Series

Látex para interiores
Mate
Serie A86-1100

Desde el 01/1/2012, cumple con:			
OTC	Sí	LEED® 09 CI	Sí
SCAQMD	Sí	LEED® 09 NC	Sí
CARB	Sí	LEED® 09 CS	Sí
CARB SCM 2007	Sí	LEED® 09 H	Sí
MPI #*	53	NGBS	Sí

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.

3/2013 www.sherwin-williams.com continúa al reverso

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 flora 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 03/29/2013 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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:

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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint ~~or rubbing (isopropyl) alcohol~~ containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. We will measure how much chemical can be removed from your hands by rinsing and scrubbing your hands with a gauze sponge soaked with a solution of ~~isopropyl~~ rubbing alcohol (also called isopropyl alcohol or IPA) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 BIT in rubbing alcohol.~~ You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, ~~or~~ paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your palms facing up. We will place a small amount of paint ~~or rubbing alcohol~~ on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands ~~one at a time~~ with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe samples, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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 might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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 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. We may take photographs or video of the study, but we will edit these so that you cannot be identified.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*			
6. Name			
7. Address			
8. City, ST, Zip			
9. Telephone(s)			
10. Age in years =	11. DOB:	12. Sex ☐M ☐F	
13. Resident in Fresno County? ☐Yes ☐No			
14. Preferred Language: ☐English ☐Spanish	15. Reads: ☐English ☐Spanish		
16. Are you pregnant? ☐NA ☐Yes ☐No	17. Are you nursing a baby? ☐NA ☐Yes ☐No		
18. Do you consider your general health good enough to participate in this study as described?	☐Yes ☐No		
19. Are you bothered by house paint smell or house paint on your skin more than family or friends?	☐Yes ☐No		
20. 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 AND BIT REFERENCE SUBSTANCE

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.

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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.

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SIGMA-ALDRICH sigma-aldrich.com

Material Safety Data Sheet

Version 4.2
Revision Date 10/05/2012
Print Date 05/30/2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Supplier	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052
Emergency Phone # (For both supplier and manufacturer)	:	(314) 776-6555
Preparation Information	:	Sigma-Aldrich Corporation Product Safety - Americas Region 1-800-521-8956

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

GHS Classification
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Serious eye damage (Category 1)
Skin sensitization (Category 1)
Acute aquatic toxicity (Category 1)

GHS Label elements, including precautionary statements

Pictogram

Signal word Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary statement(s)

P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

HMIS Classification

Health hazard:	2
Flammability:	0
Physical hazards:	0

NFPA Rating

Health hazard:	2
Fire:	0
Reactivity Hazard:	0

Potential Health Effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.
Ingestion	Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula : C_7H_5NOS

Molecular Weight : 151.19 g/mol

Component		Concentration
1,2-Benzisothiazolin-3-one		
CAS-No.	2634-33-5	-
EC-No.	220-120-9	
Index-No.	613-088-00-6	

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	crystalline
Colour	light yellow

Safety data

pH	no data available
Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Autoignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Vapour pressure	no data available
Density	no data available
Water solubility	no data available

Partition coefficient: n-octanol/water	no data available
Relative vapour density	no data available
Odour	no data available
Odour Threshold	no data available
Evaporation rate	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
no data available

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides
Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50
LD50 Oral - rat - 1,020 mg/kg

Inhalation LC50
no data available

Dermal LD50
no data available

Other information on acute toxicity
no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
May cause allergic skin reaction.

Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects
no data available

Additional Information
RTECS: DE4620000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Spanish Material Safety Data Sheet for Sherwin-Williams Latex Paint here after translation of approved English version

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint ~~or rubbing alcohol~~ on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: ~~502~~/~~3002~~/~~2013~~2015

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 removal efficiency 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 removed from the palms of your hand when paint ~~or rubbing alcohol~~ containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint ~~or rubbing alcohol~~ on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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:
vii

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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Target BIT Concentration
AEA08-RE-01-PL-~~LH~~	1	120 ppm
AEA08-RE-~~0~~102-PL-~~RH~~	~~1~~2	120 ppm
AEA08-RE-0~~3~~2-PL-~~LH~~	~~2~~3	120 ppm
AEA08-RE-0~~4~~2-PL-~~RH~~	~~2~~4	120 ppm
AEA08-RE-0~~5~~3-PL-~~LH~~	~~3~~5	120 ppm
AEA08-RE-0~~6~~3-PL-~~RH~~	~~3~~6	120 ppm
AEA08-RE-0~~7~~4-PL-~~LH~~	~~4~~7	120 ppm
AEA08-RE-0~~8~~4-PL-~~RH~~	~~4~~8	120 ppm
AEA08-RE-0~~9~~5-PL-~~LH~~	~~5~~9	120 ppm
AEA08-RE-~~10~~05-PL-~~RH~~	~~5~~10	120 ppm
AEA08-RE-~~11~~06-PH-~~LH~~	~~6~~11	600 ppm
AEA08-RE-~~12~~06-PH-~~RH~~	~~6~~12	600 ppm
AEA08-RE-~~13~~07-PH-~~LH~~	~~7~~13	600 ppm
AEA08-RE-~~14~~07-PH-~~RH~~	~~7~~14	600 ppm
AEA08-RE-~~15~~08-PH-~~LH~~	~~8~~15	600 ppm
AEA08-RE-~~16~~08-PH-~~RH~~	~~8~~16	600 ppm
AEA08-RE-~~17~~09-PH-~~LH~~	~~9~~17	600 ppm
AEA08-RE-~~18-09~~-PH-~~RH~~	~~9~~18	600 ppm
AEA08-RE-~~19~~0-PH-~~LH~~	~~10~~19	600 ppm
AEA08-RE-~~20~~10-PH-~~RH~~	~~10~~20	600 ppm
~~AEA08-RE-11-SL-LH~~	~~11~~	~~786 µg/mL~~
~~AEA08-RE-11-SL-RH~~	~~11~~	~~786 µg/mL~~
~~AEA08-RE-12-SL-LH~~	~~12~~	~~786 µg/mL~~
~~AEA08-RE-12-SL-RH~~	~~12~~	~~786 µg/mL~~
~~AEA08-RE-13-SL-LH~~	~~13~~	~~786 µg/mL~~
~~AEA08-RE-13-SL-RH~~	~~13~~	~~786 µg/mL~~
~~AEA08-RE-14-SL-LH~~	~~14~~	~~786 µg/mL~~
~~AEA08-RE-14-SL-RH~~	~~14~~	~~786 µg/mL~~
~~AEA08-RE-15-SL-LH~~	~~15~~	~~786 µg/mL~~
~~AEA08-RE-15-SL-RH~~	~~15~~	~~786 µg/mL~~
~~AEA08-RE-16-SH-LH~~	~~16~~	~~3.9 mg/mL~~
~~AEA08-RE-16-SH-RH~~	~~16~~	~~3.9 mg/mL~~
~~AEA08-RE-17-SH-LH~~	~~17~~	~~3.9 mg/mL~~
~~AEA08-RE-17-SH-RH~~	~~17~~	~~3.9 mg/mL~~
~~AEA08-RE-18-SH-LH~~	~~18~~	~~3.9 mg/mL~~
~~AEA08-RE-18-SH-RH~~	~~18~~	~~3.9 mg/mL~~
~~AEA08-RE-19-SH-LH~~	~~19~~	~~3.9 mg/mL~~
~~AEA08-RE-19-PH-RH~~	~~19~~	~~3.9 mg/mL~~
~~AEA08-RE-20-PH-LH~~	~~20~~	~~3.9 mg/mL~~

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AEA08-RE-20-PH-RH	20	3.9 mg/mL

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-S-01-C	Control	None
AEA08-FF-S-01-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-01-H2	High Fortified with Solvent	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg
AEA08-FF-S-02-C	Control	None
AEA08-FF-S-02-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-02-H2	High Fortified with Solvent	390 µg

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Megan Boatwright

'om: Robert Testman
ɔent: Tuesday, April 18, 2017 8:56 AM
To: Megan Boatwright
Subject: FW: Invoicing for 120463 and 130503
Attachments: 130503 Newspaper Advertisement Soliciting Subjects - English.docx; 130503 Subject Invitation to Participate Script - English.docx; 130503 Subject Self Reporting Form - English.docx

From: Robert Testman
Sent: Monday, February 2, 2015 9:33 AM
To: Jeffrey Atlas <JAtlas@sairb.com>
Subject: RE: Invoicing for 120463 and 130503

Hi Jeff,

The standalone Word versions are attached.

Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Monday, February 2, 2015 9:16 AM
To: Robert Testman
Subject: RE: Invoicing for 120463 and 130503

Thank you. Also, for the purpose of translations, I will need the Word version of Appendix D, F, & G.

Thanks!

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: Robert Testman [mailto:rtestman@gplabs.com]
ent: Monday, February 02, 2015 11:59 AM
To: Jeffrey Atlas
Subject: RE: Invoicing for 120463 and 130503

Hi Jeff,

'es, please process with Rush handling at additional charge.

Thanks,
Rob

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Monday, February 2, 2015 8:57 AM
To: Robert Testman
Subject: RE: Invoicing for 120463 and 130503

Hi Rob,

We will not require separate Word versions as we can pull them out of the protocol if need be. Please confirm you would like us to process all submission documents, including the new study documents, for additional RUSH charges.

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
ıtlas@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**

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Sent: Monday, February 02, 2015 11:52 AM
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Subject: RE: Invoicing for 120463 and 130503

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VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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

Subject Invitation to Participate Script

[Identify yourself and company affiliation, ask if they are calling about the removal efficiency 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 removed from the palms of your hand when paint containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright or the Spanish speaking researcher.)

Qualification Worksheet

AEATF Worker Exposure Study AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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 heart failure? Do you have uncontrolled high blood pressure?	☐Yes ☐ No congestive			
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*				
6. Name				
7. Address				
8. City, ST, Zip				
9. Telephone(s)				
10. Age in years =	11. DOB:	12. Sex ☐ M ☐ F		
13. Resident in Fresno County? ☐ Yes ☐ No				
14. Preferred Language: ☐ English ☐ Spanish	15. Reads: ☐ English ☐ Spanish			
16. Are you pregnant? ☐ NA ☐Yes ☐ No	17. Are you nursing a baby? ☐ NA ☐Yes ☐ No			
18. Do you consider your general health good enough to participate in this study as described? ☐ Yes ☐ No				
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐ No				
20. 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:

Megan Boatwright

From: Robert Testman
Sent: Monday, April 17, 2017 4:08 PM
To: Megan Boatwright
Subject: FW: Invoicing for 120463 and 130503

From: Jeffrey Atlas [mailto:JAtlas@sairb.com]
Sent: Monday, February 2, 2015 1:30 PM
To: Robert Testman <rtestman@gplabs.com>
Cc: Denisse Guzman <DGuzman@sairb.com>
Subject: RE: Invoicing for 120463 and 130503

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Thank you.

Best Regards,

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From:	Robert Testman
Sent:	Monday, April 17, 2017 4:04 PM
To:	Megan Boatwright
Subject:	FW: Invoicing for 120463 and 130503
Attachments:	science-ethics-review-removal-efficiency-protocol-march-2014.pdf; CDPR letter 23Jan2014 - Response to review (130503).pdf; DPR Review of GPL Response Letter to DPR.pdf; ny12-19a.pdf

From: Robert Testman
Sent: Monday, February 2, 2015 2:13 PM
To: Jeffrey Atlas <JAtlas@sairb.com>
Cc: Denisse Guzman <DGuzman@sairb.com>
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Hi Jeff,

Attached are the HSRB review document, the initial CDPR review comments, GPL's response and the email from CDPR accepting these modifications. CDPR and EPA will issue final approval letters after full IRB approval is in place.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 18, 2014

MEMORANDUM

SUBJECT: Science and Ethics Review of AEATF II Paint Hand Wash Removal Efficiency Protocol

FROM: Timothy Leighton, Senior Scientist
Antimicrobials Division
Office of Pesticide Programs

Kelly Sherman, Human Research Ethics Review Officer
Office of the Director
Office of Pesticide Programs

Jonathan Cohen, Ph.D.
Statistician
ICF International (EPA Contractor)

TO: Steven Weiss, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division
Office of Pesticide Programs

We have reviewed the referenced proposal from both scientific and ethics perspectives. Scientific aspects of the proposed research are assessed in terms of the recommendations of Brouwer et al (2000) and of the EPA Human Studies Review Board. Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L and the recommendations of the EPA Human Studies Review Board. Below is a summary of the conclusions reached in our science and ethics reviews.

Science Review

- The EPA recommends that the AEATF II video this hand wash procedure so that researchers that use this same procedure in future studies can better gauge and mimic this procedure.

Ethics Review

- The protocol meets the applicable ethical requirements of 40 CFR part 26, subparts K and L.

- Before the research is initiated, the documents should be revised as follows and resubmitted for review and approval by the reviewing IRB:

    - Expand the exclusion criteria in the protocol and consent form to exclude subjects with allergies or sensitivities to BIT[1] or other chemical-based products

    - In the section of the consent form titled "Test Product," please describe the test product as a pesticide. The following revision is recommended:

        - *"The test product contains a* ~~***chemical***~~ ***pesticide*** *known as BIT which helps keep bacteria from growing."*

    - In the section of the consent form titled "Risks," please revise the beginning of item #1 as follows:

        - *"Risk of a reaction to the latex paint* ***or the pesticide ingredient (BIT) contained in it****. Direct contact with the paint...."*

- The AEATF should incorporate the forthcoming guidance from the HSRB about how to provide personal exposure results to subjects.

Completeness of Protocol Submission

The submitted protocol was reviewed for completeness against the required elements listed in 40 CFR §26.1125. EPA's checklist is appended to this review as Attachment 6. All elements of required documentation are provided in the submitted protocol package.

Volume 1 of the submitted package includes the following supporting documents—all considered in this review:

- Transmittal Letter (p. 2)
- 40 CFR 26.1125 Checklist (pp. 7-8)

Volume 2 of the submitted package includes the following documents:

- SAIRB conditionally-approved draft protocol dated 1/23/14 (pp. 3-38)
- SAIRB Study Status Notification I dated 11/14/13 (pp. 132-3)
- SAIRB Study Status Notification II dated 12/4/13 (p. 134)

[1] BIT = 1,2-Benzisothiazol-3(2H)-one

- Protocol review by California Department of Pesticide Regulation (CDPR) (pp. 135-141)
- Golden Pacific Laboratories response to protocol review by CDPR (pp. 135-150)
- Informed Consent Form and Experimental Subject's Bill of Rights (draft 1/23/14) (pp. 44-53) – English version provided; will be translated to Spanish after final approval
- Qualification Worksheet (draft 1/23/14) (p. 56) – English version provided; will be translated to Spanish after final approval
- Newspaper Advertisement (draft 1/23/14) (p. 71) – English version provided; will be translated to Spanish after final approval
- Script for receiving phone calls in response to advertisement (draft 1/23/14) (pp. 74-5) – English version provided; will be translated to Spanish after final approval

Volume 3 of the submitted package includes documentation of communications with SAIRB and CDPR, as well as copies of CVs and ethics training records for field investigators..

Volume 4 of the submitted package includes copies of the AEATF II Standard Operating Procedures (SOPs) that are referenced in the AEA08 Removal Efficiency Study protocol.

A. Summary Assessment of the Scenario Design

Supporting details are in Attachment 1.

1. Scenario Design: This proposal is to measure the hand wash removal methodology to determine its efficiency to support the AEATF II's protocol to monitor exposure of test subjects while they paint with brush/rollers. The AEATF II defines the objective of this efficiency study as: *"This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT."* (V2:7)[2] *"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."* (V2:9) The AEATF II proposes to recruit test subjects from the general population. *"Adult subjects will be recruited from the population of Fresno County, CA and the surrounding area"* (V2:20) In summary, the test subjects will have their right and left palm surfaces fortified with BIT-treated paint or BIT-treated isopropyl alcohol (IPA). The test substance will be allowed to dry on the subject's hands for 45 minutes and then the researchers will perform a hand wash procedure to mimic the hand wash procedure in the actual painting study. The results of the paint portion of the efficiency study will be used to correct for any losses on the test subject's hands in the paint brush/roller exposure study. The results of the IPA portion of the efficiency study will be

[2] This pagination convention is used throughout this review. "V1" refers Volume 1, "V2" refers to Volume 2, etc. Entries after the colon are page references; many page images bear more than one page number. In Volume 1, the cited page number is from the expression "Page n of 5" found at the bottom right-hand corner. Volume 2 page references are from the expression "Page n of 105" found at the bottom right-hand corner. Volume 3 page references are from the expression "Page n of 318" found at the bottom right-hand corner. Volume 4 page references are from the expression "Page n of 74" found at the bottom right-hand corner.

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 following are the basic procedures to be performed by the researchers in this hand wash efficiency study:

- Prior to fortification the hands will be washed with Ivory soap and water and dried with paper towels. (V2:18)
- *"BIT in paint or solvent will be applied to hands using positive displacement micropipettes...."* (V2:16)
- *"The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. ... A glass capillary tube will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The capillary tube from each subject will be placed into a glass test tube and stored frozen prior to analysis."* (V2:18-19)
- *"After 45 minutes* [of drying time] *the subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with a gauze sponges (J&J Mirasorb 4-ply each)* [stacked together]. *The gauze sponge will be soaked with 50% IPA I 50% distilled water and used for scrubbing until all dried paint is loosened or removed. The researchers will then rinse the hand with the same solvent by pouring the solvent over the hand and having the subject rub their fingers and palm together. The total volume of IPA/water solution used will be 250 mL. The used gauze sponges will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis. The procedure will then be repeated for the second hand producing a second sample."* (V2:19)

The AEATF II proposes to use a total of 20 test subjects to measure hand wash efficiency. The subjects will be randomly assigned to either paint or IPA solutions at two concentrations of BIT per solution as depicted in Table 1. The proposal reports the fortifications as 78.5 µg/hand and 390 µg/hand (same as calculated in Table 1). (V2:17) Based on the conversion of the solution concentrations to a loading on the palmar surface area, it is estimated that the loadings on the hands are 1.6 and 7.8 µg/cm^2 for Groups 1/3 and 2/4, respectively.

In comparison, the paint brush scenario in the Pesticide Handlers Exposure Database (PHED) indicates the loading on the subjects ranged from 4.8 to 19.7 µg/cm^2 with an arithmetic mean of 10.5 µg/cm^2. The proposed loadings are within the range of anticipated hand wash residue from the proposed brush/roller painting scenario. Note: A glass capillary tube will be used to spread the test substance across the palm. The amount remaining on the tube will be accounted for in the efficiency calculations; and this amount will be subtracted from the loading estimate provided in Table 1 (i.e., the loading in Table 1 is the nominal amount and the actual will be a little less).

Table 1. Summary of Hand Wash Efficiency Proposal.

Group	No. Test Subjects	Solution (per hand)	Concentration of BIT	AaiH (per hand)		Loading ($\mu g/cm^2$)[c]
				Pounds[a]	μg[b]	
1	5	500 µL Latex Paint	120 ppm	1.73E-7	78.2	~1.6
2	5		600 ppm	8.63E-7	391	~7.8
3	5	100 µL IPA	0.786 mg BIT/mL IPA	--	78.5	~1.6
4	5		3.9 mg BIT/mL IPA	--	390	~7.8

[a]AaiH (pounds) for paint = mg/kg BIT conc x µL solution x 1 kg/1E6 mg conversion x 1 L/1E6 µL conversion x 10.88 lb/gal paint density x 1 gal/3.785 L conversion

[b]AaiH (µg) for the IPA solution is based on the values reported in the protocol (V2:17). EPA estimate of AaiH is similar but differences in the IPA density used in the calculation may account for rounding differences (therefore, EPA's estimate is not provided for IPA). The paint estimates are based on EPA's calculations.

[c]Loading ($\mu g/cm^2$) = AaiH (mg) x (1000 µg/mg conversion) / (50 cm^2 palm surface area; EPA reviewer's estimate).

EPA intends to use the paint portion of the hand wash removal efficiency study results to correct for potential loses during the hand wash sampling to be conducted in the AEATF II's brush/roller painting exposure study (and the future airless paint sprayer exposure study if performed with BIT as the surrogate chemical). The AEATF II indicates that the IPA portion of the results *"...will better enable extrapolation of the paint data to other antimicrobial active ingredients."* (V2:11) This means that the IPA results can be used (1) in future exposure studies to correct for hand wash removal efficiencies where a non-paint liquid solution is used; and (2) to make comparisons of removal efficiency differences between paint versus liquids (non-paint).

EPA believes that the AEATF II hand wash removal efficiency study is well defined, and we expect that the resulting data will meet the needs of EPA and other regulatory agencies (e.g., hand wash removal efficiency data corrections).

2. Sampling Design: *"This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT."* (V2:7) The study will also measure the removal efficiency of BIT from an isopropyl alcohol (IPA) solution.

"The test substances in this study are latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 ug/ml and 3.9 mg/ml. The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). ... The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. ... All study participants will be adult subjects

capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 10 subjects at one of two concentrations (5 subjects each). A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. Hand exposure will be measured by scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs fingers to their palm. The gauze pads will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in IPA or latex paint, and correction of data from monitoring events (MEs) for this factor." (V2:10)

"Each subject will be placed into one of four groups. Subjects assigned to group one will have each hand fortified with a 500 ~L volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 uL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 uL of a fortification solution of BIT targeted to be at a concentration of 786 ug/ml in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 uL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/ml in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 ug per hand or 390 ug per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tube. The glass capillary tube will be placed into a glass test tube and retained for analysis. The paint or solution will be left on the hands to dry for 45 minutes. Each hand will then be washed by scrubbing with a gauze sponge soaked in 50% IPA/50% distilled water solution and rinsed with the same solution. The solution and gauze sponge will be collected as a single sample for each hand, extracted and analyzed." (V2:17)

3. Choice of Surrogate Material: The test substance for this study is the formulated product, Sherwin-Williams latex paint, containing 1, 2-benzisothiazoline-3-one (BIT). This is the same substance that is being monitored in the brush/roller exposure study for which the results of the hand wash efficiency study will be used to correct loses of BIT during the hand exposure monitoring/sampling. In addition, the AEATF II plans to also

use IPA treated with BIT to determine the hand wash efficiency in a solvent other than paint. The CAS number for BIT is 2634-33-5. The *EPA registration for Mergal® BIT20 is 5383-121. BIT has been selected as the surrogate compound in the brush/roller exposure study because of "... its stability, abundance in the formulation, and sensitivity of its analytical method."* (Volume 2 of the separate Brush/Roller Protocol on page 17) The vapor pressure of BIT is 4.4E-7 mmHg at 20° C which is considered to be low.

C. Summary Assessment of the Scientific Aspects of the Study Design

Supporting details are in Attachment 2.

1. **Statistical design:** The sample size for this proposal is for 20 test subjects to be placed in 4 groups, 5 subjects per group, each subject will have their left and right hand sampled (see Table 1 above). The protocol does not mention a rationale for the sample size. There are no guidelines for the hand wash removal efficiency study. In fact, this is the first removal efficiency study being conducted for the Office of Pesticide Programs (OPP) since the Human Studies Rule in 2006. Brouwer et al (2000) reviewed the literature and reported the sample size for 10 different chemicals. Typically researchers conducting these types of studies used a sample size of 4 for each different hand loading tested. AEATF II proposes to use 5 test subjects per different loading and both the left and right hands per subject will be tested (n=10 per loading). As detailed in Subsection 2.1a of Attachment 2, the proposed sample sizes will give an estimated precision of within plus or minus 10% for the mean percentage removal efficiency for each of the four groups.

2. **Proposed pattern of human exposure:** The proposal is an experiment to measure the hand wash removal efficiency rather than to capture a specific pattern of exposure such as potential exposure from painting with a brush/roller. EPA is basing our assessment of the proposal based on the findings in the review of the literature by Brouwer et al (2000). Brouwer et al (2000) did not identify a standard approach for hand wash efficiency sampling. However, the authors did list two approaches they reviewed in the literature: (1) mass balance and (2) direct spiking. The mass balance approach is based on transferring residues from surfaces and the direct spiking approach is for exposure to liquids. The direct spiking approach is proposed in this protocol and is appropriate to support the proposed AEATF II study for monitoring exposure during painting with brush/rollers (in a separate study). The AEATF II's proposed study is assessed by EPA based on the various variables suggested by Brouwer et al (2000):

    - **Residence time** – Residence time is the duration of exposure of the test substance on the subject's hand prior to the wash procedure. Various citations are provided suggesting that the sampling efficiency over time is reduced for some compounds. This is *"of major importance"* for chemicals that are absorbed or adsorbed to the skin. The dermal absorption of BIT in rats is ~40% over 72 hours (MRID 46327901). The AEATF II's proposes to use a 45 minute residence time. The

painting study, for which this efficiency study is being conducted, anticipates the exposure time to be from 120 to 180 minutes (maximum of 3 to 4 hours). Subjects will be exposed throughout this anticipated sampling time; not all of the exposure occurs at time zero. Given the dermal absorption over time in this rat study of 1.7% after 4 hours, 3.2% after 8 hours, 19.1% after 24 hours, 35.3% after 48 hours, and 40.6% after 72 hours, the absorption at the proposed residence time of 45 minutes should not be too different than the absorption at the maximum of 4 hours anticipated in the painting exposure study. 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. Note: Absorbable material remained on the rat skin after washing; these values were as follows: 15.1% after 4 hours, 23.9% after 8 hours, 36.8% after 24 hours, 48.7% after 48 hours, and 47.6% after 72 hours. A substantial amount remained on the skin indicating a vigorous wash procedure is necessary and an efficiency study is warranted.

- **Skin loading (mass)** – *"...shows some, but not consistent, evidence for the assumption of decrease of removal efficiencies for low skin loadings."* While the total mass (µg) of a surrogate chemical reported in PHED for the paint brush scenario is greater than the AEATF II's proposed efficiency study, the two are not a good comparison because PHED is based on the entire hand and the efficiency study is based on only the palmer surface area only. A better comparison is the loading ($\mu g/cm^2$) of BIT and the loading observed in the PHED paint brush scenario ($\mu g/cm^2$); and the two are very similar. PHED reports a range of loadings from 4.8 to 19.7 with a mean of 10.5 $\mu g/cm^2$ compared to the hand loadings of 1.6 and 7.8 $\mu g/cm^2$ in this BIT proposal. The loading ($\mu g/cm^2$) in the BIT proposal is based on EPA's estimate (see Table 1) assuming a 50 cm^2 palm surface area (estimated by EPA as a palm surface area minus the 2 cm edge not proposed to be treated, and then rounded). The actual surface area to be fortified in the BIT proposal is not provided. If Brouwer's observation is correct (decreased removal efficiencies for low skin loadings), this would lead to a more conservative (protective) correction factor rather than less. This research will also provide some data to answer Brouwer's question of *"...no data are available to evaluate the influence on sampling performance for ... similar surface area exposed for different mass of the contaminant, i.e., different amounts of contaminant per surface area contaminated ($\mu g/cm^2$)."*
- **Method of contamination and chemical/physical state** – The hand exposure in the painting study will be to the BIT-treated latex paint. The efficiency study is also using the same BIT-treated latex paint matrix, plus the IPA-treated solution. The actual method of contamination in the painting study results from splashes/drips/physical contact resulting in paint exposure to various parts of the hand. A controlled efficiency study is based on application of the test substance with a pipette and spread on palm with a glass tube. Although there are differences in the exposure/application, it is the nature of the studies.
- **Number of consecutive washes** – The same wash procedure used in this efficiency study will be used in the brush/roller exposure study (i.e., scrubbing

hand with gauze sponge with a follow-up 250 mL rinse while subject rubs their fingers to their palm).

- **Wash time** -- The same wash procedure used in this efficiency study will be used in the brush/roller exposure study. The wash time will be similar if the same procedures are followed. EPA recommends that the AEATF II video the procedure so that researchers in future studies can gauge and mimic this hand wash procedure.
- **Washing fashion/time and rinsing time** -- The same wash procedure used in this efficiency study will be used in the brush/roller exposure study (i.e., *"...scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs their fingers to their palms. The gauze pads will be added to the rinse solvent for extraction."* (V2:10)). The researchers will need to be sure they use the same vigor/pressure/time for this wash procedure in the paint brush/roller study as in this efficiency study.
- **Solvent rinsing** – The gauze sponges used for scrubbing the hand to loosen or remove the dry paint will be soaked with a 50/50 solution of IPA/distilled water and then the hand subsequently rinsed with 250 mL of the 50/50 IPA/distilled water.
- **Water/soap methods** – not applicable to the proposed procedure.
- **Water hardness** – the hand wash solution is a 50/50 solution of IPA/distilled water. Therefore, the water hardness is not applicable.
- **Pre-wash** – The test subjects will have their hands washed with Ivory liquid soap prior to being fortified with the test substance.

The EPA believes that the AEATF II hand wash efficiency study will be useful in correcting the potential losses during the sampling of test subject's hands in the painting exposure study.

3. **Endpoints and Measures:** The AEATF II proposes to measure the hand wash removal efficiency for BIT-treated paint and BIT-treated IPA solution.

   "Air temperature and relative humidity of the room for the duration of the 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." (V2:27)

4. **QA/QC Plan:** The study will be conducted under the FIFRA GLP Standards (40CFR160) (V2:8). The AEATF II QA/QC plan for the efficiency study is described in sufficient detail and is adequate to ensure that the measurements are accurate and reliable. The QA/QC plan includes: *"Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint or in solvent will be prepared at the appropriate concentrations."* (V2:27) *"Field*

fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed." (V2:28)

5. **Statistical Analysis Plan:** The results of monitoring data will be provided in the final report. *"At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the capillary tubes used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100. Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report."* (V2:31-32)

D. Compliance with Applicable Scientific Standards

This protocol adequately addresses the following elements according to applicable scientific standards:

- Scientific objective
- Experimental design for achieving objectives
- Quantification of the test materials
- Data collection, compilation and summary of test results
- Justification for selection of test substance and dilution rate
- Justification for sample size (Although the protocol itself does not adequately justify the sample size used, EPA's calculations using the literature review by Brouwer et al (2000) provide that justification.)
- Fortification levels and number of samples for laboratory, field, and storage stability samples

Additionally, the AEATF II is conducting the study under the Good Laboratory Practices (GLPs).

Recommendations:

EPA recommends that the AEATF II video tapes the hand wash procedure so that it can be duplicated in future BIT studies.

E. Summary Assessment of Ethical Aspects of the Proposed Research

Supporting details are in Attachment 2.

1. **Societal Value of Proposed Research:** The purpose of this study is to measure the removal efficiency of the antimicrobial active ingredient BIT in latex paint and in isopropyl alcohol from human hands. The data produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. Because many professional and non-professional painters use latex paint containing antimicrobial products, the research question is important; it cannot be answered with confidence without new monitoring data meeting contemporary standards of quality and reliability.

2. **Subject Selection:** Twenty-eight adult subjects will be recruited from the Fresno, California area (20 initially assigned for monitoring plus eight alternates). Participants will self-identify in response to newspaper advertisements in three different newspapers targeting different demographic groups. Callers responding to the newspaper advertisements will be screened, scheduled for informed consent meetings, and enrolled.

   While it is possible that people who respond to the advertisements are different in some unknowable ways from those who do not respond, there is no reason to think that respondents in Fresno, California area are not typical of people who would respond to these types of advertisements in other areas of the United States. Placing advertisements in three newspapers with different circulations furthers the goal of minimizing bias and achieving as much diversity as possible among respondents and subjects.

   The inclusion/exclusion criteria are complete and appropriate except that "sensitivities to BIT or other chemical-based products" should be added to the list of exclusions. Pregnant or nursing women are excluded from participation. Employees or relatives of employees of the investigators, of any of the companies that are members of the AEATF-II task force, or of the American Chemistry Council are also excluded from participation.

   No potential subjects are from a vulnerable population. Recruitment materials and interactions with potential subjects will be conducted in English or Spanish, depending on subject preference. Subjects will be recruited through newspaper advertisements, not through employers, which will minimize the potential for coercion or undue influence.

3. **Risks to Subjects** The proposed test material, BIT, is an EPA-registered antimicrobial pesticide active ingredient with an essentially complete supporting database. It has been tested extensively in animals and was shown to be moderately toxic by oral and dermal routes, a slight dermal irritant, and a moderate dermal sensitizer. Based on its safety profile, BIT has been approved for use in many

household products including paint, laundry detergents, and household cleaners. In this study, BIT would be contained in latex paint consistent with existing EPA approvals and its EPA-approved label.

Risks to subjects include the risk of a reaction to the test material or the latex paint or the risk irritation due to rubbing alcohol used on the hands; and the risks associated with pregnancy testing, including an unexpected result or loss of privacy. All identified risks are characterized as of low probability.

Risks are minimized by exclusion of candidates known to be allergic or sensitive to latex paint, isopropyl alcohol, BIT or other chemical-based products, in poor health, or with broken skin on hands; alerting subjects to signs and symptoms of a skin reaction; medical professional on-site observing the subjects; and incorporation of procedures to keep the results of pregnancy testing private and to permit discrete withdrawal.

4. **Benefits:** This research offers no direct benefits to the subjects. The principal benefit of this research is to allow accurate interpretation of results from a separate study measuring exposure of individuals who apply latex paint containing BIT. This information could be used by EPA and other regulatory agencies to support exposure assessments.

5. **Risk/Benefit Balance:** Risks to subjects have been thoughtfully and thoroughly minimized in the design of the research. The low residual risk is reasonable, in light of the likely benefits to society from new data supporting more accurate exposure assessments for antimicrobial products.

6. **Independent Ethics Review:** The proposed research has been reviewed and conditionally approved by the Schulman Associates IRB. The approval (issued in November 2013) is conditioned on reviews being completed by CDPR and HSRB. CDPR provided comments in December 2013, and the versions of the protocol and consent materials that were reviewed herein incorporate the CDPR's recommended revisions. EPA anticipates that SAIRB will issue a full approval once the HSRB review process is complete. This research may not be initiated until IRB approval is granted.

7. **Informed Consent:** Informed consent will be obtained from each prospective subject and appropriately documented in the language preferred by the subject. Literacy in English or Spanish is a requirement for inclusion in the study.

   All written recruitment, consent, and risk communication materials will be available in both English and Spanish. In order to ensure effective communication and thorough comprehension by anyone preferring Spanish over English, a Spanish-speaking member of the research team will be present at the meetings at which candidates are qualified and sign consent forms.

8. **Respect for Subjects:** Subject-identifying information will be recorded only once; all subsequent data records and reports will refer to individual subjects only by an arbitrary code. Provision is made for discrete handling of the pregnancy testing that is required of female subjects on the day of testing. Candidates and subjects will be repeatedly informed that they are free to decline to participate or to withdraw at any time for any reason, without penalty.

F. Compliance with Applicable Ethical Standards

This is a protocol for third-party research involving intentional exposure of human subjects to a pesticide, with the intention of submitting the resulting data to EPA under the pesticide laws. 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.

A detailed evaluation of how this proposal addresses applicable standards of ethical conduct is included in Attachments 2-5 to this review.

EPA Ethics Comments

Before the research is conducted, the documents should be revised as follows and resubmitted for review and approval by the reviewing IRB:

- Revise the fourth exclusion criteria as follows: ***Allergies or sensitivities to latex paint, soaps, isopropyl alcohol, BIT, or other chemical-based products***

- In the section of the consent form titled "Test Product," please describe the test product as a pesticide. The following revision is recommended:

  - *"The test product contains a ~~chemical~~ **pesticide** known as BIT which helps keep bacteria from growing."*

- In the section of the consent form titled "Risks," please revise the beginning of item #1 as follows:

  - *"Risk of a reaction to the latex paint **or the pesticide ingredient (BIT) contained in it**. Direct contact with the paint...."*

The AEATF should incorporate the forthcoming guidance from the HSRB about how to provide personal exposure results to subjects.

EPA Ethics Conclusions

40 CFR 26 Subpart L, at §26.1703, as amended effective April 15, 2013, provides in pertinent part:

> EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

The protocol requires that subjects be at least 18 years old and excludes female subjects who are pregnant or lactating. Thus §26.1703 would not forbid EPA to rely on a study executed according to this protocol.

If the comments noted above are addressed and the amended protocol is approved by the overseeing IRB, this research should meet the ethical standards of FIFRA §12(a)(2)(P) and 40 CFR 26 subparts K and L.

Attachments:

1. Summary Review of AEATF Removal Efficiency Study protocol dated February 5, 2014
2. Summary Review of AEATF Removal Efficiency Study protocol dated February 5, 2014
3. §26.1111 Criteria for IRB approval of research
4. §26.1116 General requirements for informed consent
5. §26.1117 Documentation of informed consent
6. §26.1125 Criteria for Completeness of Proposals for Human Research

EPA Scenario Review: AEATF-II Hand Wash Removal Efficiency Protocol

Title: **REMOVAL EFFICIENCY STUDY** (Volume II)

Date: February 5, 2014

Sponsor: American Chemistry Council
Antimicrobial Exposure Assessment Task Force II
c/o Hasmukh Shah, Ph.D.
700 2nd Street, NE
Washington, DC 20002

1. Scope of Scenario Design

(a) Is the scenario adequately defined?

"This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT." (V2:7) The study will also determine the removal efficiency for an IPA-BIT treated solution.

"The test substances in this study are latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 ug/ml and 3.9 mg/ml. The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). ... The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. ... All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 10 subjects at one of two concentrations (5 subjects each). A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. Hand exposure will be

measured by scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs fingers to their palm. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in IPA or latex paint, and correction of data from monitoring events (MEs) for this factor." (V2:10)

"Each subject will be placed into one of four groups. Subjects assigned to group one will have each hand fortified with a 500 ~L volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 uL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 uL of a fortification solution of BIT targeted to be at a concentration of 786 ug/ml in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 uL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/ml in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 ug per hand or 390 ug per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tube. The glass capillary tube will be placed into a glass test tube and retained for analysis. The paint or solution will be left on the hands to dry for 45 minutes. Each hand will then be washed by scrubbing with a gauze sponge soaked in 50% IPA/50% distilled water solution and rinsed with the same solution. The solution and gauze sponge will be collected as a single sample for each hand, extracted and analyzed." (V2:17)

(b) Is there a need for the data? Will it fill an important gap in understanding?

In a separate study, the AEATF II plans to conduct dermal exposure monitoring for test subjects using treated paint. The hand exposure in the AEATF II's other study on painting will use the same hand wash approach as proposed in this protocol's hand wash efficiency study. As noted in Brouwer et al (2000), *"when removal techniques are used to assess dermal exposure monitoring for risk assessment purposes, it is recommended to conduct sampling efficiency studies as a key issue for method performance."* The proposed study will fill that data gap.

2. Rationale for Scenario Sampling Design

(a) Are the variables in the brush and roller painting scenario design likely to capture diverse exposures at the high-end?

The important variables in a hand wash efficiency study are discussed in Brouwer et al (2000) and described above in this review. The hand wash methodology proposed in this protocol is the same hand wash approach/procedure being proposed in the AEATF II's

painting exposure study. The hand wash procedures in the efficiency study need to be very similar, if not identical, to the hand wash procedures in the exposure study to be able to use the efficiency results to correct for loses (i.e., incomplete residue removal from subject's hands).

(b) How have random elements been incorporated into the scenario sampling design?

Random elements have been incorporated into the design as follows: *"The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four groups, each corresponding to one of the four test substance/concentration combinations. The first set of seven subjects will be placed into Group 1, the second set of seven subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4.*

Within each group of seven, the first five subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the group of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into four groups, subjects from the first group will be scheduled into the study. No more than two groups will be monitored in one day. The randomization process will prevent bias." (V2:19-20)

(c) What feasible opportunities to incorporate random elements in the design—if any—have been overlooked?

None.

(d) What typical patterns of exposure will likely be included by the sampling design?

This protocol is a controlled exposure experiment (i.e., test subject's hands will be fortified with a BIT-treated substance by the researchers). The procedures that the researchers will use to fortify the subject's hands are described above.

(e) What typical patterns of exposure will likely be excluded by the sampling design?

The sampling design uses the palmar surfaces of the hands to measure hand wash removal efficiency. Fortifying the tops of the hands and the fingers will be excluded in the design.

3. Is the proposed test material an appropriate surrogate?

The proposed test substance, latex paint treated with BIT, is an appropriate surrogate for the brush and roller study. The second test solution to be tested, BIT in an IPA solution, will provide hand wash efficiency results for future studies conducted with BIT. The IPA solution will also provide differences in hand wash efficiency between paint and IPA.

"The test substances for this study are the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1, 2-benzisothiazoline-3-one (BIT) and BIT prepared in isopropyl alcohol (IPA). BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study." (V2:14-15) The vapor pressure for BIT is 4.4E-7 mmHg at 20° C which is considered to be low (i.e., off-gassing expected to be minimal).

4. What is the rationale for the proposed cluster design and sample size?

A rationale for the proposed sample size was not provided. There are no guidelines available to suggest a sample size. The sample size for this proposal is for 20 test subjects to be placed in 4 groups, 5 subjects per group (see Table 1 above). Brouwer et al (2000) reviewed the literature and reported the sample size for 10 different chemicals. Typically researchers used a sample size of 4 for each different hand loading tested. AEATF II proposes to use 5 subjects per different loading and both the left and right hand per subject (n=10 hands per loading). A statistical rationale for the proposed sample size based on data from Brouwer et al (2000) is provided in Subsection 2.1 (a) of Attachment 2.

EPA Protocol Review: AEATF II Hand Wash Removal Efficiency Study Protocol

Title: Removal Efficiency Study

Date: February 5, 2014

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1. Societal Value of Proposed Research

(a) What is the stated purpose of the proposed research?

"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." (V2:9)

(b) What research question does it address? Why is this question important? Would the research fill an important gap in understanding?

This proposed study will address the removal efficiency of the hand wash sampling procedure. In a separate study, the AEATF II plans to conduct dermal exposure monitoring for test subjects using treated paint. The hand exposure in the AEATF II's other study on painting will use the same hand wash approach as proposed in this protocol's hand wash efficiency study. The hand wash removal efficiency is important to know so that users of the exposure data can quantify the hand wash method's performance. As noted in Brouwer et al (2000), *"when removal techniques are used to assess dermal exposure monitoring for risk assessment purposes, it is recommended to conduct sampling efficiency studies as a key issue for method performance."* The proposed study will fill that data gap.

(c) How would the study be used by EPA?

EPA will use these data to correct any loses measured for the hand wash procedure to be used in the AEATF II painting exposure studies. The IPA portion of this study can be used in future exposure studies using BIT as a test compound that use the identical hand wash procedure.

(d) Could the research question be answered with existing data? If so, how?

Although there are some hand wash removal efficiency studies in the literature and some conducted by pesticide registrants, none of the studies used BIT or a paint matrix. *"Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques."* (V2:11).

(e) Could the question be answered without newly exposing human subjects? If so how? If not, why not?

"Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to extrapolate data from existing human hand removal efficiency studies. In this study, at least 20 subjects (5 for each scenario) will be monitored in order to capture the expected variation in skin differences, concentration, and paint or solvent as a carrier of the BIT." (V2:11).

(f) Is the research likely to produce data that address an important scientific or policy question that cannot be resolved on the basis of animal data or human observational research?

Yes. The purpose of monitoring test subject's hands to measure hand wash removal efficiency will allow the researchers to correct for loses of BIT residue from the hand wash methodology in the AEATF II paint exposure studies.

2. Study Design

(a) What is the scientific objective of the study? If there is an explicit hypothesis, what is it?

"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." (V2:9)

No hypothesis is stated, nor is the study designed to test a hypothesis.

(b) Can the study as proposed achieve that objective or test this hypothesis?

The objective cited above can be achieved by the study as proposed.

2.1 Statistical Design

(a) What is the rationale for the choice of sample size?

A rationale for the sample size was not reported in the protocol. In the literature review by Brouwer et al (2000), sample sizes for various hand wash sampling studies using direct spiking of different compounds and different loadings ranged from 3 to 12. The corresponding standard deviations of the percentage removal efficiency ranged from 3 to 14 percent. To estimate the precision of the estimated mean percentage removal efficiencies, we can assume that the removal efficiencies for BIT in latex paint have similar distributions to the efficiencies for the compounds studied by Brouwer et al and that the measurements are independent, even though both hands of the same test subject are tested. On that basis the mean percentage removal efficiency at each concentration level can be estimated from the ten measurements with 95% confidence to be within plus or minus 2.1% using the lowest reported standard deviation, and to be within plus or minus 10.0% using the highest reported standard deviation. (These numbers were calculated assuming the efficiencies are approximately normally distributed. The 10.0% means that the unsigned error in the estimated mean percentage removal efficiency is no more than 10). If the study results indicate that the BIT removal efficiencies are the same at both BIT in latex paint concentration levels (120 and 600 ppm), so that the data can be combined, then the estimated precision improves to 1.4% and 6.6%, respectively. The same calculations apply to the BIT in IPA data. These statistical calculations suggest that the proposed study sample sizes should be adequate. However, if the proposed study finds much higher standard deviations than those summarized in Brouwer et al (2000) using different compounds and carriers, then additional hand wash removal efficiency testing may be necessary to obtain sufficiently accurate estimates of the mean hand wash removal efficiency.

(b) What negative and positive controls are proposed? Are proposed controls appropriate for the study design and statistical analysis plan?

No positive or negative controls are proposed. This is appropriate for the study design and statistical analysis plan.

(c) How is the study blinded?

The study is not blinded.

(d) What is the plan for allocating individuals to treatment or control groups?

The test subjects will be allocated to the treatment group as proposed by the AEATF II below; there is no control group.

"The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four groups, each corresponding to one of the four test substance/concentration combinations. The first set of seven subjects will be placed into Group 1, the second set of seven subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4. Within each group of seven, the first five subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the group of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study. Once the subjects have been randomized into four groups, subjects from the first group will be scheduled into the study. No more than two groups will be monitored in one day. The randomization process will prevent bias. (V2:19-20)

(e) Is the proposed research designed in accordance with current scientific standards and practices to include representative study populations for the endpoint in question?

Yes, the proposed research includes the key parameters suggested by Brouwer et al (2000). Test subjects will be drawn from the same populations as the painting exposure study.

(f) Can the data be statistically analyzed?

The results of the analysis from the sampling will be provided in the final report and will be analyzed by EPA. See response below for the analysis (Subsection (g)).

(g) What is the plan for statistical analysis of the data?

"At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the capillary tubes used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to

the skin times 100. Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report." (V2:31-32)

(h) Are proposed statistical methods appropriate to answer the research question?

Yes.

(i) Does the proposed design have adequate statistical power to definitively answer the research question?

Since the proposed design is intended to develop estimates of the hand removal efficiency, rather than applying a statistical test, calculations of statistical power are not relevant for this study. See item (a) in this section for estimates of the precision of the estimated mean hand removal efficiencies.

(j) Does the investigator propose to conduct the research in accordance with recognized good research practices, including, when appropriate, good clinical practice guidelines and monitoring for the safety of subjects?

This study is proposed to be conducted in accordance with recognized good research practices. This is not a clinical study and therefore good clinical practice guidelines are not applicable.

2.2 How and to what will human subjects be exposed?

Each test subject will be exposed to latex paint or an IPA solution treated with BIT.

"Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate controlled room prior to the application and until the hand-wiping procedure is completed." (V2:27)

"The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, either a 500 uL volume of the appropriate paint concentration or a 100 uL volume of the appropriate solvent concentration will be applied. A glass capillary tube will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The capillary tube from each subject will be placed into a glass test tube and stored frozen prior to analysis.

The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

After 45 minutes the subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their fingers and palm together. The total volume of IPA/water solution used will be 250 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis. The procedure will then be repeated for the second hand producing a second sample. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels." (V2:18-19)

(a) What is the rationale for the choice of test material and formulation?

The choice of the formulation types (i.e., latex paint and an IPA solution) is to determine hand wash efficiencies for future exposure studies using either paint or a non-paint liquid in the exposure scenarios. The addition of the IPA solution will also allow for a comparison between the efficiencies of paint and a non-paint liquid. BIT is the choice for the test substance to be able to use the results of this efficiency study for other studies using BIT as the chemical/surrogate.

(b) What is the rationale for the choice of dose/exposure levels and the staging of dose administration?

Two concentrations are proposed, 120 and 600 ppm BIT. Based on these solution concentrations, it is estimated that the loading on the hands are 1.6 and 7.8 $\mu g/cm^2$ for treatment Groups 1/3 and 2/4, respectively. In comparison, the paint brush scenario in the Pesticide Handlers Exposure Database (PHED) indicates the loading on the subject's hands ranged from 4.8 to 19.7 $\mu g/cm^2$ with an arithmetic mean of 10.5 $\mu g/cm^2$. The proposed loadings are within the range of anticipated hand wash residue from the proposed brush/roller painting scenario.

(c) What duration of exposure is proposed?

The entire monitoring event is expected to be no more than 1.5 to 2 hours, of which, 45 minutes of exposure to the test substance is proposed. (V2:18-19)

2.3 Endpoints and Measures

(a) What endpoints will be measured? Are they appropriate to the question(s) being asked?

The AEATF II proposes to measure the hand wash removal efficiency for BIT-treated paint and BIT-treated IPA solution.

"Air temperature and relative humidity of the room for the duration of the 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." (V2:27)

(b) What steps are proposed to ensure measurements are accurate and reliable?

"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) ... [20 SOPs listed]." (V2:8)

(c) What QA methods are proposed?

The study will be conducted according to FIFRA GLP Standards (40 CFR 160).

Field recoveries will be used to correct for any losses due to field, storage and transport. *"Sample matrix fortifications designed to assess the stability of the active ingredient under field, storage and transit conditions in or on the sampling materials (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint or in solvent will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used. 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."* (V2:27)

"BIT in paint or solvent will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects." (V2:16)

(d) How will uncertainty be addressed?

The study report will include means and standard deviations of the replicate measurements of the hand wash recovery percentages in each group. It is

recommended that these data are also used to calculate 95% confidence intervals for the mean hand wash recovery percentage. In addition it is recommended that a t test is used to compare the mean hand wash recovery percentages for the two concentrations, and thus evaluate whether it is appropriate to combine all of the BIT in latex paint data or all of the BIT in solvent data to reduce the uncertainty in the mean hand wash recovery percentage.

3. Subject Selection

3.1 Representativeness of Sample

(a) What is the population of concern? How was it identified?

The population of concern is people who use latex paint that contains an antimicrobial ingredient.

(b) From what populations will subjects be recruited?

"*Adult subjects will be recruited from the population of Fresno County, CA, and the surrounding area." (V2:20)*

(c) Are expected participants representative of the population of concern? If not, why not?

Potential subjects will self-identify in response to advertisements placed within the same week in the following three local newspapers in Fresno, California: 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.*" (V2:21)

Expected participants will self-identify in response to advertisements placed in local newspapers. The placement of advertisements in newspapers targeting different demographic groups should minimize bias and achieve diversity among respondents and subjects. While individuals who express interest in response to a newspaper advertisement about this study may differ in unknowable ways from other individuals who do not step forward, there is no reason to think that respondents in the Fresno, California area are atypical of similar individuals in any other area of the United States.

(d) Can the findings from the proposed study be generalized beyond the study sample?

The results of this hand wash efficiency study for BIT in paint or BIT in an IPA solution may be used in conjunction with exposure studies that employ the same hand wash procedures for exposures to BIT in paint or liquid solutions.

3.2 Equitable Selection of Subjects

(a) What are the inclusion/exclusion criteria? Are they complete and appropriate?

Inclusion/exclusion criteria are complete and appropriate, except that "sensitivities to BIT or other chemical-based products" should be added to the list of exclusions.

The inclusion/exclusion criteria are listed in Volume 2, page 27-28, and below. The recommended revisions are shown underlined and in red.

"Inclusion Criteria

- *Males or females, at least 18 years of age as verified by a government issued photo ID*
- *Consider their self to be in good health*
- *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*

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* ***or sensitivities*** to *latex paint, soaps,* ~~*or*~~ *isopropyl alcohol,* ***BIT 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)*
- *Severe diabetes*
- *Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)*
- *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."* (V2:23-24)

(b) What, if any, is the relationship between the investigator and the subjects?

Employees and spouses of employees of the investigators are excluded from participation as subjects. (V2:24)

(c) Are any potential subjects are from a vulnerable population?

No.

(d) What process is proposed for recruiting and informing potential subjects?

The recruiting process is described in V2:21-23.

(e) If any subjects are potentially subject to coercion or undue influence, what specific safeguards are proposed to protect their rights and welfare?

Subjects will be recruited through advertisements in local newspapers. There will be no connection or communication between the researchers and the potential subjects' employers, which minimizes the potential for coercion or undue influence.

3.3 Remuneration of Subjects

(a) What remuneration, if any, is proposed for the subjects?

"After 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." (V2:25)

(b) Is the remuneration consistent with the principles of justice and respect for persons?

Yes. The proposed payment amount is fair and reasonable compensation for the subjects' time and inconvenience. *"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."* (V2:25)

(b) Is proposed remuneration so high as to be an undue inducement?

No

(c) Is proposed remuneration so low that it will only be attractive to economically disadvantaged subjects?

No

(d) How and when would subjects be paid?

Compensation will be paid in cash when subjects leave the study site. (V2:25)

4. Risks to Subjects

4.1 Risk characterization

(a) Is adequate information available from prior animal studies or from other sources to assess the potential risks to subjects in the proposed research?

The proposed test material is EPA-registered, with an essentially complete supporting database. Additional discussion is provided below on the comparison of the hazard and anticipated exposures for the test subjects in this study.

(b) What is the nature of the risks to subjects of the proposed research?

Risks are of a reaction to the active ingredient BIT, to the latex paint, and/or to the alcohol wash and wipes; of an unexpected result of pregnancy testing; and the potential for a break of confidentiality. (V2:49-50)

(c) How do proposed dose/exposure levels compare to the established NOAELs for the test materials?

The dosing levels for the hands in this protocol are 1.6 and 7.8 μg BIT/cm^2 of hand surface area.

EPA has proposed to use the LOAEL of 100 mg/kg/day as the point of departure, where the effects seen were macroscopic and microscopic changes to the stomach mucosa. A NOAEL was not established for this study. The dermal Target MOE is 1000 based on 10x for the interspecies extrapolation, 10x for intraspecies variation, and 10x for lack of a NOAEL. However, there are many uncertainties in the 90-day dermal toxicity study, such as how did the stomach irritation effects result from a dermally applied dose? The dermal toxicity study report indicates:

- *"The treated site of each rat was covered with a 4-ply gauze patch (Abco #052123) and further covered with Zonas non-irritating tape to retain the gauze dressing and to ensure that the animal could not ingest the test article.*
- *...at which time the wrappings were removed and the residual test article was gently wiped in order to prevent ingestion."*

Even though the researchers took these precautions to avoid ingestion by the rats, the report also indicates:

- *"Also, epidermal hyperplasia/hyperkeratosis, sebaceous gland hyperplasia and some dermal inflammation was seen in the untreated skin sites of a few rats of all compound-treated groups. This change at the untreated sites was also likely the result of the taping and wrapping procedures and/or migration of the test substance onto the adjacent skin.*
- *Although the test material was wiped from the treatment sites after the removal of the wrapping, it is very possible that some residual compound was still present. These changes in the stomach are consistent with those caused by ingestion of an irritating substance and are likely the result of ingestion of some of the compound. These changes are considered to be the result of local superficial irritation of the gastric mucosa and not a systemic effect."*

EPA notes in the oral (gavage) rat toxicity study (MRID 46346201), macroscopic and microscopic lesions were seen in the stomach at the LOAEL of 25 mg/kg/day (NOAEL of 8 mg/kg/day). Given the precautions taken in the dermal toxicity study to preclude incidental ingestion during grooming, the fact that a dose of 8 to 25 mg/kg/day would be needed to observe stomach irritation, coupled with no direct observations noted in the dermal toxicity study report of incidental ingestion, EPA is proposing to use the LOAEL of 100 mg/kg/day as the point of departure to represent the dermal route as a conservative (protective) approach. The acute dermal irritation of BIT is classified as a category IV (slight irritant) and as a moderate dermal sensitizer. The 90-day dermal toxicity study in rats indicated some dermal reactions at the dose of 100, 300, and 1000 mg/kg/day dose at the 3, 2, and 1 week timeframes, respectively.

Table 2 provides a comparison of the anticipated hand doses to the point of departure (POD) from the 90-day dermal rat study (LOAEL = 100 mg/kg/day). The dermal MOEs are based on the following equation: LOAEL 100 mg/kg/day / dose level mg/kg/day. The maximum dose (mg/kg/day) to the hands is 0.39 mg/hand x 2 hands x (1/80 kg BW) = 0.0098 mg/kg/day. The dermal MOE at the highest dose is 10,000 (i.e., LOAEL 100 mg/kg/day / 2 hand dose 0.0098 mg/kg/day). The MOE is the unitless ratio of the POD/dose where the target MOE is 1000. Based on this estimate, there is minimal dermal risk of concern.

(d) Does the research proposal adequately indentify anticipated risks to human subjects and their likelihood of occurrence? How was this likelihood estimated?

The potential dermal risks have been evaluated by EPA through a comparison between the dermal LOAEL and the dermal dose. The comparison indicates minimal dermal risks. Please see part 4.1(c) (above) for details.

(e) If any person with a condition that would put them at increased risk for adverse effects may become a subject in the proposed research, is there a convincing justification for selection of such a person and are there sufficient measures to protect such subjects?

Individuals who may be at an increased risk for adverse effects are not eligible to become subjects in this study, including individuals known to be allergic to latex paint, soaps, or isopropyl alcohol, subjects in poor health, or with broken skin.

4.2 Risk Minimization

(a) What specific steps are specified in the protocol to minimize risks to subjects?

Skin reaction symptoms will be explained to subjects; and researchers will closely observe subjects for possible signs or symptoms of a reaction. Subjects with cuts or abrasions or other skin conditions on their hands, subjects with a history of allergies or sensitivities to materials similar to those in this study, and subjects in poor health will be excluded.

"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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

"If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

"Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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." (V2:25-27)

Other protections include:

- Candidates with skin conditions on the surface of the hands (e.g., psoriasis, eczema, cuts or abrasions) are excluded (V2:24)
- Candidates known to be allergic to latex paint, soaps, or isopropyl alcohol are excluded (V2:24)
    - *EPA recommends that the sponsors expand this exclusion to also exclude individuals who have allergies <u>or sensitivities to BIT or other chemical-based products</u>*
- Candidates who are pregnant, nursing, or in poor health are excluded (V2:24)
- The consent form alerts subjects to signs and symptoms of skin reactions and advises them to alert one of the researchers if they experience a reaction or any discomfort (V2:66)
- A medical professional (a registered nurse) will be hired for this study and will be present during the monitoring events. (V2:29, and confirmed via email between K. Sherman, EPA, and R. Testman, GPL)
- The protocol minimizes the risk of psychological harm related to the pregnancy tests by providing a private place for women to take the test and following procedures designed to protect the confidentiality of any test result (SOP 11A.1, Pregnancy Testing and Nursing Status). (V4:85-86)

(c) What stopping rules are proposed in the protocol?

"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." (V2:26)

(d) How does the protocol provide for medical management of potential illness or injury to subjects?

SOP 11.C.2 for Emergency Procedures (V4:69-72)

(e) How does the protocol provide for safety monitoring?

"Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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. (V2:26-27)

(f) How does the protocol provide for post-exposure monitoring or follow-up? Is it of long enough duration to discover adverse events which might occur?

The consent form states: "*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, at Golden Pacific Laboratories (559 275-9091) as soon as possible.*" (V2:50)

"If two or more subjects develop an adverse skin reaction after they leave the study site, all subjects will be contacted by the Study Director to determine whether further medical management is appropriate." (V2:26)

(g) How and by whom will medical care for research-related injuries to subjects be paid?

The informed consent form states: *"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, at Golden Pacific Laboratories (559 275-9091) as soon as possible."* (V2:50)

5. Benefits

(a) What benefits of the proposed research, if any, would accrue to individual subjects?

There are no benefits to the subjects of participating in this research study.

(b) What benefits to society are anticipated from the information likely to be gained through the research?

"While there are no direct benefits to the subjects participating in this research study, there are indirect benefits to both the subjects and society. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal exposure of workers and the general population performing these tasks." (V2:14)

(c) How would societal benefits be distributed? Who would benefit from the proposed research?

"The resulting data will improve the completeness and accuracy of the database used by the EPA to assess exposure to these chemicals. 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." (V2:14)

(d) What is the likelihood that the identified societal benefits would be realized?

The research is very likely to produce more accurate and reliable information concerning exposure to people who use latex paint, with resulting societal benefits in the form of more accurate and confident assessments of exposure and risk.

6. Risk/Benefit Balance: How do the risks to subjects weigh against the anticipated benefits of the research, to subjects or to society?

The likely benefit to society in general, in the form of more accurate measurements of potential exposure to antimicrobial products, must be weighed against the risks to study participants. Antimicrobial products are widely used both by workers in occupational settings and the general public. Exposure data for the painting scenario meeting contemporary standards of reliability and quality will likely provide a significant benefit to society. Because the margins of exposure are acceptable for the antimicrobial product proposed for use in this research study, subjects are unlikely to experience toxic effects, and because procedures will be in place to minimize these and other risks to participants, the likelihood of serious adverse effects is very small. In summary, the risks to study participants from participating in this study are reasonable in light of the likely benefit to society of the knowledge to be gained.

7. Independent Ethics Review

(a) What IRB reviewed the proposed research?

Schulman Associates IRB

(b) Is this IRB independent of the investigators and sponsors of the research?

Yes

(c) Is this IRB registered with OHRP?

Yes

(d) Is this IRB accredited? If so, by whom?

Schulman Associates IRB earned "Full Accreditation" from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in June 2008.

(e) Does this IRB hold a Federal-Wide Assurance from OHRP?

Yes.

(f) Are complete records of the IRB review as required by 40 CFR 26.1125 provided?

Yes.

(g) What standard(s) of ethical conduct would govern the work?

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.

8. Informed Consent

(a) Will free and fully voluntary informed consent be obtained from each prospective subject?

Yes.

(b) Will informed consent be appropriately documented, consistent with the requirements of 40 CFR §26.1117?

Yes. See Attachment 5.

(c) Do the informed consent materials meet the requirements of 40 CFR §26.1116, including adequate characterization of the risks and discomforts to subjects from participation in the research, the potential benefits to the subject or others, and the right to withdraw from the research?

Yes. See Attachment 4.

(d) What is the literacy rate in English or other languages among the intended research subjects?

Ability to speak and read English or Spanish is specified as a criterion for inclusion in the study. (V2:24)

(e) What measures are proposed to overcome language differences, if any, between investigators and subjects?

"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." (V2:23)

Recruitment materials and all communications with potential subjects will be available in English and Spanish as it is anticipated that the population of interest may include some Spanish-speakers.

(f) What measures are proposed to ensure subject comprehension of risks and discomforts?

All written recruitment, consent, and risk communication materials will be available in both English and Spanish (including paint and BIT label, paint MSDS, recruiting materials, and flyers).

During the private consent meeting, the researcher will provide each volunteer with a full overview of the study, participation requirements, any potential risks and benefits, alternatives to participation, etc. To make sure that the potential subjects understand what is being asked of them, a short list of standardized questions requiring a response will be asked of each potential subject (SOP AEATF II-11J.1). (SOP 11-J.1 was not submitted in Volume 4 of the Removal Efficiency Study; however, it is provided in Volume 4 of the AEATF II's Solid Pour Study submission)

SOP AEATFII-11J.1 provides the following with respect to ensuring subject comprehension:

> *"3.0 Ensuring Comprehension*
>
> *"3.1 During the consent process, time will be allocated for questions and answers. The IRB-approved Consent Form (and all supporting documents, except product labels and MSDS forms) will be presented in English or an alternative language (e.g. Spanish if they cannot read English) to the subject. Alternative language specifications will be protocol specific and dependent on the demographics of where the study is conducted; further information is provided in the Governing document of the AEATF II. All sections of the Consent Form must be explained in detail to the subject.*
>
> *"3.2 When the person obtaining consent is finished, he/she must ascertain whether the potential subjects really understand the procedures, requirements, and risks associated with participation in the study. This assessment of comprehension will be done by asking specific questions of the potential subjects to indicate their understanding of key issues. The form in Attachment 11-J-1 will be used to establish general understanding of the informed consent form and what is being asked of the volunteer. This must be filled out for each study participant and retained with their signed consent form.*
>
> *"3.3 If after this process the subject demonstrates comprehension of the material, meets the requirements, and wants to participate, he/she will be asked to sign and date the Consent Form. Once the form is signed, the person obtaining consent will provide a copy of the signed form to the subject. If the subject needs more time to decide on his participation, he can take the unsigned consent form home and set up a follow-up appointment.*

"3.4 The Study Director (or designee) obtaining the consent will not sign the Consent Form unless he/she believes that the process has been free of coercion or undue influence and that the candidate fully understands the information presented." (SOP 11-J.1 was not submitted in Volume 4 of the Brush and Roller Study; however, it was submitted as part of the Solid Pour Study submission)

(g) What specific procedure will be followed to inform prospective subjects and to seek and obtain their consent?

Please see the text quoted from SOP AEATFII-11J.1, above

(h) What measures are proposed to ensure fully voluntary participation and to avoid coercion or undue influence?

Recruiting will take place through advertisements in newspapers, not through the workplace, thus removing the possibility of coercion or undue influence exerted by an employer.

SOP AEATF II-11J.1 states: "The Study Director (or designee) obtaining the consent will not sign the Consent Form unless he/she believes that the process has been free of coercion or undue influence and that the candidate fully understands the information presented." (SOP 11-J.1 was not submitted in Volume 4 of the Brush and Roller Study; however, it was submitted as part of the Solid Pour Study submission)

The consent form states: "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." (V2:50)

9. Respect for Subjects

(a) How will information about prospective and enrolled subjects be managed to ensure their privacy?

"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."(V2:25)

"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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject." (V2:18)

(b) How will subjects be informed of their freedom to withdraw from the research at any time without penalty?

The informed consent form states:

"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." (V2:50)

"You are free to withdraw from this study at any time, for any reason. Simply tell any member of the research team that you no longer want to participate. 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." (V2:51)

(c) How will subjects who decline to participate or who withdraw from the research be dealt with?

All individuals that participate in an informed consent interview will be compensated $20 in cash at completion of the interview, regardless of whether they decide to participate. 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. (V2:25)

Subjects who are withdrawn by the investigators—and all participating subjects in the case that the entire study is stopped—are promised payment in full. (V2:51)

§ 26.1111 Criteria for IRB approval of research
AEATF II Removal Efficiency Study AEA08: February 5, 2014

Criterion	Y/N	Comment/Page Reference
(a)(1)(i) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	Y	
(a)(1)(ii) Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	n/a	
(a)(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.	Y	
(a)(3) Selection of subjects is equitable, taking into account the purposes of the research and the setting in which it will be conducted, and being particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.	Y	
(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §26.1116.	Y	
(a)(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §26.1117.	Y	
(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	Y	
(a)(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	Y	
(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.	Y	

§26.1116 General requirements for informed consent
AEATF II Removal Efficiency Study AEA08: February 5, 2014

Criterion		Y/N	Comments
No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative		Y	
An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence		Y	
The information that is given to the subject or the representative shall be in language understandable to the subject or the representative		Y	
No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence		Y	
(a) In seeking informed consent the following information shall be provided to each subject	(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental	Y	
	(2) A description of any reasonably foreseeable risks or discomforts to the subject	Y	
	(3) A description of any benefits to the subject or to others which may reasonably be expected from the research	Y	
	(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	n/a	
	(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	Y	
	(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained	Y	Although research doesn't involve more than minimal risk, compensation and treatment of injuries are provided for
	(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject	Y	
	(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	Y	
(b) When appropriate, one or more of the following elements of information shall also be provided to each subject	(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable	Y	
	(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	Y	
	(3) Any additional costs to the subject that may result from participation in the research	Y	
	(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	Y	
	(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject	n/a	
	(6) The approximate number of subjects involved in the study	Y	
(e) If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.		Y	

§26.1117 Documentation of informed consent
AEATF II Removal Efficiency Study AEA08: February 5, 2014

Criterion	Y/N	Comments
(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.	Y	
(b)(1) The consent form may be a written consent document that embodies the elements of informed consent required by §26.1116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or	Y	
(b)(2) The consent form may be a short form written consent document stating that the elements of informed consent required by §26.1116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.	n/a	

40 CFR 26.1125 Prior submission of proposed human research for EPA review
AEATF II Removal Efficiency Study AEA08: February 5, 2014

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
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 n/a Y n/a	V3:37-113 V3:184-191, conditionally approved
			(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 Y	 V3:86-88 V3:134, Unanimous V3:116-130
			(3) Records of continuing review activities.	n/a	None
			(4) Copies of all correspondence between the IRB and the investigators.	Y	V3:5-140
			(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.	Y N	V3:139-140
			(6) Written procedures for the IRB in the same detail as described in §26.1108(a) and §26.1108(b).	Y	Previously provided to EPA by Schulman Associates
			(7) Statements of significant new findings provided to subjects, as required by §26.1116(b)(5).	n/a	
The following Information, to the extent not already included:	§1125(a) a discussion of:		(1) The potential risks to human subjects	Y	V2:12-14, 49-50
			(2) The measures proposed to minimize risks to the human subjects;	Y	V2:11-12, 17-20, 25
			(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue	Y	V2:14
			(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and	Y	V2:14
			(5) The balance of risks and benefits of the proposed research.	Y	V2:14
			§1125(b): All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.	Y	Orig. V3:29-36 Approved: N//a
			§1125(c): Information about how subjects will be recruited, including any advertisements proposed to be used.	Y	V2:20-24, 71
			§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.	Y	V2:74-75
			§1125(e): All correspondence between the IRB and the investigators or sponsors.	Y	V3:5-140
			§1125(f): Official notification to the sponsor or investigator . . . that research involving human subjects has been reviewed and approved by an IRB.	N	Conditionally approved

Department of Pesticide Regulation

Brian R. Leahy
Director

Edmund G. Brown Jr.
Governor

December 19, 2013

Megan Boatwright
Golden Pacific Laboratories, LLC (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, CA 93722

Dear Ms. Boatwright:

On November 4, 2013, the Department of Pesticide Regulation (DPR) received the protocol for the study **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure."** 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 the *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

- The terms gauze sponges, gauze pads, and gauze wipes are used interchangeably throughout the protocol. We suggest using the same term consistently throughout the protocol.
- Clarify the amount of paint applied to the hands of each subject. *Section 6A, Risks to Subjects, page 11, paragraph 1* states" The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint..." Se*ction 8, Study Design, Overview, page 15, paragraph 3* states "Subjects assigned to group 1 will have each hand fortified with a 500µL volume of paint..." Per section 8A, the total exposure to the paint is 1.0 ml. *Section 8B, Removal Proficiency Procedure # 6* specifies the amount being applied, but does not state whether the amount is per hand or the combined amount for both hands.
- Clarify the number of samples per subject. Se*ction 8, Study Design, Overview, page 15, paragraph 5* indicates **two** samples per subject. This section states "The solution and gauze will be collected as a single sample for each hand..." On the other hand, *Section 8B, Removal Proficiency Procedure # 8* indicates **one** sample per subject. This section states "The subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges... The researchers will then rinse with the same solvent while the subject rubs their hands together."
- The protocol should address the possibility that a subject may withdraw before the end of the and under what circumstances the researchers would collect and analyze the samples.
- *Section 2, Summary; Section 8A, Study Design, Overview*; and *Section 8B, Removal Efficiency Procedure # 5* states the subjects will wash their hands with Ivory soap and water, and dry their hands using paper towels. The US EPA's Reregistration Eligibility Document for BIT states that BIT is used as an antimicrobial in Pulp and Paper Mill Systems and is commonly found in many consumer products including soap. This raises the possibility that the Ivory soap and paper towels used in the study could contain BIT, and that their use could leave measurable residues on the skin. Consider analyzing the soap and paper towels for the presence of BIT prior to use in the study.
- *Section 3, Rationale and Objective of the Study*. The study objective is to determine the removal efficiency of BIT from the hands. The study involves applying BIT in latex paint or

in isopropyl alcohol to the palms of research subjects. Because the "thick-skinned palmar surface of the hands will be exposed," subjects are expected to have limited absorption of BIT, and thus reduced dermal exposure (*Section 6A, Risks to Subjects, page 11, lines 9-11*). The removal of BIT from the palms may be significantly greater than from the back of the hands which have thinner skin than the palms. For this reason, the protocol may actually underestimate exposure because it will overestimate the removal efficiency of washing. Therefore, we suggest that this section include a discussion of why the palmar surface was selected over the thinner dorsal surface of the hand, or why not treat both the dorsal and palmar surfaces, since dermal characteristics may have an impact on the results.

- *Section 4, Rationale for Use of Human Subjects – page 9*. The protocol states "The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing the task." 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 5, Oversight of Ethical Conduct – page 10,* and *Section 19, Protocol Changes*.
  - 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 6A, Risks to the Subjects – page 11, line 6*. The referenced default body weight of 50 kg is low. U.S. EPA and DPR both use a default body weight value of 70 kg (EPA Exposure Factors Handbook). Consider revising the default body weight to 70 kg.
- Discrepancy in duration of exposure. *Section 6A, Risks to Subject – page 11, paragraph 2, line 23* states "exposure to one of the test substances will be limited to 30 minutes." *Section 8A, Study Design Overview – page 15, paragraph 5* states "The paint or solution will be left on the hands to dry for 45 minutes." The ICF Study Procedures # 5 also list the duration of exposure as 45 minutes. Revise this section to indicate exposure will be limited to 45 minutes.
- *Section 6A, Risks to the Subjects – page 11, paragraph 4*. "The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is quite low." Specify the potential damage that would be caused by the release of positive pregnancy findings. Alternatively, consider using a different word for "damage" in the sentence which probably refers to the consequences following the unintentional release of the positive pregnancy findings.
- *Section 7D, Test Substance, Safety Precautions – page 14*. 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 8B, Removal Proficiency Procedure # 8 – page 17*. 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 8B, Removal Proficiency Procedures # 8 – page 17.* 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 9Aii, Recruitment of Surrogate Workers – page 19, paragraph 4, line 6.* During the recruitment meeting, the investigator will ask the potential subjects some questions on the Subject Self-Reporting Demographic Form. Five questions deal with prior history of medical conditions that would exclude the subject from participating in the study. These medical conditions are listed in the exclusion criteria in Section 9Aiii. In addition to these questions, the protocol states "The investigator will ask the subject if he/she is taking any medication." There is no exclusion for subjects taking medication. If there are medications that would exclude the subject from participation, the list of medications should be included in the exclusion criteria. The protocol should explain why this question is being asked.
- *Section 9Aii, Recruitment of Surrogate Workers – page 20, 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, Recruitment of Surrogate Workers – page 21, paragraph 4.* 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 Sequence Number – page 23, paragraph 3; and Section 13A, Field Records – page 30.* Clarify storage of records. Section 9A 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 24.* 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, Field Recovery Evaluation – page 25.* To ensure there is no background contamination, include field blanks of the gauze wipes and the rinse solution.
- *Section 12B, Analytical Methods – page 28.* It is unclear from the analytical methods whether dried latex paint is soluble in isopropyl alcohol (the solvent used to clean the hands) and if the BIT can be separated from the latex paint matrix once it is dried. This information may be known, but not included in the protocol.

Informed Consent Form (ICF)

- 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.
- *Protocol section 9b, Subject Sequence Number, page 2* 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 Procedures 5 – page 45*. The procedure as written may not describe how the subjects will hold their hands during the application and drying period and may lead to concern about how to hold the hands upright for 45 minutes during the drying period. Suggest revising the second sentence from "We will ask you to place your hands upright on the table in front of you" to "We will ask you to place your hands on a padded surface on the table with your palms facing up."

II. Exposure Assessment

- None

III. Human Subject Protection/Ethical Considerations

Protocol

- None

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.
- *Risks 1 – page 45.* In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.

IV. Editorial Comments

Protocol

- Define acronyms when first used: QAU (page 31) and PR 2011-3 (page 32).
- *Section 2, Summary – page 8, paragraph 2, line 18*. Revise sentence to "...subjects rub their hands together."
- *Section 6A, Risks to the Subjects – page 10*. The Reregistration Eligibility Decision document is referenced as EPA, 2006a. Revise to EPA, 2005 as listed in *Section 22, References*.
- *Section 6D, Alternative Data Sources – page 12, lines 3 & 4; Section 7C, Alternative Data Sources – page 14, line 4.* Suggest replacing "actives" with "active ingredients."
- *Section 9Aii, Subject Recruitment – page 19, paragraph 4*. Revise form name to Subject Self-Reporting Demographic Form

- *Section 22, page 35.* The following references are not cited in the text of the protocol: AEATF II (2012, 2008); Gijsbers et al (2004); Popendorf et al (1992); and Ross et al (2008).

Informed Consent Form (ICF)

- *Questions about this Study – page 46, paragraph 1.* Suggest revising the sentence to: "If you have any questions, you may ask Megan Boatwright or any other member of the research team at any time – before, during, or after the study."
- *Questions about the Study – page 46, paragraph.* Revise the name of the IRB to Schulman Associates Institutional Review Board.

Experimental Subject's Bill of Rights

- *Page 48.* 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

Golden Pacific
LABORATORIES

January 23, 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 **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure."** 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 (559) 275-9091 or mboatwright@gplabs.com.

Sincerely,

Megan Boatwright

Megan T. Boatwright
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
The terms gauze sponges, gauze pads, and gauze wipes are used interchangeably throughout the protocol. We suggest using the same term consistently throughout the protocol.	Gauze sponge(s) is the correct term.	All references were changed to sponge(s) to make it consistent throughout the protocol.
Clarify the amount of paint applied to the hands of each subject. *Section 6A, Risks to Subjects, page 11, paragraph 1* states" The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint..." S*ection 8, Study Design, Overview, page 15, paragraph 3* states "Subjects assigned to group 1 will have each hand fortified with a 500µL volume of paint..." Per section 8A, the total exposure to the paint is 1.0 ml. *Section 8B, Removal Proficiency Procedure # 6* specifies the amount being applied, but does not state whether the amount is per hand or the combined amount for both hands.	Section 6A and 8B will be updated to clarify the volumes are per hand as already done in section 8A.	Section 6A and 8B were changed to clarify the volumes are per hand.
Clarify the number of samples per subject. S*ection 8, Study Design, Overview, page 15, paragraph 5* indicates **two** samples per subject. This section states "The solution and gauze will be collected as a single sample for each hand..." On the other hand, *Section 8B, Removal Proficiency Procedure # 8* indicates **one** sample per subject. This section states "The subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges... The researchers will then rinse with the same solvent while the subject rubs their hands together."	Section 8B Procedure #8 is wrong.	Section 8B Procedure #8 was changed to reflect collection per hand creating two samples.

CA DPR Comments	GPL Response	Protocol Modifications
The protocol should address the possibility that a subject may withdraw before the end of the and under what circumstances the researchers would collect and analyze the samples.	If a subject withdraws at any time prior to the 45 minutes, the samples will not be collected. The subject will be allowed to wash up and leave.	Statement added to section 9D Stop Criteria and Medical Management.
Section 2, Summary; Section 8A, Study Design, Overview; and *Section 8B, Removal Efficiency Procedure # 5* states the subjects will wash their hands with Ivory soap and water, and dry their hands using paper towels. The US EPA's Reregistration Eligibility Document for BIT states that BIT is used as an antimicrobial in Pulp and Paper Mill Systems and is commonly found in many consumer products including soap. This raises the possibility that the Ivory soap and paper towels used in the study could contain BIT, and that their use could leave measurable residues on the skin. Consider analyzing the soap and paper towels for the presence of BIT prior to use in the study.	During set up and preparation of the study the soap and towels will be screened for presence of BIT.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 3, Rationale and Objective of the Study. The study objective is to determine the removal efficiency of BIT from the hands. The study involves applying BIT in latex paint or surface of the hands will be exposed," subjects are expected to have limited absorption of BIT, and thus reduced dermal exposure (*Section 6A, Risks to Subjects, page 11, lines 9-11*). The removal of BIT from the palms may be significantly greater than from the back of the hands which have thinner skin than the palms. For this reason, the protocol may actually underestimate exposure because it will overestimate the removal efficiency of washing. Therefore, we suggest that this section include a discussion of why the palmar surface was selected over the thinner dorsal surface of the hand, or why not treat both the dorsal and palmar surfaces, since dermal characteristics may have an impact on the results.	Although paint can get on the backside of hands during painting activities, the majority of exposure is expected on the palmer side of the hand (fingers and palm). In addition, applying liquid paint to the backside of hands would increase risk of loss due to drips and run off. The palmar surface was thus considered more representative and more likely to produce reliable data.	N/A
Section 4, Rationale for Use of Human Subjects – page 9. The protocol states "The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing the task." 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 regarding low dermal penetration will be deleted.	Modified Section 4 to remove reference to low penetration.

CA DPR Comments	GPL Response	Protocol Modifications
Section 5, Oversight of Ethical Conduct – page 10, and *Section 19, Protocol Changes.* - 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.	Both sections have existing statements covering the fact. Last paragraph of Section 5 and first paragraph of section 19	N/A
Section 6A, Risks to the Subjects – page 11, line 6. The referenced default body weight of 50 kg is low. U.S. EPA and DPR both use a default body weight value of 70 kg (EPA Exposure Factors Handbook). Consider revising the default body weight to 70 kg.	Section will be changed to reflect the default weight of CDPR and the EPA.	Section 6A was changed to a weight of 70 Kg and the calculated mg/Kg was recalculated and updated.
Discrepancy in duration of exposure. *Section 6A, Risks to Subject – page 11, paragraph 2, line 23* states "exposure to one of the test substances will be limited to 30 minutes." *Section 8A, Study Design Overview – page 15, paragraph 5* states "The paint or solution will be left on the hands to dry for 45 minutes." The ICF Study Procedures # 5 also list the duration of exposure as 45 minutes. Revise this section to indicate exposure will be limited to 45 minutes.	Typographical error in section 6A.	Section 6A corrected to correct time of 45 minutes.

CA DPR Comments	GPL Response	Protocol Modifications
Section 6A, Risks to the Subjects – page 11, paragraph 4. "The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is quite low." Specify the potential damage that would be caused by the release of positive pregnancy findings. Alternatively, consider using a different word for "damage" in the sentence which probably refers to the consequences following the unintentional release of the positive pregnancy findings.	Sentence will be removed since issue was addressed in previous paragraph.	Deleted sentence from protocol.
Section 7D, Test Substance, Safety Precautions – page 14. 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 8B, Removal Proficiency Procedure # 8 – page 17. 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.	Procedure will be described with more detail.	Section 8B Procedure #8 was modified to add more details of how the procedure is done.

CA DPR Comments	GPL Response	Protocol Modifications
Section 8B, Removal Proficiency Procedures # 8 – page 17. 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 substance from the hands is a more complex system than dissolving neat compound. 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
Section 9Aii, Recruitment of Surrogate Workers – page 19, paragraph 4, line 6. During the recruitment meeting, the investigator will ask the potential subjects some questions on the Subject Self-Reporting Demographic Form. Five questions deal with prior history of medical conditions that would exclude the subject from participating in the study. These medical conditions are listed in the exclusion criteria in Section 9Aiii. In addition to these questions, the protocol states "The investigator will ask the subject if he/she is taking any medication." There is no exclusion for subjects taking medication. If there are medications that would exclude the subject from participation, the list of medications should be included in the exclusion criteria. The protocol should explain why this question is being asked.	The line about medicine was accidentally left in and will be removed from the protocol.	Line stating "The investigator will ask the subject if he/she is taking any medication and answer any questions" was deleted.

CA DPR Comments	GPL Response	Protocol Modifications
Section 9Aii, Recruitment of Surrogate Workers – page 20, 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.	Sentence will be updated to reflect this fact.	Section 9Aii sentence was updated to verify age not identity.
Section 9Aii, Recruitment of Surrogate Workers – page 21, paragraph 4. 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
Section 9B, Subject Sequence Number – page 23, paragraph 3; and Section 13A, Field Records – page 30. Clarify storage of records. Section 9A 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.

CA DPR Comments	GPL Response	Protocol Modifications
Section 9D, Stop Criteria and Medical Management – page 24. 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 sentence 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."
Section 10C, Field Recovery Evaluation – page 25. To ensure there is no background contamination, include field blanks of the gauze wipes and the rinse solution.	The duplicate control samples are collected and analyzed for that purpose.	Section was edited to better describe procedure.
Section 12B, Analytical Method – page 28. It is unclear from the analytical method whether dried latex paint is soluble in isopropyl alcohol (the solvent used to clean the hands) and if the BIT can be separated from the latex paint matrix once it is dried. This information may be known, but not included in the protocol.	Pre-study activities have demonstrated that BIT can be extracted from dried paint with solvent/water mixtures, including IPA/water.	N/A
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.	Will be added to Informed Consent form (ICF).	Added to ICF Consent Signature page.
Protocol section 9b, Subject Sequence Number, page 2 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.	Will add language to ICF.	Added the following language to ICF: "You may obtain a copy of your own records from the Principal Investigator upon request."

CA DPR Comments	GPL Response	Protocol Modifications
Study Procedures 5 – page 45. The procedure as written may not describe how the subjects will hold their hands during the application and drying period and may lead to concern about how to hold the hands upright for 45 minutes during the drying period. Suggest revising the second sentence from "We will ask you to place your hands upright on the table in front of you" to "We will ask you to place your hands on a padded surface on the table with your palms facing up."	Wording could be clearer so protocol will be edited.	Wording was edited as suggested by DPR.
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).
Risks 1 – page 45. In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.	Potential symptoms described on label will be added.	Risk 1 updated to include allergic reaction, dizziness and headache.
EDITORIAL COMMENTS Define acronyms when first used: QAU (page 31) and PR 2011-3 (page 32).	QAU will be defined at first use, however will not be changing PR 2011-3 since this is how the guideline is written/ referenced when not citing the entire title.	Protocol edited accordingly on page 31.
Section 2, Summary – page 8, paragraph 2, line 18. Revise sentence to "...subjects rub their hands together."	Description incorrect.	Sentence was edited to reflect correct actions.
Section 6A, Risks to the Subjects – page 10. The Reregistration Eligibility Decision document is referenced as EPA, 2006a. Revise to EPA, 2005 as listed in *Section 22, References.*	Dates do not agree, reference will be verified and corrected accordingly.	Updated text to 2005

CA DPR Comments	GPL Response	Protocol Modifications
Section *6D, Alternative Data Sources – page 12, lines 3 & 4; Section 7C, Alternative Data Sources – page 14, line 4.* Suggest replacing "actives" with "active ingredients."	Actives is slang and incomplete; will be replaced in all places with active ingredients.	Word "actives" was replaced with phase active ingredients.
Section 9Aii, Subject Recruitment – page 19, paragraph 4. Revise form name to Subject Self-Reporting Demographic Form	Missing Subject in title of form to keep consistency.	Section 9Aii was edited to add Subject to form title for consistency.
Section 22, page 35. The following references are not cited in the text of the protocol: AEATF II (2012, 2008); Gijsbers et al (2004); Popendorf et al (1992); and Ross et al (2008).	References verified if needed or not and removed accordingly.	Three references were removed, the others were kept.
Questions about this Study – page 46, paragraph 1. Suggest revising the sentence to: "If you have any questions, you may ask Megan Boatwright or any other member of the research team at any time – before, during, or after the study."	Wording is more complex than the ICF is supposed to be.	NA
Questions about the Study – page 46, paragraph. Revise the name of the IRB to Schulman Associates Institutional Review Board.	Typographic error.	Independent corrected to Institutional
Experimental Subject's Bill of Rights • Page 48. Revise the name of the IRB to Schulman Associates Institutional Review Board.	Typographic error.	Independent corrected to Institutional

From:	Richmond, Don@CDPR
To:	Megan Boatwright
Cc:	Robert Testman
Subject:	DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "
Date:	Wednesday, February 26, 2014 1:36:56 PM

Megan,

I reviewed the revisions and responses to our comments on the protocol. I found these acceptable. If EPA's HSRB requires any substantial changes, please forward the changes to me for review. Once you receive IRB approval of the protocol and the Spanish translation of the ICF and other documents are done, please submit copies of the translated documents to me. You may submit these documents when requesting final approval of the protocol.

If you have any questions, please call or email me.

Don

Don Richmond
Research Scientist II
Exposure Monitoring and Industrial Hygiene Program
Worker Health and Safety Branch
Department of Pesticide Regulation
Phone: (916) 445-4192

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, January 24, 2014 3:50 PM
To: Richmond, Don@CDPR
Cc: Robert Testman
Subject: Response to DPR Reviewof Protocol for the study "Determination of Removal.... "

Hi Don,

Attached is a letter with responses to the CDPR comments on the removal efficiency 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.

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:	Denisse Guzman <DGuzman@sairb.com>
Sent:	Thursday, February 05, 2015 11:08 AM
To:	Robert Testman
Cc:	Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject:	RE: Study Status Notification III for Protocol AEA08
Attachments:	SSN III.pdf

Dear Rob,

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 12/10/2013).

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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.

Study Status Notification III

DATE: 2/5/2015

TO: Megan T. Boatwright

FROM: Denisse Guzman, Board Liaison
Schulman Associates Institutional Review Board, Inc.

RE: **Protocol#:** AEA08
Sponsor: American Chemistry Council
IRB#: 201307365
Title: Determination of Removal Efficiency of 1, 2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The above referenced item was *Conditionally Approved* on 12/06/2013 by the Board in an expedited manner. On 02/05/2015, the full Board reviewed the documentation submitted in response to the Study Status Notification dated 12/10/2013.

The study status remains ***Conditionally Approved*** pending response to the following ***conditions of approval:***

1. The Board requests submission of a revised protocol to include language within the body of the protocol regarding photographs or videotaping during the study as well as the process for management of confidentiality of these photos and videotapes.

2. The Board requests submission of a revised protocol including EPA required consent form language with regards to pesticide BIT for Board review.

3. The Board requests confirmation that subjects will not be provided with personal exposure results and requests that when the personal exposure reporting guidance from the EPA Human Studies Review Board (HSRB) is issued, it is submitted for Board review as well as any documents updated based on the guidance.

The Board requests your written response to this Study Status Notification. Your response will be reviewed by a Board member to determine whether the conditions of approval are met. You will be contacted if further information is necessary.

You may submit your response to via e-mail: **dguzman**@sairb.com

Board comments regarding the informed consent are currently being processed. 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.

Megan Boatwright

From: Robert Testman
Sent: Thursday, February 05, 2015 1:43 PM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Hi Denisse and Jeff,

I am uncertain of exactly what the board is looking for regarding the video recording and subject reporting. I wrote the following text to insert into appropriate spots in the protocol, but would like to have you take a quick look before we submit it formally. I know you can't make any commitment, but I am hoping to get some advice based on prior board reviews. If you can comment I will write up a response with the revised protocol and submit that.

Thanks,
Rob

Insert to Section 10 "Monitoring Event Procedures"

A. Video Recording and Photography of Study

The study procedures involving subjects, including preparation, application, drying, and removal procedures will be recorded using video and may include photography. Efforts will be made by investigators to avoid recording personally identifiable characteristics of subjects such as faces, tattoos, etc. The recordings will be made under the supervision of the principal investigator and access to the unedited recordings will be limited by the principal investigator to research staff directly involved in recording or editing. The recorded material will be edited by research staff to ensure any personally identifiable characteristics are removed or obscured. Edited recordings will be reviewed by the principal investigator and quality assurance, and approved as not containing personally identifiable information. Following approval of the edited recordings, the raw recordings will be destroyed, and the destruction documented by the principal investigator. Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training or other purposes.

Insert to Section 5 "Oversight of Ethical Conduct"

This protocol does not contain instructions offering subjects the option to receive their personal results. When guidance on subject result reporting is received from HSRB those instructions will be amended to the protocol.

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, February 5, 2015 11:08 AM
To: Robert Testman

Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Dear Rob,

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 12/10/2013).

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Friday, February 06, 2015 6:46 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Good morning Robert,

Your proposed language seems relatively good. It seems to reflect the usual photography statements we see in protecting the identity of subjects. One thing we would recommend is to disclose is the use of the videotaping/photography in publications (if applicable). At the end of the suggested paragraph we see "Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training or other purposes.". Please describe what "other purposes" could be (i.e., publications, journal articles, marketing etc.).

In addition, please be advise that the IC should reflect the protocol processes for this therefore language should be added to both the Protocol and IC.

I hope this helps. Please feel free to contact us should you have additional questions.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, February 05, 2015 4:43 PM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Hi Denisse and Jeff,

I am uncertain of exactly what the board is looking for regarding the video recording and subject reporting. I wrote the following text to insert into appropriate spots in the protocol, but would like to have you take a quick look before we submit it formally. I know you can't make any commitment, but I am hoping to get some advice based on prior board reviews. If you can comment I will write up a response with the revised protocol and submit that.

Thanks,
Rob

Insert to Section 10 "Monitoring Event Procedures"

A. Video Recording and Photography of Study

The study procedures involving subjects, including preparation, application, drying, and removal procedures will be recorded using video and may include photography. Efforts will be made by investigators to avoid recording personally identifiable characteristics of subjects such as faces, tattoos, etc. The recordings will be made under the supervision of the principal investigator and access to the unedited recordings will be limited by the principal investigator to research staff directly involved in recording or editing. The recorded material will be edited by research staff to ensure any personally identifiable characteristics are removed or obscured. Edited recordings will be reviewed by the principal investigator and quality assurance, and approved as not containing personally identifiable information. Following approval of the edited recordings, the raw recordings will be destroyed, and the destruction documented by the principal investigator. Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training or other purposes.

Insert to Section 5 "Oversight of Ethical Conduct"

This protocol does not contain instructions offering subjects the option to receive their personal results. When guidance on subject result reporting is received from HSRB those instructions will be amended to the protocol.

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, February 5, 2015 11:08 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Dear Rob,

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 12/10/2013).

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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

Megan Boatwright

From: Robert Testman
Sent: Friday, February 06, 2015 9:20 AM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08
Attachments: 130503 sairb letter.pdf; Protocol 130503 BIT Removal Effeciency 05Feb2015 tracked.docx; Protocol 130503 BIT Removal Effeciency 05Feb2015.docx

Hi Denisse,

Please find attached a response letter regarding the conditions of approval, as well as the revised protocol with informed consent, and a tracked changes version of the protocol. Please note the tracked changes version includes the prior changes as well as these most recent revisions.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, February 5, 2015 11:08 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Dear Rob,

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 12/10/2013).

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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.

Golden Pacific
LABORATORIES

February 6, 2015

Ms. Denisse Guzman
Board Liason
SAIRB

Dear Ms. Guzman:

We have reviewed the Study Status Notification III for the protocol AEA08 entitled, "Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure" (GPL Study 130503). The conditions of approval listed have been addressed in the attached revised protocol dated February 05, 2015, which includes the revised informed consent as Appendix C. Changes made include the addition of section 10A to address the video recording and photography procedures, and addition of language to section 5 to address reporting of subject personal results. The informed consent was also updated to increase the video recording information and to address the BIT as pesticide language.

Please feel free to contact me with any questions. I can be reached at (559) 275-9091 or mboatwright@gplabs.com.

Sincerely,

Megan Boatwright

Megan Boatwright
Principal Investigator

4720 West Jennifer Avenue, Suite 105 • Fresno, CA 93722 • T: (559)275-9091 • F: (559)275-1810

~~*DRAFT*~~ **PROTOCOL**

~~23~~ 05 ~~January~~ February ~~2014~~2015

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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

~~April~~ March ~~2014~~2015

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: : 87~~83~~

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List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	~~April~~ March ~~2014~~2015
Proposed Experimental Termination Date:	June ~~2014~~2015
Proposed Final Report Issue Date:	~~August~~ October ~~2014~~2015

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8F.1	Sample Identification	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.2	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

Sponsor:

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

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Field Research Associates:	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
Quality Assurance Unit:	Margaret A. Hamelin Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mhamelin@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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. ~~The data generated by testing BIT in solvent will better enable extrapolation of the BIT in paint data to other antimicrobial active ingredients.~~ The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. 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.

The test substance~~s~~ in this study ~~are~~ is latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5~~, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 µg/mL and 3.9 mg/mL.~~ The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of ~~10~~ 20 subjects at one of two concentrations (~~5~~ 10 subjects each). ~~A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each).~~ After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. ~~Hand exposure will be measured by~~ The researchers ~~scrubbing~~ will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then ~~rinsing with~~ the researchers will pour the same solvent over the hands while the subject rubs their ~~fingers to their palm~~hands together. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in ~~IPA or~~ latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The data generated by testing BIT in solvent will better enable extrapolation of the paint data to other antimicrobial active ingredients. The primary objective of this study is to determine the removal efficiency of BIT in latex paint and in IPA from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to extrapolate interpret data from existing human hand removal efficiency studiespainter exposure monitoring studies. In this study, at least 20 subjects (5 10 for each scenarioconcentration) will be monitored in order to capture the expected variation in skin differences, and BIT concentration, and using paint or solvent as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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.

This protocol does not contain instructions offering subjects the option to receive their personal results. When guidance on subject result reporting is received from HSRB those instructions will be amended to the protocol.

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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used ~~on~~ for cleaning the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint ~~or solvent~~ from human skin is not available. Removal efficiency studies which have been conducted with other active ~~ingrediaents~~ingredients do not provide for interpretation of BIT removal, or the removal of any active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substance~~s~~ for this study ~~are~~ is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT)~~ and BIT prepared in isopropyl alcohol (IPA)~~. BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

~~B. Test Substance Identification – BIT in Solvent~~

~~The reference substance 1,2-Benzisothiazol-3(2H)-one (BIT) will be prepared at approximately 786 µg/mL and 3.9 mg/mL using isopropyl alcohol (HPLC grade) as the dilution solvent.~~

~~Name: 1,2-Benzisothiazol-3(2H)-one (BIT)~~
~~CAS Number: [2634-33-5]~~
~~Active Ingredient: BIT~~
~~Lot Number: to be recorded in the raw data~~
~~Purity: to be recorded in the raw data~~
~~Date Received: to be recorded in the raw data~~
~~Expiration Date: to be recorded in the raw data~~

~~C.~~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.

~~BIT in solvent will be used as a second test substance in order to provide comparative removal efficiency information between a paint matrix and solvent. This information will be used to improve extrapolation of data for other active ingredients which may have removal efficiency data in solvent to a paint matrix.~~

The analytical method for the determination of BIT in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

~~D.~~C. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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.

~~E.~~D. Calibration of Application Equipment

BIT in paint ~~or solvent~~ will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

F.E. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint or IPA.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of four two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 786 µg/mL in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/mL in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tubestirring rod with rounded annealed ends. The glass capillary tubestirring rod will be placed into a glass test tube and retained for analysis.

The paint or solution will be left on the hands to dry for 45 minutes. Each The hands will then be washed by . The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. scrubbing with a gauze sponge soaked in 50% IPA / 50% distilled water solution and rinsed with the same

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~~solution.~~ The solution and gauze sponge will be collected as a single sample for ~~each hand~~both hands of each subject, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

5. Subjects will wash their hands with Ivory soap and water, and dry

them thoroughly using paper towels.

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, ~~either~~ a 500 µL volume of the appropriate paint concentration ~~or a 100 µL volume of the appropriate solvent concentration~~ will be applied. A glass ~~capillary tube~~stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The ~~capillary tube~~stirring rod from each subject will be placed into a ~~glass~~ test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold ~~their hand~~both hands over a stainless steel bowl while researchers scrub the hand with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their ~~fingers and palm~~hands together. The total volume of IPA/water solution used will be ~~250~~ 500 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis. ~~The procedure will then be repeated for the second hand producing a second sample.~~

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into ~~four~~ two groups. ~~Two groups will receive BIT applied in paint, and two groups will receive BIT applied in IPA.~~ The ~~four~~ two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT
Group 3 100 µL of ~ 786 µg/mL fortification solution of BIT in IPA
Group 4 100 µL of ~ 3.9 mg/mL fortification solution of BIT in IPA

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four two groups, each corresponding to one of the four two test substance/concentration combinations. The first set of seven fourteen subjects will be placed into Group 1, and the second set of seven fourteen subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4.

Within each group of sevenfourteen, the first five ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two four subjects in the group of seven fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into four two groups, subjects from the first group will be scheduled into the study. No more than two one groups will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., five ten subjects for each of four two groups). As described above, an additional eight subjects (two four per clustergroup) are included as

insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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. 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper

identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- Consider their own health sufficient to conduct the described activities
- ~~Consider their self to be in good health~~
- 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

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 or sensitivities to latex paint, soaps, ~~or~~ isopropyl alcohol, BIT 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)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical

reasons, 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

A. Video Recording and Photography of Study

The study procedures involving subjects, including preparation, application, drying, and removal procedures will be recorded using video and may include photography. Efforts will be made during recording to avoid recording personally identifiable characteristics of subjects such as faces, tattoos, etc. The recording will be made under the supervision of the principal investigator and access to the unedited recordings will be limited by the principal investigator to research staff directly involved in recording or editing. The recorded material will be edited by research staff to ensure any personally identifiable characteristics are removed or obscured. Edited recordings will be reviewed by the principal investigator and quality assurance, and approved as not containing personally identifiable information. Following approval of the edited recordings, the raw recordings will be destroyed, and the destruction documented by the principal investigator. Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training, presentations, or publication in scientific journals. ~~Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training or other purposes.~~

~~A.~~B. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and

completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

~~B.~~C. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

~~C.~~D. 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 (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint ~~or in solvent~~ will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm
~~IPA~~	~~100 µL~~	~~Approximately 786 µg/mL~~
~~IPA~~	~~100 µL~~	~~Approximately 3.9 mg/mL~~

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL-~~LH~~:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
~~LH = Left Hand~~
Additional designations are as follows:
~~S = Solvent~~
H = High Concentration Level
~~RH = Right Hand~~

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. ~~The IPA test substances will be analyzed by diluting to an appropriate concentration with 50% acetonitrile /50% water, vialing with internal standard, and analyzing by HPLC/MS/MS.~~ The ~~capillary pipets~~glass stir rods used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the ~~capillary tubes~~glass stir rods used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.

3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

_____

Has Shah, Ph.D. Date
Sponsor's Representative

_____

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

_____

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

_____

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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.

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.

APPENDIX A: LABEL FOR MERGAL® BIT20

MERGAL® BIT20

For Industrial Use Only As A Microbiostat Preservative Intended To Protect Polymer Emulsions, Emulsion Paint And Coatings, Mineral Slurries And Dispersions, Latex Adhesives, Paper Coatings, Metalworking Fluids, Textile Spin-Finish And Coatings, Building And Construction Compositions, Inks, Leather Processing Additives, Cleaning Products Including Car Washes, Car Waxes, Solid Cast Products Including Air Fresheners, Polishes, 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

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, 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.

Do not reuse them

USER SAFETY RECOMMENDATIONS

Users should:

- Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- Users should remove clothing/PPE immediately if pesticide gets inside clothing. Then wash thoroughly and put on clean clothing
- Users should remove PPE immediately after handing 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

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 supplied for use in aqueous or water-containing products and systems including water-based, solvent-based and solventless systems. Mergal® BIT 20 is typically used at 0.05% to 0.25% active of Mergal® BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 100 gallons 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 food or 0.01 mg/in² (0.0016 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 regulations. The following table lists the clearances for solvent ingredients (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)(ix).

OIL RECOVERY SYSTEMS Drilling fluids, packer fluids, completion fluids Polysaccharide fluid loss control agents and viscosifiers such as starch, guar gum, hydroxyethyl cellulose (HEC) etc. at 0.1% 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-0.0015-0.15% 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 1/29/2012 Complies with:			
OTC	Yes	LEED® 09 IO	Yes
SCAQMD	Yes	LEED® 09 NC	Yes
CARB	Yes	LEED® 09 CS	Yes
CARB SCM 2007	Yes	LEED® 09 H	Yes
MPI #	53	MPI®	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 SCAQMD 2004, 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.

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 A86WA00151 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

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	Sí	LEED® 09 CI	Sí
SCAQMD	Sí	LEED® 09 NC	Sí
CARB	Sí	LEED® 09 CS	Sí
CARB SCM 2007	Sí	LEED® 09 H	Sí
MPI N.°	53	MGBS	Sí

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.

3/2013 www.sherwin-williams.com continúa al reverso

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
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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:

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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint ~~or rubbing (isopropyl) alcohol~~ containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. We will measure how much chemical can be removed from your hands by rinsing and scrubbing your hands with a gauze sponge soaked with a solution of ~~isopropyl~~ rubbing alcohol (also called isopropyl alcohol or IPA) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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~~ pesticide known as BIT which helps keep bacteria from growing. ~~We will also test a solution of BIT in rubbing alcohol.~~ You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, ~~or~~ paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your palms facing up. We will place a small amount of paint ~~or rubbing alcohol~~ on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands ~~one at a time~~ with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe samples, you will wash your hands again with soap and water. 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 few 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 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 might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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 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. We may take photographs or video of the study, but we will edit these so that you cannot be identified. The edited photographs or video may be used for training other researchers, presenting the study to the people who are paying for it, or publication in scientific journals.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*					
6. Name					
7. Address					
8. City, ST, Zip					
9. Telephone(s)					
10. Age in years =	11. DOB:	12. Sex ☐M ☐F			
13. Resident in Fresno County? ☐Yes ☐No					
14. Preferred Language: ☐English ☐Spanish	15. Reads: ☐English ☐Spanish				
16. Are you pregnant? ☐NA ☐Yes ☐No	17. Are you nursing a baby? ☐NA ☐Yes ☐No				
18. Do you consider your general health good enough to participate in this study as described? ☐Yes ☐No					
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐No					
20. 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 AND BIT REFERENCE SUBSTANCE

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

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.

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.

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SIGMA-ALDRICH

sigma-aldrich.com

Material Safety Data Sheet

Version 4.2
Revision Date 10/05/2012
Print Date 05/30/2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Supplier	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052
Emergency Phone # (For both supplier and manufacturer)	:	(314) 776-6555
Preparation Information	:	Sigma-Aldrich Corporation Product Safety - Americas Region 1-800-521-8956

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

GHS Classification
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Serious eye damage (Category 1)
Skin sensitization (Category 1)
Acute aquatic toxicity (Category 1)

GHS Label elements, including precautionary statements

Pictogram

Signal word Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary statement(s)

P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

HMIS Classification

Health hazard:	2
Flammability:	0
Physical hazards:	0

NFPA Rating

Health hazard:	2
Fire:	0
Reactivity Hazard.	0

Potential Health Effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.
Ingestion	Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula : C_7H_5NOS

Molecular Weight : 151.19 g/mol

Component		Concentration
1,2-Benzisothiazolin-3-one		
CAS-No.	2634-33-5	-
EC-No.	220-120-9	
Index-No.	613-088-00-6	

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	crystalline
Colour	light yellow

Safety data

pH	no data available
Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Autoignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Vapour pressure	no data available
Density	no data available
Water solubility	no data available

Partition coefficient: n-octanol/water	no data available
Relative vapour density	no data available
Odour	no data available
Odour Threshold	no data available
Evaporation rate	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
no data available

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides
Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50
LD50 Oral - rat - 1,020 mg/kg

Inhalation LC50
no data available

Dermal LD50
no data available

Other information on acute toxicity
no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
May cause allergic skin reaction.

Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects
no data available

Additional Information
RTECS: DE4620000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Spanish Material Safety Data Sheet for Sherwin-Williams Latex Paint here after translation of approved English version

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint ~~or rubbing alcohol~~ on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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

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 removal efficiency 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 removed from the palms of your hand when paint ~~or rubbing alcohol~~ containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint ~~or rubbing alcohol~~ on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Target BIT Concentration
AEA08-RE-01-PL-LH	1	120 ppm
AEA08-RE-0102-PL-RH	12	120 ppm
AEA08-RE-032-PL-LH	23	120 ppm
AEA08-RE-042-PL-RH	24	120 ppm
AEA08-RE-053-PL-LH	35	120 ppm
AEA08-RE-063-PL-RH	36	120 ppm
AEA08-RE-074-PL-LH	47	120 ppm
AEA08-RE-084-PL-RH	48	120 ppm
AEA08-RE-095-PL-LH	59	120 ppm
AEA08-RE-1005-PL-RH	510	120 ppm
AEA08-RE-1106-PH-LH	611	600 ppm
AEA08-RE-1206-PH-RH	612	600 ppm
AEA08-RE-1307-PH-LH	713	600 ppm
AEA08-RE-1407-PH-RH	714	600 ppm
AEA08-RE-1508-PH-LH	815	600 ppm
AEA08-RE-1608-PH-RH	816	600 ppm
AEA08-RE-1709-PH-LH	917	600 ppm
AEA08-RE-18-09-PH-RH	918	600 ppm
AEA08-RE-180-PH-LH	1019	600 ppm
AEA08-RE-210-PH-RH	1020	600 ppm
AEA08-RE-11-SL-LH	11	786 µg/mL
AEA08-RE-11-SL-RH	11	786 µg/mL
AEA08-RE-12-SL-LH	12	786 µg/mL
AEA08-RE-12-SL-RH	12	786 µg/mL
AEA08-RE-13-SL-LH	13	786 µg/mL
AEA08-RE-13-SL-RH	13	786 µg/mL
AEA08-RE-14-SL-LH	14	786 µg/mL
AEA08-RE-14-SL-RH	14	786 µg/mL
AEA08-RE-15-SL-LH	15	786 µg/mL
AEA08-RE-15-SL-RH	15	786 µg/mL
AEA08-RE-16-SH-LH	16	3.9 mg/mL
AEA08-RE-16-SH-RH	16	3.9 mg/mL
AEA08-RE-17-SH-LH	17	3.9 mg/mL
AEA08-RE-17-SH-RH	17	3.9 mg/mL
AEA08-RE-18-SH-LH	18	3.9 mg/mL
AEA08-RE-18-SH-RH	18	3.9 mg/mL
AEA08-RE-19-SH-LH	19	3.9 mg/mL
AEA08-RE-19-PH-RH	19	3.9 mg/mL
AEA08-RE-20-PH-LH	20	3.9 mg/mL

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AEA08-RE-20-PH-RH	20	3.9 mg/mL

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-S-01-C	Control	None
AEA08-FF-S-01-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-01-H2	High Fortified with Solvent	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg
AEA08-FF-S-02-C	Control	None
AEA08-FF-S-02-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-02-H2	High Fortified with Solvent	390 µg

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PROTOCOL

05 February 2015

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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

March 2015

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 103

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List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	March 2015
Proposed Experimental Termination Date:	June 2015
Proposed Final Report Issue Date:	October 2015

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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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8C.2	Dermal Face/Neck Wipe Samples	10.0
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11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.2	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

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Quality Assurance Unit:	Margaret A. Hamelin Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mhamelin@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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

The test substance in this study is latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5The latex paint will be

tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 20 subjects at one of two concentrations (10 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. The researchers will scrub the subjects hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The primary objective of this study is to determine the removal efficiency of BIT in latex paint from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to interpret data from painter exposure monitoring studies. In this study, at least 20 subjects (10 for each concentration) will be monitored in order to capture the expected variation in skin differences, and BIT concentration using paint as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions (Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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.

This protocol does not contain instructions offering subjects the option to receive their personal results. When guidance on subject result reporting is received from HSRB those instructions will be amended to the protocol.

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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than the dermal exposure assumed by

EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used for cleaning the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. 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.

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. Society may benefit from continued ability to use antimicrobials that

improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint from human skin is not available. Removal efficiency studies which have been conducted with other active ingredients do not provide for interpretation of BIT removal, or the removal of any active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substance for this study is the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT). BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name: Sherwin-Williams Latex Paint A86W00151

Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

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 in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

C. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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

BIT in paint will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

E. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass stirring rod with rounded annealed ends. The glass stirring rod will be placed into a test tube and retained for analysis.

The paint will be left on the hands to dry for 45 minutes. The hands will then be washed. The researchers will scrub the subjects hands with gauze

sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then the researchers will pour the same solvent over the hands while the subject rubs their hands together. The gauze sponges will be added to the rinse solvent for extraction. The solution and gauze sponge will be collected as a single sample for both hands of each subject, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance

with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold both hands over a stainless steel bowl while researchers scrub the hand with a gauze sponge (J&J Mirasorb 4-ply each). The gauze sponge 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 the hand with the same solvent by pouring the solvent over the hand and having the subject rub their hands together. The total volume of IPA/water solution used will be 500 mL. The used gauze sponge will be added to the hand wash solution collected in the stainless steel bowl and saved with the rinse solution for analysis.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into two groups, each corresponding to one of the two test substance/concentration combinations. The first set of fourteen subjects will be placed into Group 1, and the second set of fourteen subjects will be placed into Group 2,.

Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into two groups, subjects from the first group will be scheduled into the study. No more than one group will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., ten subjects for each of two groups). As described above, an additional eight subjects (four per group) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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. 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- 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

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 or sensitivities to latex paint, soaps. isopropyl alcohol, BIT 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)
- Severe diabetes
- Immunologically suppressed (e.g. undergoing chemotherapy, transplant patients)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, samples from the subject will not be collected. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Video Recording and Photography of Study

The study procedures involving subjects, including preparation, application, drying, and removal procedures will be recorded using video and may include photography. Efforts will be made during recording to avoid recording personally identifiable characteristics of subjects such as faces, tattoos, etc. The recording will be made under the supervision of the principal investigator and access to the unedited recordings will be limited by the principal investigator to research staff directly involved in recording or editing. The recorded material will be edited by research staff to ensure any personally identifiable characteristics are removed or obscured. Edited recordings will be reviewed by the principal investigator and quality assurance, and approved as not containing personally identifiable information. Following approval of the edited recordings, the raw recordings will be destroyed, and the destruction documented by the principal investigator. Edited and approved footage will be maintained with the study data files and may be provided to the sponsor and EPA for training, presentations, or publication in scientific journals.

B. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

C. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

D. 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 (hand wipe/wash solutions containing gauze sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
Additional designations are as follows:
H = High Concentration Level

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for

very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The glass stir rods used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the glass stir rods used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.
3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

_____

Has Shah, Ph.D. Date
Sponsor's Representative

_____

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

_____

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

_____

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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.

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.

APPENDIX A: 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. When mixing, loading or cleaning wear 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, Carpet Care Products Including Car Washes, Car Waxes, And Silicone Emulsions, Household Cleaning Products Including Floor Cleaners, Floor Waxes, Floor Polishes And Surface Cleaning 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 latex and emulsion polymers, at concentrations sufficient to provide 0.05-0.15% active ingredient. For example, use 0.5-2.5 lbs. of Mergal® BIT 20 per 1000 lbs. of 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 may be safely used in food-contact articles 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 gum, cellulose, 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

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.

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

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.
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 C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:
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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. We will measure how much chemical can be removed from your hands by rinsing and scrubbing your hands with a gauze sponge soaked with a solution of rubbing alcohol (also called isopropyl alcohol or IPA) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 pesticide known as BIT which helps keep bacteria from growing. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your palms facing up. We will place a small amount of paint on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe samples, you will wash your hands again with soap and water. 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 few 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 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 might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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 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. We may take photographs or video of the study, but we will edit these so that you cannot be identified. The edited photographs or video may be used for training other researchers, presenting the study to the people who are paying for it, or publication in scientific journals.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*			
6. Name			
7. Address			
8. City, ST, Zip			
9. Telephone(s)			
10. Age in years =	11. DOB:	12. Sex ☐M ☐F	
13. Resident in Fresno County? ☐Yes ☐No			
14. Preferred Language: ☐English ☐Spanish	15. Reads: ☐English ☐Spanish		
16. Are you pregnant? ☐NA ☐Yes ☐No	17. Are you nursing a baby? ☐NA ☐Yes ☐No		
18. Do you consider your general health good enough to participate in this study as described? ☐Yes ☐No			
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? ☐Yes ☐No			
20. 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 AND BIT REFERENCE SUBSTANCE

MATERIAL SAFETY DATA SHEET

A86W151
12 00

DATE OF PREPARATION
Oct 27, 2014

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NUMBER
A86W151
PRODUCT NAME
SUPERPAINT® Interior Flat 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
15	14808-60-7	Quartz		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.1 mg/m3 as Resp. Dust	
1	14464-46-1	Cristobalite		
		ACGIH TLV	0.025 mg/m3 as Resp. Dust	
		OSHA PEL	0.05 mg/m3 as Resp. Dust	
2	1332-58-7	Kaolin		
		ACGIH TLV	Not Available	
		OSHA PEL	15 mg/m3 Total Dust	
		OSHA PEL	5 mg/m3 Respirable Fraction	
17	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	12.05 lb/gal	1443 g/l
SPECIFIC GRAVITY	1.45	
BOILING POINT	212 - 213 °F	100 - 100 °C
MELTING POINT	Not Available	
VOLATILE VOLUME	57%	
EVAPORATION RATE	Slower than ether	
VAPOR DENSITY	Heavier than air	
SOLUBILITY IN WATER	Not Available	
pH	9.3	

VOLATILE ORGANIC COMPOUNDS (VOC Theoretical - As Packaged)

0.35 lb/gal	42 g/l	Less Water and Federally Exempt Solvents
0.16 lb/gal	19 g/l	Emitted VOC

VOLATILE ORGANIC COMPOUNDS (VOC - As Applied)

<0.41 lb/gal	<50 g/l	Less Water and Federally Exempt Solvents

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			
14808-60-7	Quartz			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
14464-46-1	Cristobalite			
		LC50 RAT	4HR	Not Available
		LD50 RAT		Not Available
1332-58-7	Kaolin			
		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.

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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 sílice 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.

SIGMA-ALDRICH

sigma-aldrich.com

SAFETY DATA SHEET

Version 4.4
Revision Date 06/30/2014
Print Date 02/02/2015

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Index-No.	:	613-088-00-6
CAS-No.	:	2634-33-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses	:	Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052

1.4 Emergency telephone number

Emergency Phone #	:	(314) 776-6555

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Acute toxicity, Oral (Category 4), H302
Skin irritation (Category 2), H315
Serious eye damage (Category 1), H318
Skin sensitisation (Category 1), H317
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word: Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.

P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/ physician.
P321	Specific treatment (see supplemental first aid instructions on this label).
P330	Rinse mouth.
P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P391	Collect spillage.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula	:	C_7H_5NOS
Molecular Weight	:	151.19 g/mol
CAS-No.	:	2634-33-5
EC-No.	:	220-120-9
Index-No.	:	613-088-00-6

Hazardous components

Component	Classification	Concentration
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

5.3 Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information
no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374
If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: crystalline Colour: light yellow
b)	Odour	no data available
c)	Odour Threshold	no data available
d)	pH	no data available
e)	Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
f)	Initial boiling point and boiling range	no data available
g)	Flash point	no data available
h)	Evapouration rate	no data available
i)	Flammability (solid, gas)	no data available
j)	Upper/lower flammability or explosive limits	no data available
k)	Vapour pressure	no data available
l)	Vapour density	no data available

m)	Relative density	no data available
n)	Water solubility	no data available
o)	Partition coefficient: n-octanol/water	no data available
p)	Auto-ignition temperature	no data available
q)	Decomposition temperature	no data available
r)	Viscosity	no data available
s)	Explosive properties	no data available
t)	Oxidizing properties	no data available

9.2 Other safety information
no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
no data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
no data available

10.4 Conditions to avoid
no data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - no data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - 1,020 mg/kg

Inhalation: no data available

Dermal: no data available

no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitisation
Germ cell mutagenicity
no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
no data available

no data available

Specific target organ toxicity - single exposure
no data available

Specific target organ toxicity - repeated exposure
no data available

Aspiration hazard
no data available

Additional Information
RTECS: DE4620000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

12.2 Persistence and degradability
no data available

12.3 Bioaccumulative potential
no data available

12.4 Mobility in soil
no data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Aquatic Chronic	Chronic aquatic toxicity
Eye Dam.	Serious eye damage
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

HMIS Rating

Health hazard:	2
Chronic Health Hazard:	
Flammability:	0
Physical Hazard	0

NFPA Rating
Health hazard: 2

Fire Hazard:	0
Reactivity Hazard:	0

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Preparation Information

Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956

Version: 4.4 Revision Date: 06/30/2014 Print Date: 02/02/2015

SIGMA-ALDRICH

sigma-aldrich.com

FICHA DE DATOS DE SEGURIDAD

Versión 4.4
Fecha de revisión 06/29/2014
Fecha de impresión 02/02/2015

1. IDENTIFICACIÓN DEL PRODUCTO Y DE LA COMPAÑÍA

1.1 Identificadores del producto

Nombre del producto	:	1,2-Benzisothiazol-3(2*H*)-one
Referencia	:	561487
Marca	:	Aldrich
No. Indice	:	613-088-00-6
No. CAS	:	2634-33-5

1.2 Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados

Usos identificados	:	Reactivos para laboratorio, Fabricación de sustancias

1.3 Datos del proveedor de la ficha de datos de seguridad

Compañía	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Teléfono	:	+1 800-325-5832
Fax	:	+1 800-325-5052

1.4 Teléfono de emergencia

Teléfono de Urgencia	:	(314) 776-6555

2. IDENTIFICACIÓN DE LOS PELIGROS

2.1 Clasificación de la sustancia o de la mezcla

Clasificación SGA de acuerdo con 29 CFR 1910 (OSHA HCS).
Toxicidad aguda, Oral (Categoría 4), H302
Irritación cutáneas (Categoría 2), H315
Lesiones oculares graves (Categoría 1), H318
Sensibilización cutánea (Categoría 1), H317
Toxicidad acuática aguda (Categoría 1), H400
Toxicidad acuática crónica (Categoría 1), H410

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

2.2 Elementos de las etiquetas del SGA, incluidos los consejos de prudencia

Pictograma

Palabra de advertencia: Peligro

Indicación(es) de peligro

H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Declaración(es) de prudencia

P261	Evitar respirar el polvo/ el humo/ el gas/ la niebla/ los vapores/ el aerosol.

P264	Lavarse la piel concienzudamente tras la manipulación.
P270	No comer, beber ni fumar durante su utilización.
P272	Las prendas de trabajo contaminadas no podrán sacarse del lugar de trabajo.
P273	Evitar su liberación al medio ambiente.
P280	Llevar guantes de protección/ gafas de protección/ máscara de protección.
P301 + P312	EN CASO DE INGESTIÓN: Llamar a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico si se encuentra mal.
P302 + P352	EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes.
P305 + P351 + P338	EN CASO DE CONTACTO CON LOS OJOS: Enjuagar con agua cuidadosamente durante varios minutos. Quitar las lentes de contacto cuando estén presentes y pueda hacerse con facilidad. Proseguir con el lavado.
P310	Llamar inmediatamente a un CENTRO DE INFORMACION TOXICOLOGICA o a un médico.
P321	Se necesita un tratamiento específico (véase las instrucciones suplementarias de primeros auxilios en esta etiqueta).
P330	Enjuagarse la boca.
P333 + P313	En caso de irritación o erupción cutánea: Consultar a un médico.
P362	Quitarse las prendas contaminadas y lavarlas antes de volver a usarlas.
P391	Recoger el vertido.
P501	Eliminar el contenido/ el recipiente en una planta de eliminación de residuos aprobada.

2.3 Peligros no clasificados de otra manera - ninguno(a)

3. COMPOSICIÓN/INFORMACIÓN SOBRE LOS COMPONENTES

3.1 Sustancias

Formula	:	C_7H_5NOS
Peso molecular	:	151.19 g/mol
No. CAS	:	2634-33-5
No. CE	:	220-120-9
No. Indice	:	613-088-00-6

Componentes peligrosos

Componente	Clasificación	Concentración
1,2-Benzisothiazolin-3-one		
	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H317, H318, H410	-

Para el texto integro de las Declaraciones-H mencionadas en esta sección, véase la Sección 16.

4. PRIMEROS AUXILIOS

4.1 Descripción de los primeros auxilios

Recomendaciones generales
Consultar a un médico. Mostrar esta ficha de seguridad al doctor que esté de servicio.Retire a la persona de la zona peligrosa.

Si es inhalado
Si aspiró, mueva la persona al aire fresco. Si ha parado de respirar, hacer la respiración artificial. Consultar a un médico.

En caso de contacto con la piel
Eliminar lavando con jabón y mucha agua. Consultar a un médico.

En caso de contacto con los ojos
Lávese a fondo con agua abundante durante 15 minutos por lo menos y consulte al médico.

Si es tragado
Nunca debe administrarse nada por la boca a una persona inconsciente. Enjuague la boca con agua. Consultar a un médico.

4.2 Principales síntomas y efectos, agudos y retardados
Los síntomas y efectos más importantes conocidos se describen en la etiqueta (ver sección 2.2) y / o en la sección 11

4.3 Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente
sin datos disponibles

5. MEDIDAS DE LUCHA CONTRA INCENDIOS

5.1 Medios de extinción

Medios de extinción apropiados
Usar agua pulverizada, espuma resistente al alcohol, polvo seco o dióxido de carbono.

5.2 Peligros específicos derivados de la sustancia o la mezcla
Óxidos de carbono, óxidos de nitrógeno (NOx), Óxidos de azufre

5.3 Recomendaciones para el personal de lucha contra incendios
Si es necesario, usar equipo de respiración autónomo para la lucha contra el fuego.

5.4 Otros datos
sin datos disponibles

6. MEDIDAS EN CASO DE VERTIDO ACCIDENTAL

6.1 Precauciones personales, equipo de protección y procedimientos de emergencia
Utilícese equipo de protección individual. Evite la formación de polvo. Evitar respirar los vapores, la neblina o el gas. Asegúrese una ventilación apropiada. Evacuar el personal a zonas seguras. Evitar respirar el polvo.
Equipo de protección individual, ver sección 8.

6.2 Precauciones relativas al medio ambiente
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

6.3 Métodos y material de contención y de limpieza
Recoger y preparar la eliminación sin originar polvo. Limpiar y traspalar. Guardar en contenedores apropiados y cerrados para su eliminación.

6.4 Referencia a otras secciones
Para eliminación de desechos ver sección 13.

7. MANIPULACIÓN Y ALMACENAMIENTO

7.1 Precauciones para una manipulación segura
Evítese el contacto con los ojos y la piel. Evítese la formación de polvo y aerosoles.
Debe disponer de extracción adecuada en aquellos lugares en los que se forma polvo.
Ver precauciones en la sección 2.2

7.2 Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades
Conservar el envase herméticamente cerrado en un lugar seco y bien ventilado.

7.3 Usos específicos finales
Aparte de los usos mencionados en la sección 1.2 no se estipulan otros usos específicos

8. CONTROLES DE EXPOSICIÓN/ PROTECCIÓN INDIVIDUAL

8.1 Parámetros de control

Componentes con valores límite ambientales de exposición profesional.
No contiene sustancias con valores límites de exposición profesional.

8.2 Controles de la exposición

Controles técnicos apropiados
Manipular con las precauciones de higiene industrial adecuadas, y respetar las prácticas de seguridad. Lávense las manos antes de los descansos y después de terminar la jornada laboral.

Protección personal

Protección de los ojos/ la cara
Caretas de protección y gafas de seguridad. Use equipo de protección para los ojos probado y aprobado según las normas gubernamentales correspondientes, tales como NIOSH (EE.UU.) o EN 166 (UE).

Protección de la piel
Manipular con guantes. Los guantes deben ser inspeccionados antes de su uso. Utilice la técnica correcta de quitarse los guantes (sin tocar la superficie exterior del guante) para evitar el contacto de la piel con este producto. Deseche los guantes contaminados después de su uso, de conformidad con las leyes aplicables y buenas prácticas de laboratorio. Lavar y secar las manos.

Sumerción
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

Salpicaduras
Material: Caucho nitrílo
espesura minima de capa: 0.11 mm
Tiempo de perforación: 480 min
Material probado:Dermatril® (KCL 740 / Aldrich Z677272, Talla M)

origen de datos: KCL GmbH, D-36124 Eichenzell, Teléfono +49 (0)6659 87300, e-mail sales@kcl.de, Método de prueba: EN374
Si es utilizado en solución, o mezclado con otras sustancias, y bajo condiciones diferentes de la EN 374, pornerse en contacto con el proveedor de los guantes aprobados CE. Esta recomendación es meramente aconsejable y deberá ser evaluada por un responsable de seguridad e higiene industrial familiarizado con la situación específica de uso previsto por nuestros clientes. No debe interpretarse como una aprobación de oferta para cualquier escenario de uso específico.

Protección Corporal
Traje de protección completo contra productos químicos, El tipo de equipamiento de protección debe ser elegido según la concentración y la cantidad de sustancia peligrosa al lugar específico de trabajo.

Protección respiratoria
Donde el asesoramiento de riesgo muestre que los respiradores purificadores de aire son apropiados, usar un respuirador que cubra toda la cara tipo N100 (EEUU) o tipo P3 (EN 143) y cartichos de respuesto para controles de ingieneria. Si el respirador es la unica protección, usar un respirador suministrado que cubra toda la cara Usar respiradores y componenetes testados y aprobados bajo los estandards gubernamentales apropiados como NIOSH (EEUU) o CEN (UE)

Control de exposición ambiental
Impedir nuevos escapes o derrames si puede hacerse sin riesgos. No dejar que el producto entre en el sistema de alcantarillado. La descarga en el ambiente debe ser evitada.

9. PROPIEDADES FÍSICAS Y QUÍMICAS

9.1 Información sobre propiedades físicas y químicas básicas

a)	Aspecto	Forma: cristalino Color: amarillo claro
b)	Olor	sin datos disponibles
c)	Umbral olfativo	sin datos disponibles
d)	pH	sin datos disponibles
e)	Punto de fusión/ punto de congelación	Punto/intervalo de fusión: 154 - 158 °C (309 - 316 °F) - lit.

f)	Punto inicial de ebullición e intervalo de ebullición	sin datos disponibles
g)	Punto de inflamación	sin datos disponibles
h)	Tasa de evaporación	sin datos disponibles
i)	Inflamabilidad (sólido, gas)	sin datos disponibles
j)	Inflamabilidad superior/inferior o límites explosivos	sin datos disponibles
k)	Presión de vapor	sin datos disponibles
l)	Densidad de vapor	sin datos disponibles
m)	Densidad relativa	sin datos disponibles
n)	Solubilidad en agua	sin datos disponibles
o)	Coeficiente de reparto n-octanol/agua	sin datos disponibles
p)	Temperatura de auto-inflamación	sin datos disponibles
q)	Temperatura de descomposición	sin datos disponibles
r)	Viscosidad	sin datos disponibles
s)	Propiedades explosivas	sin datos disponibles
t)	Propiedades comburentes	sin datos disponibles

9.2 Otra información de seguridad
sin datos disponibles

10. ESTABILIDAD Y REACTIVIDAD

10.1 Reactividad
sin datos disponibles

10.2 Estabilidad química
Estable bajo las condiciones de almacenamiento recomendadas.

10.3 Posibilidad de reacciones peligrosas
sin datos disponibles

10.4 Condiciones que deben evitarse
sin datos disponibles

10.5 Materiales incompatibles
Agentes oxidantes fuertes

10.6 Productos de descomposición peligrosos
Otros productos de descomposición peligrosos - sin datos disponibles
En caso de incendio: véase sección 5

11. INFORMACIÓN TOXICOLÓGICA

11.1 Información sobre los efectos toxicológicos

Toxicidad aguda
DL50 Oral - rata - 1,020 mg/kg

Inhalación: sin datos disponibles

Cutáneo: sin datos disponibles

sin datos disponibles

Corrosión o irritación cutáneas
sin datos disponibles

Lesiones o irritación ocular graves
sin datos disponibles

Sensibilización respiratoria o cutánea
Mutagenicidad en células germinales
sin datos disponibles

Carcinogenicidad

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la ACGIH.
NTP:	En este producto no se identifica ningún componente, que presente niveles mayores que o iguales a 0.1%, como agente carcinógeno conocido o anticipado por el (NTP) Programa Nacional de Toxicología.
OSHA:	No se identifica ningún componente de este producto, que presente niveles mayores que o el igual a 0,1% como cancerígeno o como carcinógeno potencial por la (OSHA) Administración de Salud y Seguridad Ocupacional.

Toxicidad para la reproducción
sin datos disponibles

sin datos disponibles

Toxicidad específica en determinados órganos - exposición única
sin datos disponibles

Toxicidad específica en determinados órganos - exposiciones repetidas
sin datos disponibles

Peligro de aspiración
sin datos disponibles

Información Adicional
RTECS: DE4620000

Según nuestras informaciones, creemos que no se han investigado adecuadamente las propiedades químicas, físicas y toxicológicas.

12. INFORMACIÓN ECOLÓGICA

12.1 Toxicidad

Toxicidad para los peces	CL50 - Oncorhynchus mykiss (Trucha irisada) - 0.8 mg/l - 96.0 h
Toxicidad para las dafnias y otros invertebrados acuáticos	CE50 - Daphnia magna (Pulga de mar grande) - 4.4 mg/l - 48 h

12.2 Persistencia y degradabilidad
sin datos disponibles

12.3 Potencial de bioacumulación
sin datos disponibles

12.4 Movilidad en el suelo
sin datos disponibles

12.5 Resultados de la valoración PBT y mPmB
La valoración de PBT / mPmB no está disponible ya que la evaluación de la seguridad química no es necesaria / no se ha realizado

12.6 Otros efectos adversos
No se puede excluir un peligro para el medio ambiente en el caso de una manipulación o eliminación no profesional.
Muy tóxico para los organismos acuáticos.

13. CONSIDERACIONES RELATIVAS A LA ELIMINACIÓN

13.1 Métodos para el tratamiento de residuos

Producto
Ofertar el sobrante y las soluciones no-aprovechables a una compañia de vertidos acreditada. Para la eliminación de este producto, dirigirse a un servicio profesional autorizado.

Envases contaminados
Eliminar como producto no usado.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

DOT (US)
Mercancía no peligrosa

IMDG
Número ONU: 3077 Clase: 9 Grupo de embalaje: III EMS-No: F-A, S-F
Designación oficial de transporte de las Naciones Unidas: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Contaminante marino: MARINE POLUTANT

IATA
Número ONU: 3077 Clase: 9 Grupo de embalaje: III
Designación oficial de transporte de las Naciones Unidas: Sustancia sólida peligrosa para el medio ambiente, n.e.p. (1,2-Benzisothiazolin-3-one)

Otros datos
Marca-EHS requerida (códigos ADR 2.2.9.1.10 e IMDG 2.10.3) para embalajes únicos y embalajes combinados que contengan embalajes interiores con Mercancías Peligrosas > 5L para líquidos o > 5Kg para sólidos.

15. INFORMACIÓN REGLAMENTARIA

SARA 302 Componentes
SARA 302: Este material no contiene productos químicos sujetos a los requisitos reportados por SARA Titulo III, sección 302.

SARA 313 Componentes
SARA 313: Este material no contiene ningún componente químico con los conocidos números CAS que exceden el umbral de los niveles reportados (De Minimis) establecidos por SARA título III, sección 313.

SARA 311/312 Peligros
Peligro Agudo para la Salud

Massachusetts Right To Know Componentes
No hay componentes sujetos al Acta de Derecho a Saber de Massachussets.

Pennsylvania Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Componentes

	No. CAS	Fecha de revisión
1,2-Benzisothiazolin-3-one	2634-33-5	

Prop. 65 de California Componentes
Este producto no contiene ninguna sustancia química conocida para el de Estado de California que pueden causar cáncer, defectos de nacimiento, o cualquier otro daño reproductivo.

16. OTRA INFORMACIÓN

Texto íntegro de las Declaraciones-H referidas en las secciones 2 y 3.

Acute Tox.	Toxicidad aguda
Aquatic Acute	Toxicidad acuática aguda
Aquatic Chronic	Toxicidad acuática crónica
Eye Dam.	Lesiones oculares graves
H302	Nocivo en caso de ingestión.
H315	Provoca irritación cutánea.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H400	Muy tóxico para los organismos acuáticos.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.

Clasificación HMIS/NFPA

Peligro para la salud:	2
Peligro Crónico para la Salud:	
Inflamabilidad:	0
Peligro Físico	0

Clasificación NFPA

Peligro para la salud:	2
Peligro de Incendio:	0
Peligro de Reactividad:	0

Otros datos

La información indicada arriba se considera correcta pero no pretende ser exhaustiva y deberá utilizarse únicamente como orientación. La información contenida en este documento esta basada en el presente estado de nuestro conocimiento y es aplicable a las precauciones de seguridad apropiadas para el producto. No representa ninguna garantía de las propiedades del producto. La Corporación Sigma-Aldrich y sus Compañías Afiliadas, no responderán por ningún daño resultante de la manipulación o contacto con el producto indicado arriba. Dirijase a www.sigma-aldrich.com y/o a los términos y condiciones de venta en el reverso de la factura o de la nota de entrega.

Información suministrada por

Corporación Sigma-Aldrich
Product Safety – Americas Region
1-800-521-8956

Versión: 4.4	Fecha de revisión: 06/29/2014	Fecha de impresión: 02/02/2015

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 02/02/2015

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 removal efficiency 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 removed from the palms of your hand when paint containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze sponge. We will collect the wash water and gauze sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Target BIT Concentration
AEA08-RE-01-PL	1	120 ppm
AEA08-RE-02-PL	2	120 ppm
AEA08-RE-03-PL	3	120 ppm
AEA08-RE-04-PL	4	120 ppm
AEA08-RE-05-PL	5	120 ppm
AEA08-RE-06-PL	6	120 ppm
AEA08-RE-07-PL	7	120 ppm
AEA08-RE-08-PL	8	120 ppm
AEA08-RE-09-PL	9	120 ppm
AEA08-RE-10-PL	10	120 ppm
AEA08-RE-11-PH	11	600 ppm
AEA08-RE-12-PH	12	600 ppm
AEA08-RE-13-PH	13	600 ppm
AEA08-RE-14-PH	14	600 ppm
AEA08-RE-15-PH	15	600 ppm
AEA08-RE-16-PH	16	600 ppm
AEA08-RE-17-PH	17	600 ppm
AEA08-RE-18-PH	18	600 ppm
AEA08-RE-18-PH	19	600 ppm
AEA08-RE-20-PH	20	600 ppm

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg

Megan Boatwright

From: Denisse Guzman <DGuzman@sairb.com>
Sent: Friday, February 06, 2015 10:04 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Thank you Robert.

I will get back to you with any question or simply to notify you on the outcome of the review.

Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Friday, February 06, 2015 12:20 PM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Hi Denisse,

Please find attached a response letter regarding the conditions of approval, as well as the revised protocol with informed consent, and a tracked changes version of the protocol. Please note the tracked changes version includes the prior changes as well as these most recent revisions.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Thursday, February 5, 2015 11:08 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification III for Protocol AEA08

Dear Rob,

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 12/10/2013).

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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: Denisse Guzman <DGuzman@sairb.com>
Sent: Monday, February 09, 2015 11:13 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08
Attachments: SSN IV.pdf

Hello Rob,

Attached please find Study Status Notification IV, which communicates to you the outcome of the review of your responses to the condition of approval as outlined in Study Status Notification III (dated 2/05/2015). We will now begin preparation of your approval documents.

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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

Study Status Notification IV

DATE: 2/9/2015

TO: Megan T. Boatwright

FROM: Denisse Guzman, Board Liaison
Schulman Associates Institutional Review Board, Inc.

RE: **Protocol#:** AEA08
IRB#: 201307365
Sponsor: American Chemistry Council
Title: Determination of Removal Efficiency of 1, 2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The above-referenced item was *Conditionally Approved* at the 2/5/2015 Board meeting. On 2/6/2015, the Board reviewed in an expedited manner, the documentation submitted in response to the Study Status Notification dated 2/5/2015.

The purpose of this memo is to inform you that the response satisfies the conditions of approval.

Board-requested revisions to the informed consent template are currently underway. Upon completion of these revisions, you will receive an approved version the informed consent.

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: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, February 09, 2015 1:53 PM
To: Megan Boatwright
Subject: INITIAL APPROVAL documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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: **AEA08 [COUNTRY:US]**
Indication: **Pesticide;**

Document Posted For:	Document Type	Posted Date
Boatwright, Megan T., B.S.	Initial Approval Letter Initial Informed Consent Initial Approval Comparison IC	Feb 09, 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 Associates IRB
www.sairb.com

APPROVED: 11/13/14
EXPIRATION DATE: 11/12/15

February 9, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") - US Board 3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Initial Approval Documents
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The following protocol items were reviewed and approved by Full Board or Expedited Review on the dates listed below:		
• **Protocol dated 11/01/13:**	**Full Board:**	**11/14/13**
• **Protocol dated 02/02/15:**	**Full Board:**	**02/05/15**
• **Protocol dated 02/05/15:**	**Expedited:**	**02/06/15**
• **Informed Consent(s):**	**Expedited:**	**02/06/15**
The following information is specific to the investigator referenced above:		
• **Your site(s) was approved to conduct this study:**	**Full Board:**	**11/14/13**
• **Site specific Informed Consent(s) approved by Schulman on:**	**Expedited:**	**02/06/15**

The Board approved the items listed above. You must use only the "Schulman Approved" informed consent(s).

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.

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 to download at the link on SiteAccess 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 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.

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.

ja

PLEASE REFERENCE IRB # 201307366 ON ALL CORRESPONDENCE FOR THIS STUDY.

WebPortal/Paperless

SCHULMAN APPROVED
IRB# 201307366
DATE: 02/06/15

INFORMED CONSENT FORM

Study Title: (Protocol AEA08) Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

Principal Investigator:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Research Associates:
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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. 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 rubbing alcohol (also called isopropyl alcohol or IPA) and water. This information will be provided to the U.S. Environmental Protection Agency (EPA). The EPA will use this information to evaluate how much chemical people are exposed to when painting.

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 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.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 pesticide known as BIT which helps keep bacteria from growing. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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 or sensitivity to soap, rubbing alcohol, paint products, BIT, or other chemical-based 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you, will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your hands facing up. We will place a small amount of paint on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe sample, you will wash your hands again with soap and water. 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 few 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 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 risks are minimal. You might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, at Golden Pacific Laboratories (559-275-9091 or 559-917-1736) 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. This may indirectly benefit you and others when you do painting. 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 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 Megan Boatwright 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. 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.

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. We may take photographs or video of the study, but we will edit these so that you cannot be identified. The edited photographs or video may be used for training other researchers, presenting the study to the people who are paying for it, or publication in scientific journals.

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
Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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# 201307366
DATE: 02/06/15

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. 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.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Megan Boatwright (559) 275-9091

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

SCHULMAN APPROVED
IRB# 201307366
DATE: 02/06/15

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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

SCHULMAN APPROVED
IRB# ~~<IRB #>~~201307366
DATE: ~~<approval~~

~~November 8, 2013~~

INFORMED CONSENT FORM

Study Title: (Protocol ~~130503~~AEA08) Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

Principal Investigator: Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Phone: 559-275-9091 or 949-939-3585

Field Research Associates:
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 (English)
Field Research Associate
General Manager
Golden Pacific Laboratories, LLC
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Phone: 559-275-9091

Field Location: Golden Pacific Laboratories, LLC
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Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

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Subject Selection

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3. Because it is important that you NOT be in this study if you are pregnant, on the day of the study 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.

4. Before the test begins you, will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands on a padded surface on the table with your hands facing up~~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 your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze ~~pads~~ sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

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Risks
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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 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 risks are minimal. You might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

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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, at Golden Pacific Laboratories (559-275-9091 or 559-917-1736) as soon as possible. Any medical records will not be a part of the study.

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Alternatives to Participation
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Benefits
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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. We may take photographs or video of the study, but we will edit these so that you cannot be identified. The edited photographs or video may be used for training other researchers, presenting the study to the people who are paying for it, or publication in scientific journals.

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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Removal from Study
Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

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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. 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.

If you have other questions, you should ask the Principal Investigator or Study Investigators

Phone contacts:

Principal Investigator: Megan Boatwright (559) 275-9091

Study Staff: Thomas Moate or Natan Chavez (559) 275-9091

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SCHULMAN APPROVED
IRB# ~~<IRB #>~~201307366
DATE: ~~<approval~~

~~November 8, 2013~~

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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

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~~November 8, 2013~~

SCHULMAN APPROVED
IRB# ~~<IRB #>~~201307366
DATE: ~~<approval~~

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Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Tuesday, February 10, 2015 10:50 AM
To: Megan Boatwright
Subject: TRANSLATION documents posted for AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**
Posted Date:	**02/10/2015**

PI Name	Document Type	Language
Boatwright, Megan T., B.S.	Recruitment / Study-Related Material Translation	Spanish

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SCHULMAN Associates IRB
www.sairb.com

2/10/2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Translated Recruitment/Study-Related Materials
IRB NO.:	201307366
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA08
CONTACT:	Megan T. Boatwright, Golden Pacific Laboratories, LLC

Material Type:	Subject Letter	**Material Item No.:**	MA1500940-0
Description:	APPENDIX G: SUBJECT INVITATION TO PARTICIPATE SCRIPT		

The Board is in receipt of the enclosed certified Spanish translation(s) of the Recruitment/Study Related Material(s) for the above protocol. The first page of each item attached is stamped according to the Board's decision. The date of review, as noted on each stamp, reflects the date the English version was approved or acknowledged.

Acknowledged 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.

js

PLEASE REFERENCE THE SPECIFIC MATERIAL ITEM NUMBER ON ALL CORRESPONDENCE
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MA1500940-0

Guión de invitación a participar para sujetos

[Identifíquese e identifique la compañía para la que trabaja; pregunte si la llamada se relaciona con el estudio de eficiencia de la eliminación. Si la respuesta es "sí", pregunte cómo se enteraron del estudio y anote la respuesta. Pregunte al posible sujeto si le gustaría recibir más información sobre el estudio. Si la respuesta es "sí", continúe.]

Queremos averiguar cuánto producto químico se elimina de las palmas de las manos cuando se aplica una pintura con el producto químico BIT en las manos y se deja secar durante 45 minutos. Mediremos la cantidad de producto químico que queda en la solución para el lavado de manos que se empleará para que se limpie las manos.

El producto en estudio será la PINTURA LÁTEX DE SHERWIN-WILLIAMS. Se utiliza para pintar superficies interiores como paredes y molduras.

El estudio en sí tomará aproximadamente de una hora y media a dos horas de su tiempo. Le pediremos que acuda al laboratorio, se siente en una silla y apoye las manos sobre una mesa, con las palmas hacia arriba. Le pondremos pintura en las palmas de las manos. Permanecerá sentado allí durante 45 minutos mientras se seca el producto. Luego le limpiaremos las manos con alcohol para frotar y agua y las restregaremos con una esponja de gasa. Recogeremos el agua del lavado y la esponja de gasa. Luego le pagaremos y podrá retirarse.

¿Le gustaría obtener más información sobre este proyecto?

(Si la respuesta es "no", agradezca a la persona por su tiempo).

(Si la respuesta es "sí", comuníquele las siguientes instrucciones).

Si lo eligen para participar en el estudio, recibirá $ 100 en efectivo al final del estudio. Deberá mostrar una identificación con fotografía para demostrar su edad y calificar para participar. Debe ser mayor de 18 años y poder leer inglés o español. Debe estar sano. Si es mujer, no debe estar embarazada ni en período de lactancia.

Si quiere participar en este proyecto, primero deberá acudir a Golden Pacific Laboratories para una entrevista. La oficina está en 4720 W. Jennifer Ave., Suite 105, en Fresno. Está justo saliendo de Shaw Avenue, detrás de Costco. Allí se reunirá con la investigadora principal, Megan Boatwright. Si prefiere, podemos entrevistarlo en español. Esta entrevista se programará cuando sea mejor para usted, 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 fotografía emitido por el gobierno, por ejemplo, una licencia de conducir. Le pagaremos $ 20 en efectivo al final de esta visita.

(Documentar la hora y fecha de la cita.)

(Nota: Si el posible sujeto hace preguntas que no se tratan en este guión telefónico, respóndale que Megan Boatwright o el investigador de habla hispana podrán responder las preguntas adicionales).

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: AEA08
IRB Number: 201307366
PI: Boatwright
Material Type (if applicable): Subject Letter – MA1500940
Description (if applicable): Appendix G - Subject Invitation

VH 2/9/2015 10:00 AM (PST)

VIRGINIA HERRERA
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

2/10/2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Translated Recruitment/Study-Related Materials
IRB NO.:	201307366
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA08
CONTACT:	Megan T. Boatwright, Golden Pacific Laboratories, LLC

Material Type:	Ad Print	**Material Item No.:**	MA1500939-0
Description:	APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS version 02/02/2015		

The Board is in receipt of the enclosed certified Spanish translation(s) of the Recruitment/Study Related Material(s) for the above protocol. The first page of each item attached is stamped according to the Board's decision. The date of review, as noted on each stamp, reflects the date the English version was approved or acknowledged.

Acknowledged 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.

js

PLEASE REFERENCE THE SPECIFIC MATERIAL ITEM NUMBER ON ALL CORRESPONDENCE
WebPortal/Paperless

All dates in mm/dd/yy format

MA1500939-0

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ONLY IN ITS ENTIRETY
SCHULMAN ASSOCIATES IRB
02/06/15

SE BUSCAN VOLUNTARIOS

Se buscan voluntarios para participar en un estudio de investigación que evalúa la exposición de la superficie de las manos a un producto antimicrobiano en pinturas. Se compensará a los voluntarios hasta $ 120 en total por su participación.

Para obtener más información, comuníquese con Megan Boatwright (inglés), Thomas Moate (inglés) o Natan Chavez (inglés/español) al 559-275-9091.

Estudio patrocinado por Antimicrobial Exposure Assessment Task Force (AEATF); administrado por American Chemistry Council (ACC) y dirigido por Golden Pacific Laboratories (GPL) of Fresno, CA.
559-275-9091

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: AEA08
IRB Number: 201307366
PI: Boatwright
Material Type (if applicable): Print Ad – MA1500939
Description (if applicable): Appendix F - Newspaper Ad

VH 2/9/2015 10:00 AM (PST)

VIRGINIA HERRERA
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

2/10/2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Translated Recruitment/Study-Related Materials
IRB NO.:	201307366
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA08
CONTACT:	Megan T. Boatwright, Golden Pacific Laboratories, LLC

Material Type:	Subject Information Sheet	**Material Item No.:**	MA1500938-0
Description:	APPENDIX D: SUBJECT SELF REPORTING DEMOGRAPHIC FORM		

The Board is in receipt of the enclosed certified Spanish translation(s) of the Recruitment/Study Related Material(s) for the above protocol. The first page of each item attached is stamped according to the Board's decision. The date of review, as noted on each stamp, reflects the date the English version was approved or acknowledged.

Acknowledged 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.

js

PLEASE REFERENCE THE SPECIFIC MATERIAL ITEM NUMBER ON ALL CORRESPONDENCE
WebPortal/Paperless

All dates in mm/dd/yy format

Hoja de trabajo para calificación

Estudio de exposición de trabajadores AEA08 de la AEATF (Antimicrobial Exposure Assessment Task Force, Grupo de trabajo de evaluación de la exposición antimicrobiana): Determinación de la eficacia de la eliminación del 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico/agua.

Parte I: *Preguntas para 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? ¿Asma moderada o grave o enfisema? ☐Sí ☐ No	
3 ¿Tiene alguna enfermedad cardiovascular? ¿Alguna vez ha tenido un infarto de miocardio o insuficiencia cardíaca congestiva? ¿Tiene presión arterial alta sin control? ☐Sí ☐ No	
4 ¿Tiene diabetes grave? ☐Sí ☐ No	
5 ¿Tiene depresión inmunológica? ¿Le han hecho algún trasplante? ¿Quimioterapia? ☐Sí ☐ No	
6 ¿Es empleado o está casado con un empleado de una compañía del AEATF, Golden Pacific Laboratories (GPL), un fabricante de pinturas o el American Chemistry Council (ACC) (el entrevistador explicará las iniciales de las distintas entidades)? ☐Sí ☐ No	
Parte II: *Para que lo llene el candidato*	
6 Nombre	
7 Dirección	
8 Ciudad, estado, código postal	
9 Teléfonos	
10 Edad en años = / 11 Fecha de nacimiento: / 12 Sexo ☐ M ☐ F	
13 ¿Residente del condado de Fresno? ☐ Sí ☐ No	
14 Idioma de preferencia: ☐ inglés ☐ español / 15 Lee: ☐ inglés ☐ español	
16 ¿Está embarazada? ☐ NC ☐Sí ☐ No / 17 ¿Está en período de lactancia? ☐ NC ☐Sí ☐ No	
18 ¿Considera que su salud general es lo suficientemente buena como para participar en este estudio como se describió? ☐ Sí ☐ No	
19 ¿Le molesta el olor de la pintura para interiores o la sensación de la pintura para interiores en la piel más que a sus familiares o amigos? ☐Sí ☐ No	
20 ¿Le molesta frotarse la piel con alcohol o jabón más que a sus familiares o amigos? ☐Sí ☐ No	
Verificación de la edad por 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:

APPROVED FOR USE
ONLY IN ITS ENTIRETY
SCHULMAN ASSOCIATES IRB
02/06/15

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: AEA08
IRB Number: 201307366
PI: Boatwright
Material Type (if applicable): Subject Information Sheet- MA1500938
Description (if applicable): Appendix D - Qualification Worksheet

VH 2/9/2015 10:00 AM (PST)

VIRGINIA HERRERA
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Thursday, February 12, 2015 12:08 PM
To: Megan Boatwright
Subject: TRANSLATION documents posted for AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**
Posted Date:	**02/12/2015**

PI Name	Document Type	Language
Boatwright, Megan T., B.S.	Initial ICD Packet Translation	Spanish

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Forgot Password? Please use **SiteAccess Reset Password** feature.
Need to Unsubscribe? You must submit **Change of Contact** request.

SCHULMAN Associates IRB
www.sairb.com

February 12, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") - Board 3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Translated Approval Documents
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO.:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

- Spanish Informed Consent , approved on 02/06/15

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).

PLEASE REFERENCE IRB # 201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates are in mm/dd/yy format

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA08) Determinación de la eficacia para la eliminación de 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico y agua

Investigadora principal:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Asociados de investigación en el campo:
Natan R. Chavez (inglés y español)
Asociado de investigación en el campo (Field Research Associate)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate (inglés)
Asociado de investigación en el campo (Field Research Associate)
Gerente general (General Manager)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Localización del campo:
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono durante las 24 horas: 559-917-1736 (Megan Boatwright)

Le pedimos que piense acerca de participar en un estudio de investigación. Su participación es voluntaria. En este formulario de consentimiento informado se explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar al respecto y hablar con amigos y familiares antes de decidir si desea participar o no en el estudio. Si tiene cualquier pregunta, o si no comprende cualquier cosa de este documento, pida a alguno de nosotros que se lo expliquemos. Si prefiere hablar en español, solicítelo. Podemos explicarle el estudio en inglés o en español.

Schulman Associates Institutional Review Board, Inc. (Schulman) ha aprobado la información contenida en este documento de consentimiento y ha dado la aprobación para que el médico del estudio lleve a cabo el estudio. Un comité de revisión institucional (IRB, *institutional review board*) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado su participación en el estudio. Usted mismo debe reflexionar sobre la información incluida en este documento de consentimiento y decidir si desea participar en el estudio.

Objetivo de este estudio
Este estudio es realizado por Golden Pacific Laboratories. No gustaría saber cuánta sustancia química es eliminada de la superficie de sus palmas cuando se aplica en cada mano una pequeña cantidad de pintura de látex para interiores que contiene la sustancia química y se deja allí durante 45 minutos. Mediremos cuánta sustancia química puede ser eliminada de sus manos enjuagando y restregando las manos con una toallita de gasa mojada con una solución de alcohol isopropílico (también llamado isopropanol o IPA) y agua. Esta información se comunicará a la Agencia de Protección Ambiental de Estados Unidos (EPA, *U.S. Environmental Protection Agency*). La EPA usará la información para evaluar a cuánta sustancia química están expuestas las personas cuando pintan.

En este estudio, la pintura será la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura que se vende en muchas tiendas. El producto se usa para pintar paredes, techos, puertas y rebordes dentro de viviendas y negocios. Contiene una pequeña cantidad de una sustancia química llamada BIT, que ayuda a impedir el crecimiento de las bacterias en la lata de pintura.

Este estudio es pagado por un grupo de empresas que fabrican productos para disminuir la cantidad de mohos y bacterias. Se llaman Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos II (AEATF, *Antimicrobial Exposure Assessment Task Force II*). Estos productos están registrados por la EPA como plaguicidas.

Megan Boatwright, Thomas Moate y Natan Chavez trabajan con Golden Pacific Laboratories. Megan Boatwright es la persona que está a cargo del estudio. Thomas Moate y Natan Chavez están además capacitados para explicarle el estudio y

responder cualquier pregunta que usted pueda tener. Natan Chavez habla español. Será el principal investigador hispanoparlante (que habla español).

Producto de prueba
El producto de prueba es la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura de uso común. Este producto se usa para pintar paredes, techos, puertas y rebordes en viviendas y negocios. El producto de prueba contiene un plaguicida conocido como BIT, que contribuye a impedir el crecimiento de las bacterias. Usted recibirá una copia de la etiqueta del producto, es decir, de la pintura. Además, si lo desea, le proporcionaremos la hoja de datos de seguridad del material o "MSDS" de la pintura y de la sustancia química BIT.

Selección de sujetos
Para participar en este estudio usted debe estar sano y ser mayor de 18 años. Debe tener la capacidad de leer y hablar en inglés o en español. Tendrá que demostrar su edad mediante una identificación con fotografía emitida por el gobierno, por ejemplo, un permiso de conducir o un pasaporte. Usted debe desear participar en este estudio. Debe estar dispuesto a firmar este consentimiento, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental, y una hoja de trabajo sobre los requisitos. Se le pedirá que proporcione cierta información personal, 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 empresas que pagan la investigación, de American Chemistry Council o de un fabricante de pinturas. No podrá participar si está embarazada o amamantando; si ha tenido reacciones alérgicas o de hipersensibilidad al jabón, el alcohol isopropílico, los productos para pintura, el BIT u otros productos basados en sustancias químicas; si tiene psoriasis, eccema, llagas o cortes abiertos en la piel; si tiene diabetes grave; si tiene el sistema inmunitario inhibido, por ejemplo, por un trasplante de órgano o por quimioterapia activa, o si ha tenido problemas cardíacos o para respirar.

En este estudio participarán veinte personas, y se seleccionarán ocho personas como suplentes por si alguna persona no puede participar el día de la prueba.

Llevaremos a cabo el estudio en Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105, en Fresno. Usted podrá participar en el estudio una sola vez. Si es suplente un día y no es seleccionado, podrá participar en el estudio otro día.

Inscripción en el estudio
Usted se reunirá en el día de hoy con la investigadora principal, Megan Boatwright, o con el gerente general del laboratorio, Thomas Moate, o, si lo prefiere, con un

investigador que hable español. Esas personas le informarán más acerca de lo que se espera durante el estudio y qué se espera de usted. También responderán las preguntas que pueda tener sobre el estudio. Usted puede decidir hoy mismo si desea participar en el estudio o puede llevarse este formulario a su casa para hablar al respecto con sus familiares y amigos antes de tomar la decisión.

Le haremos preguntas sobre su salud general. Le preguntaremos su nombre y edad, y si tiene algún problema de piel en las manos. Si decidimos que reúne los requisitos para participar, y si usted decide que desea participar en el estudio, le pediremos que firme este consentimiento informado, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental.

Si lo inscribimos en el estudio le pediremos que acuda al centro de estudio cierto día y a una hora determinada. Lo llamaremos el día anterior para recordárselo y para asegurarnos de que aún desea participar en el estudio.

Procedimientos del estudio

1. Si es seleccionado como uno de los sujetos, acudirá a este lugar en Fresno: Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105; irá en el momento en que se le haya indicado y se encontrará con el equipo del estudio.

2. Megan Boatwright y el equipo de investigación revisarán con usted y otros participantes qué sucederá y usted tendrá otra oportunidad para hacer preguntas. Le recordaremos que podrá cambiar de idea acerca de la participación en el estudio en cualquier momento, antes o después del comienzo del estudio. Todo lo que tendrá que hacer será decirnos que ha cambiado de idea. No sufrirá sanciones de ningún tipo si decide retirarse del estudio.

3. Debido a que es importante que usted NO participe en el estudio si está embarazada, el día del estudio cada voluntaria mujer pasará a un área privada y se le entregará un kit para prueba de embarazo en orina como los que se pueden comprar en las farmacias. Una investigadora mujer le explicará cómo se usa el kit y responderá las preguntas. Después de que se haga usted misma la prueba, le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no le preguntaremos por qué, y los resultados de la prueba no quedarán anotados. Se le pagará $100 por acudir al centro de la prueba, y luego usted será libre de retirarse. Si desea permanecer en el estudio, una investigadora mujer capacitada comprobará nuevamente los resultados con usted. Ninguna otra persona, aparte de usted y esa investigadora, verá los resultados, pero haremos una nota de que la prueba se realizó.

4. Antes de comenzar la prueba, se lavará las manos con jabón Ivory y agua, y se las secará con toallas de papel. Le revisaremos las manos para asegurarnos de que no tenga cortes, raspaduras ni ninguna alteración que pudiera aumentar el riesgo de problemas de la piel durante la prueba.

5. Le pediremos que se siente en una silla y se asegure de estar cómodo. Le pediremos que ponga las manos sobre una superficie acolchada, en la mesa, con las palmas hacia arriba. Le pondremos una pequeña cantidad de pintura en la palma de cada mano, y luego le pediremos que mantenga las palmas hacia arriba sobre la mesa durante 45 minutos. Después de 45 minutos le restregaremos las manos con esponjas de gasa mojadas con una mezcla de alcohol isopropílico y agua, se las enjuagaremos con la misma mezcla y guardaremos el agua del enjuague.

6. Cuando hayamos tomado la muestra de la toallita de mano, usted volverá a lavarse las manos con agua y jabón. Le revisaremos las manos antes de que se retire para observar si hay enrojecimiento u otros signos de irritación. Le pagaremos $100 en efectivo y podrá retirarse.

Riesgos
Si participa en este estudio, estará expuesto a unas pocas clases de riesgos:

1. Riesgo de una reacción a la pintura de látex o al componente plaguicida (BIT) presente en la pintura. El contacto directo con la pintura puede causar comezón o irritación pasajeras de la piel, y respirar el vapor puede producir tos e irritación de la garganta. Se usará una cantidad de pintura muy pequeña, menos de una cucharadita, para que estos riesgos sean mínimos. Además, podría presentar una reacción alérgica a la pintura, sentir mareos o dolor de cabeza. Si ha tenido anteriormente una reacción alérgica a un producto para pintura, recuerde que nos debe informar eso. Si nota enrojecimiento o comezón, siente mareos, tiene dolor de cabeza, o siente alguna otra molestia, infórmelo a un investigador.

2. Riesgo de irritación de la piel por la mezcla de alcohol isopropílico y agua, y las toallitas. El alcohol isopropílico diluido que se usa para restregar y enjuagar sus manos puede arder si usted tiene algún corte o raspadura en las manos que fuera demasiado pequeño como para ser visto antes del comienzo del estudio.

3. Si usted es mujer, podría sorprenderse el día de la investigación al enterarse de que está embarazada. Ninguna persona, aparte de usted, sabrá si la prueba indica que está embarazada, y los resultados no quedarán anotados.

Riesgos desconocidos / imprevisibles
La participación en este estudio puede plantear otros riesgos de los que no tenemos conocimiento o que no podemos predecir. Si aprendemos algo nuevo que pudiera influir en su decisión de participar, lo compartiremos inmediatamente con usted.

Lesiones relacionadas con la investigación
Si usted sufre un daño o se enferma mientras participa en este estudio, se le dará atención en una institución médica cercana. Si fuera necesario, lo llevaremos hasta allí. El AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no sea pagada por su seguro ni el seguro de un tercero que le dé a usted cobertura. La investigadora principal, en consulta con el profesional médico del centro, decidirá si usted presenta una lesión o enfermedad que se deba a su participación en el estudio. Si en las 24 horas siguientes a su participación en el estudio sufre una reacción en la piel u otro efecto adverso que usted considere relacionado con su participación en el estudio, debe buscar tratamiento médico y llamar a la investigadora principal, Megan Boatwright, a Golden Pacific Laboratories (559-275-9091 o 559-917-1736), lo antes posible. Ningún expediente médico será parte del estudio.

Al firmar este formulario, usted no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio, será porque usted lo desea. No habrá ningún beneficio directo para usted si participa, y no se verá perjudicado de ningún modo si decide no participar. La decisión depende de usted.

Beneficios
Usted no obtendrá ningún beneficio directo por participar en este estudio. Lo que aprendamos en este estudio ayudará a garantizar que los productos para pintura como la pintura de látex Sherwin-Williams se puedan usar de manera segura. Esto puede ser un beneficio indirecto para usted y otras personas cuando pinten. Las personas que pagan el estudio también se beneficiarán con ese conocimiento, ya que necesitan realizar este estudio para mantener en el mercado sus productos antimicrobianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede hacerlas en cualquier momento; antes, durante o después del estudio. Simplemente hágaselas a Megan Boatwright o a cualquier otro integrante del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a

Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Costos y pago
La participación en este estudio no tendrá ningún costo. Al final de cada entrevista de consentimiento informado, se le pagará $20 en efectivo por su tiempo y las molestias de acudir a nuestro consultorio. Si es seleccionado para el estudio y acude al centro de estudio asignado, se le pagará $100 en efectivo cuando haya finalizado su día, ya sea que se le haya hecho la prueba o no.

Confidencialidad
Para este estudio le asignaremos un número de identificación especial, y anotaremos e informaremos todos los datos con ese número. Conservaremos solamente un registro que relacione su nombre con ese número de identificación, y lo guardaremos separado del resto de los datos, en un armario bajo llave. No lo identificaremos a usted por su nombre ni de ningún otro modo en los informes del estudio. Posiblemente tomemos fotografías o grabemos videos del estudio, pero los modificaremos para que usted no pueda ser identificado. Las fotografías o videos modificados se podrán usar para capacitar a otros investigadores, presentar el estudio a las personas que lo pagan o para su publicación en revistas científicas.

Restringiremos el acceso a los expedientes de este estudio; solo accederán a ellos unas pocas personas. Sin embargo, podrán revisar todos los expedientes del estudio las personas que pagan el estudio, los organismos del gobierno que revisan los informes y SAIRB, Inc., que se ocupa de cuidar la seguridad de los participantes. Por ese motivo, no podemos garantizar completamente la confidencialidad. Usted podrá obtener una copia de sus expedientes si se la solicita a la investigadora principal.

Derecho a retirarse
Usted puede retirarse del estudio en cualquier momento y por cualquier motivo. Simplemente, dígaselo a cualquier integrante del equipo de investigación. Si decide no participar en este estudio o retirarse de él, no sufrirá ninguna sanción ni perderá ningún beneficio.

Motivos para ser retirado del estudio
Megan Boatwright, la investigadora principal a cargo de este estudio, puede retirarlo del estudio incluso si usted quisiera permanecer en él. Puede retirarlo si, por ejemplo:

- Ella considera que permanecer en el estudio podría implicar un riesgo para usted.
- Usted no cumple las instrucciones de los investigadores.
- El estudio se interrumpe por otros motivos.

Si usted es retirado del estudio o si el estudio completo se interrumpe, aun así se le pagará por su tiempo y molestias.

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE DECLARACIÓN DE DERECHOS DE LOS SUJETOS EN INVESTIGACIÓN EXPERIMENTAL

Los derechos que se exponen a continuación son los derechos de toda persona a quien se invite a participar en un estudio de investigación. Como sujeto de investigación experimental, tengo los siguientes derechos:

1. Ser informado acerca del objetivo del estudio;
2. Ser informado acerca de qué me sucederá y si alguno de los procedimientos, plaguicidas o dispositivos es diferente o no de los que se usarían en la práctica habitual;
3. Ser informado acerca de los riesgos, efectos secundarios o molestias frecuentes y/o importantes de las cosas que me sucederán durante el estudio;
4. Ser informado acerca de si puedo esperar algún beneficio de la participación y, si lo hubiera, cuál podría ser el beneficio;
5. Ser informado acerca de las alternativas a la participación en el estudio;
6. Se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el transcurso del estudio;
7. Ser informado acerca de qué tipo de tratamiento médico está disponible si surgen complicaciones;
8. Negarme completamente a participar o cambiar de idea acerca de la participación después de que el estudio haya comenzado. Esta decisión no influirá en mi situación respecto a mi empleador;
9. Recibir una copia de este formulario de consentimiento firmado y fechado, y
10. Estar libre de presiones cuando considere si deseo participar o no en el estudio.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Si tiene otras preguntas, debe hacérselas a la investigadora principal o a los investigadores del estudio

Contactos telefónicos:

Investigadora principal: Megan Boatwright (559) 275-9091

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de derechos de los sujetos en investigación experimental, se han respondido todas mis preguntas en un lenguaje que comprendo bien. Doy mi consentimiento voluntariamente para participar en este estudio como sujeto de investigación. No renuncio a ningún derecho legal al firmar este formulario. Recibiré mi copia de este formulario con todas las firmas.

Fecha/hora: _____ _____
Firma del sujeto

_____
Nombre del sujeto (en letra de imprenta)

[*Solo para la versión en español del documento de consentimiento informado, no para la versión en inglés*]

Este formulario de consentimiento informado ha sido explicado al voluntario antes mencionado en español. He respondido con exactitud todas las preguntas del voluntario. Considero que el voluntario comprende la información y ha aceptado participar en la investigación de manera libre y voluntaria.

Fecha/hora: _____ _____
Firma del investigador que habla español

_____
Nombre de la persona que habla español (en letra de imprenta)

He revisado este formulario de consentimiento informado con el voluntario antes mencionado y he respondido todas sus preguntas. He hecho todo lo posible para garantizar que el voluntario comprenda el objetivo, los riesgos y los beneficios de la investigación, qué sucederá el día de la prueba y su libertad para retirarse en cualquier momento y por cualquier motivo. He realizado esto en circunstancias que reducen al mínimo la posibilidad de coerción o influencia indebida, y considero que el voluntario ha hecho una elección libre y con conocimiento de causa para participar.

Fecha/hora: _____ _____
Megan Boatwright
Investigadora principal, Golden Pacific Laboratories, LLC

Copia del formulario de consentimiento proporcionado al sujeto:
(FECHA)_____POR (INICIALES)_____

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

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 AEA08
IRB Number 201307366
PI Boatwright
Material Type (if applicable): Informed Consent
Description (if applicable): N/A

DO 2/12/2015 10:00 AM (PST)

DANIEL OSORIO
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

Megan Boatwright

From: Robert Testman
Sent: Thursday, February 12, 2015 4:56 PM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08

Hi Denisse,

Thank you for getting the approval and documents posted. I believe there is one change needed in the Spanish language informed consent. The section on page 10 starting with the highlighted text to the end of that page should be in English rather than Spanish. Please review and if you agree hopefully this is a simple fix.

Thanks,
Rob

From: Denisse Guzman [mailto:DGuzman@sairb.com]
Sent: Monday, February 9, 2015 11:13 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08

Hello Rob,

Attached please find Study Status Notification IV, which communicates to you the outcome of the review of your responses to the condition of approval as outlined in Study Status Notification III (dated 2/05/2015). We will now begin preparation of your approval documents.

Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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: Denisse Guzman <DGuzman@sairb.com>
Sent: Friday, February 13, 2015 6:43 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08

Hello Robert,

We will follow-up with the translator and get back to you in a timely manner.

Please note that management of this study within Schulman has been 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 Atlas at jatlas@sairb.com.

Best Regards,

Denisse Guzman, CIM | Board Liaison
Schulman 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.

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, February 12, 2015 7:56 PM
To: Denisse Guzman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08

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Office: 954-327-0778 | FAX: 866-258-6774
dguzman@sairb.com |Visit us at http://www.sairb.com

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Friday, February 13, 2015 9:54 AM
To: Robert Testman
Cc: Megan Boatwright
Subject: RE: Study Status Notification IV for Protocol AEA08

Hi Rob,

To follow up, we have received a revised version of the consent so that the entire highlighted portion is now in English. We are in the process of issuing the corrected IC now. We should have this to you by end of business today.

Please let me know if there is anything else you require.

Thanks!

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: Denisse Guzman
Sent: Friday, February 13, 2015 9:43 AM
To: Robert Testman
Cc: Megan Boatwright; Jeffrey Atlas; Danni Melita
Subject: RE: Study Status Notification IV for Protocol AEA08

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Best Regards,

Denisse Guzman, CIM | Board Liaison
Schulman Associates IRB
Sawgrass Plaza, Suite 120 | 1550 Sawgrass Corporate Parkway | Sunrise, FL 33323
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dguzman@sairb.com |Visit us at http://www.sairb.com
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Please let us know if you have any questions.

Thank you for your assistance with this study.

Kindest Regards,

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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.

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Friday, February 13, 2015 10:56 AM
To: Megan Boatwright
Subject: TRANSLATION documents posted for AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**
Posted Date:	**02/13/2015**

PI Name	Document Type	Language
Boatwright, Megan T., B.S.	Initial ICD Packet Translation - Corrected	Spanish

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SCHULMAN Associates IRB
www.sairb.com

Memorandum

February 13, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, BS
SUBJECT:	Corrected Spanish Informed Consent
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
IRB NO:	201307366

It has come to our attention that the Spanish Informed Consent, approved on 02/06/15, inadvertently translated a section on page 10 of the informed consent into Spanish that should have remained in English.

We have corrected the Spanish Informed Consent so that the aforementioned section is in English as originally intended.

Please use the Spanish Informed Consent, approved 02/06/15, corrected 02/13/15 for all new enrollees.

Please file this Memo and corrected Spanish Informed Consent in your regulatory binder.

cm

PLEASE REFERENCE IRB # 201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA08) Determinación de la eficacia para la eliminación de 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico y agua

Investigadora principal:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Asociados de investigación en el campo:
Natan R. Chavez (inglés y español)
Asociado de investigación en el campo (Field Research Associate)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate (inglés)
Asociado de investigación en el campo (Field Research Associate)
Gerente general (General Manager)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Localización del campo:
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono durante las 24 horas: 559-917-1736 (Megan Boatwright)

Le pedimos que piense acerca de participar en un estudio de investigación. Su participación es voluntaria. En este formulario de consentimiento informado se explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar al respecto y hablar con amigos y familiares antes de decidir si desea participar o no en el estudio. Si tiene cualquier pregunta, o si no comprende cualquier cosa de este documento, pida a alguno de nosotros que se lo expliquemos. Si prefiere hablar en español, solicítelo. Podemos explicarle el estudio en inglés o en español.

Schulman Associates Institutional Review Board, Inc. (Schulman) ha aprobado la información contenida en este documento de consentimiento y ha dado la aprobación para que el médico del estudio lleve a cabo el estudio. Un comité de revisión institucional (IRB, *institutional review board*) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado su participación en el estudio. Usted mismo debe reflexionar sobre la información incluida en este documento de consentimiento y decidir si desea participar en el estudio.

Objetivo de este estudio

Este estudio es realizado por Golden Pacific Laboratories. No gustaría saber cuánta sustancia química es eliminada de la superficie de sus palmas cuando se aplica en cada mano una pequeña cantidad de pintura de látex para interiores que contiene la sustancia química y se deja allí durante 45 minutos. Mediremos cuánta sustancia química puede ser eliminada de sus manos enjuagando y restregando las manos con una toallita de gasa mojada con una solución de alcohol isopropílico (también llamado isopropanol o IPA) y agua. Esta información se comunicará a la Agencia de Protección Ambiental de Estados Unidos (EPA, *U.S. Environmental Protection Agency*). La EPA usará la información para evaluar a cuánta sustancia química están expuestas las personas cuando pintan.

En este estudio, la pintura será la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura que se vende en muchas tiendas. El producto se usa para pintar paredes, techos, puertas y rebordes dentro de viviendas y negocios. Contiene una pequeña cantidad de una sustancia química llamada BIT, que ayuda a impedir el crecimiento de las bacterias en la lata de pintura.

Este estudio es pagado por un grupo de empresas que fabrican productos para disminuir la cantidad de mohos y bacterias. Se llaman Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos II (AEATF, *Antimicrobial Exposure Assessment Task Force II*). Estos productos están registrados por la EPA como plaguicidas.

Megan Boatwright, Thomas Moate y Natan Chavez trabajan con Golden Pacific Laboratories. Megan Boatwright es la persona que está a cargo del estudio. Thomas Moate y Natan Chavez están además capacitados para explicarle el estudio y

responder cualquier pregunta que usted pueda tener. Natan Chavez habla español. Será el principal investigador hispanoparlante (que habla español).

Producto de prueba
El producto de prueba es la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura de uso común. Este producto se usa para pintar paredes, techos, puertas y rebordes en viviendas y negocios. El producto de prueba contiene un plaguicida conocido como BIT, que contribuye a impedir el crecimiento de las bacterias. Usted recibirá una copia de la etiqueta del producto, es decir, de la pintura. Además, si lo desea, le proporcionaremos la hoja de datos de seguridad del material o "MSDS" de la pintura y de la sustancia química BIT.

Selección de sujetos
Para participar en este estudio usted debe estar sano y ser mayor de 18 años. Debe tener la capacidad de leer y hablar en inglés o en español. Tendrá que demostrar su edad mediante una identificación con fotografía emitida por el gobierno, por ejemplo, un permiso de conducir o un pasaporte. Usted debe desear participar en este estudio. Debe estar dispuesto a firmar este consentimiento, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental, y una hoja de trabajo sobre los requisitos. Se le pedirá que proporcione cierta información personal, 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 empresas que pagan la investigación, de American Chemistry Council o de un fabricante de pinturas. No podrá participar si está embarazada o amamantando; si ha tenido reacciones alérgicas o de hipersensibilidad al jabón, el alcohol isopropílico, los productos para pintura, el BIT u otros productos basados en sustancias químicas; si tiene psoriasis, eccema, llagas o cortes abiertos en la piel; si tiene diabetes grave; si tiene el sistema inmunitario inhibido, por ejemplo, por un trasplante de órgano o por quimioterapia activa, o si ha tenido problemas cardíacos o para respirar.

En este estudio participarán veinte personas, y se seleccionarán ocho personas como suplentes por si alguna persona no puede participar el día de la prueba.

Llevaremos a cabo el estudio en Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105, en Fresno. Usted podrá participar en el estudio una sola vez. Si es suplente un día y no es seleccionado, podrá participar en el estudio otro día.

Inscripción en el estudio
Usted se reunirá en el día de hoy con la investigadora principal, Megan Boatwright, o con el gerente general del laboratorio, Thomas Moate, o, si lo prefiere, con un

investigador que hable español. Esas personas le informarán más acerca de lo que se espera durante el estudio y qué se espera de usted. También responderán las preguntas que pueda tener sobre el estudio. Usted puede decidir hoy mismo si desea participar en el estudio o puede llevarse este formulario a su casa para hablar al respecto con sus familiares y amigos antes de tomar la decisión.

Le haremos preguntas sobre su salud general. Le preguntaremos su nombre y edad, y si tiene algún problema de piel en las manos. Si decidimos que reúne los requisitos para participar, y si usted decide que desea participar en el estudio, le pediremos que firme este consentimiento informado, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental.

Si lo inscribimos en el estudio le pediremos que acuda al centro de estudio cierto día y a una hora determinada. Lo llamaremos el día anterior para recordárselo y para asegurarnos de que aún desea participar en el estudio.

Procedimientos del estudio

1. Si es seleccionado como uno de los sujetos, acudirá a este lugar en Fresno: Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105; irá en el momento en que se le haya indicado y se encontrará con el equipo del estudio.

2. Megan Boatwright y el equipo de investigación revisarán con usted y otros participantes qué sucederá y usted tendrá otra oportunidad para hacer preguntas. Le recordaremos que podrá cambiar de idea acerca de la participación en el estudio en cualquier momento, antes o después del comienzo del estudio. Todo lo que tendrá que hacer será decirnos que ha cambiado de idea. No sufrirá sanciones de ningún tipo si decide retirarse del estudio.

3. Debido a que es importante que usted NO participe en el estudio si está embarazada, el día del estudio cada voluntaria mujer pasará a un área privada y se le entregará un kit para prueba de embarazo en orina como los que se pueden comprar en las farmacias. Una investigadora mujer le explicará cómo se usa el kit y responderá las preguntas. Después de que se haga usted misma la prueba, le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no le preguntaremos por qué, y los resultados de la prueba no quedarán anotados. Se le pagará $100 por acudir al centro de la prueba, y luego usted será libre de retirarse. Si desea permanecer en el estudio, una investigadora mujer capacitada comprobará nuevamente los resultados con usted. Ninguna otra persona, aparte de usted y esa investigadora, verá los resultados, pero haremos una nota de que la prueba se realizó.

4. Antes de comenzar la prueba, se lavará las manos con jabón Ivory y agua, y se las secará con toallas de papel. Le revisaremos las manos para asegurarnos de que no tenga cortes, raspaduras ni ninguna alteración que pudiera aumentar el riesgo de problemas de la piel durante la prueba.

5. Le pediremos que se siente en una silla y se asegure de estar cómodo. Le pediremos que ponga las manos sobre una superficie acolchada, en la mesa, con las palmas hacia arriba. Le pondremos una pequeña cantidad de pintura en la palma de cada mano, y luego le pediremos que mantenga las palmas hacia arriba sobre la mesa durante 45 minutos. Después de 45 minutos le restregaremos las manos con esponjas de gasa mojadas con una mezcla de alcohol isopropílico y agua, se las enjuagaremos con la misma mezcla y guardaremos el agua del enjuague.

6. Cuando hayamos tomado la muestra de la toallita de mano, usted volverá a lavarse las manos con agua y jabón. Le revisaremos las manos antes de que se retire para observar si hay enrojecimiento u otros signos de irritación. Le pagaremos $100 en efectivo y podrá retirarse.

Riesgos

Si participa en este estudio, estará expuesto a unas pocas clases de riesgos:

1. Riesgo de una reacción a la pintura de látex o al componente plaguicida (BIT) presente en la pintura. El contacto directo con la pintura puede causar comezón o irritación pasajeras de la piel, y respirar el vapor puede producir tos e irritación de la garganta. Se usará una cantidad de pintura muy pequeña, menos de una cucharadita, para que estos riesgos sean mínimos. Además, podría presentar una reacción alérgica a la pintura, sentir mareos o dolor de cabeza. Si ha tenido anteriormente una reacción alérgica a un producto para pintura, recuerde que nos debe informar eso. Si nota enrojecimiento o comezón, siente mareos, tiene dolor de cabeza, o siente alguna otra molestia, infórmelo a un investigador.

2. Riesgo de irritación de la piel por la mezcla de alcohol isopropílico y agua, y las toallitas. El alcohol isopropílico diluido que se usa para restregar y enjuagar sus manos puede arder si usted tiene algún corte o raspadura en las manos que fuera demasiado pequeño como para ser visto antes del comienzo del estudio.

3. Si usted es mujer, podría sorprenderse el día de la investigación al enterarse de que está embarazada. Ninguna persona, aparte de usted, sabrá si la prueba indica que está embarazada, y los resultados no quedarán anotados.

Riesgos desconocidos / imprevisibles
La participación en este estudio puede plantear otros riesgos de los que no tenemos conocimiento o que no podemos predecir. Si aprendemos algo nuevo que pudiera influir en su decisión de participar, lo compartiremos inmediatamente con usted.

Lesiones relacionadas con la investigación
Si usted sufre un daño o se enferma mientras participa en este estudio, se le dará atención en una institución médica cercana. Si fuera necesario, lo llevaremos hasta allí. El AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no sea pagada por su seguro ni el seguro de un tercero que le dé a usted cobertura. La investigadora principal, en consulta con el profesional médico del centro, decidirá si usted presenta una lesión o enfermedad que se deba a su participación en el estudio. Si en las 24 horas siguientes a su participación en el estudio sufre una reacción en la piel u otro efecto adverso que usted considere relacionado con su participación en el estudio, debe buscar tratamiento médico y llamar a la investigadora principal, Megan Boatwright, a Golden Pacific Laboratories (559-275-9091 o 559-917-1736), lo antes posible. Ningún expediente médico será parte del estudio.

Al firmar este formulario, usted no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio, será porque usted lo desea. No habrá ningún beneficio directo para usted si participa, y no se verá perjudicado de ningún modo si decide no participar. La decisión depende de usted.

Beneficios
Usted no obtendrá ningún beneficio directo por participar en este estudio. Lo que aprendamos en este estudio ayudará a garantizar que los productos para pintura como la pintura de látex Sherwin-Williams se puedan usar de manera segura. Esto puede ser un beneficio indirecto para usted y otras personas cuando pinten. Las personas que pagan el estudio también se beneficiarán con ese conocimiento, ya que necesitan realizar este estudio para mantener en el mercado sus productos antimicrobianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede hacerlas en cualquier momento; antes, durante o después del estudio. Simplemente hágaselas a Megan Boatwright o a cualquier otro integrante del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a

Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Costos y pago
La participación en este estudio no tendrá ningún costo. Al final de cada entrevista de consentimiento informado, se le pagará $20 en efectivo por su tiempo y las molestias de acudir a nuestro consultorio. Si es seleccionado para el estudio y acude al centro de estudio asignado, se le pagará $100 en efectivo cuando haya finalizado su día, ya sea que se le haya hecho la prueba o no.

Confidencialidad
Para este estudio le asignaremos un número de identificación especial, y anotaremos e informaremos todos los datos con ese número. Conservaremos solamente un registro que relacione su nombre con ese número de identificación, y lo guardaremos separado del resto de los datos, en un armario bajo llave. No lo identificaremos a usted por su nombre ni de ningún otro modo en los informes del estudio. Posiblemente tomemos fotografías o grabemos videos del estudio, pero los modificaremos para que usted no pueda ser identificado. Las fotografías o videos modificados se podrán usar para capacitar a otros investigadores, presentar el estudio a las personas que lo pagan o para su publicación en revistas científicas.

Restringiremos el acceso a los expedientes de este estudio; solo accederán a ellos unas pocas personas. Sin embargo, podrán revisar todos los expedientes del estudio las personas que pagan el estudio, los organismos del gobierno que revisan los informes y SAIRB, Inc., que se ocupa de cuidar la seguridad de los participantes. Por ese motivo, no podemos garantizar completamente la confidencialidad. Usted podrá obtener una copia de sus expedientes si se la solicita a la investigadora principal.

Derecho a retirarse
Usted puede retirarse del estudio en cualquier momento y por cualquier motivo. Simplemente, dígaselo a cualquier integrante del equipo de investigación. Si decide no participar en este estudio o retirarse de él, no sufrirá ninguna sanción ni perderá ningún beneficio.

Motivos para ser retirado del estudio
Megan Boatwright, la investigadora principal a cargo de este estudio, puede retirarlo del estudio incluso si usted quisiera permanecer en él. Puede retirarlo si, por ejemplo:

- Ella considera que permanecer en el estudio podría implicar un riesgo para usted.
- Usted no cumple las instrucciones de los investigadores.
- El estudio se interrumpe por otros motivos.

Si usted es retirado del estudio o si el estudio completo se interrumpe, aun así se le pagará por su tiempo y molestias.

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE DECLARACIÓN DE DERECHOS DE LOS SUJETOS EN INVESTIGACIÓN EXPERIMENTAL

Los derechos que se exponen a continuación son los derechos de toda persona a quien se invite a participar en un estudio de investigación. Como sujeto de investigación experimental, tengo los siguientes derechos:

1. Ser informado acerca del objetivo del estudio;
2. Ser informado acerca de qué me sucederá y si alguno de los procedimientos, plaguicidas o dispositivos es diferente o no de los que se usarían en la práctica habitual;
3. Ser informado acerca de los riesgos, efectos secundarios o molestias frecuentes y/o importantes de las cosas que me sucederán durante el estudio;
4. Ser informado acerca de si puedo esperar algún beneficio de la participación y, si lo hubiera, cuál podría ser el beneficio;
5. Ser informado acerca de las alternativas a la participación en el estudio;
6. Se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el transcurso del estudio;
7. Ser informado acerca de qué tipo de tratamiento médico está disponible si surgen complicaciones;
8. Negarme completamente a participar o cambiar de idea acerca de la participación después de que el estudio haya comenzado. Esta decisión no influirá en mi situación respecto a mi empleador;
9. Recibir una copia de este formulario de consentimiento firmado y fechado, y
10. Estar libre de presiones cuando considere si deseo participar o no en el estudio.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Si tiene otras preguntas, debe hacérselas a la investigadora principal o a los investigadores del estudio

Contactos telefónicos:

Investigadora principal: Megan Boatwright (559) 275-9091

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de derechos de los sujetos en investigación experimental, se han respondido todas mis preguntas en un lenguaje que comprendo bien. Doy mi consentimiento voluntariamente para participar en este estudio como sujeto de investigación. No renuncio a ningún derecho legal al firmar este formulario. Recibiré mi copia de este formulario con todas las firmas.

Fecha/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: _____ _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE)_____BY (INITIALS)_____

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

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: AEA08
IRB Number: 201307366
PI: Boatwright
Material Type (if applicable): Informed Consent
Description (if applicable): N/A

DO 2/13/2015 9:00 AM (PST)

DANIEL OSORIO
PROJECT MANAGER
GLOBAL LANGUAGE SOLUTIONS

Megan Boatwright

From: Megan Boatwright
Sent: Friday, March 27, 2015 12:26 PM
To: Jeffrey Atlas (JAtlas@sairb.com)
Subject: An Amendment to Protocol AEA08
Attachments: 130503_Amendment_1 signed.pdf

Dear Jeff,

Please find attached an amendment to protocol AEA08 for approval by the SAIRB. Please let me know if you have any questions or need anything else.

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

PROTOCOL AMENDMENT NO.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 6.A Risks to the Subjects**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

...The largest amount a subject will be exposed to in this study is 0.1 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.001 mg/Kg for a 70 Kg subject. This is much less than...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

2. **Section 8.A Study Design Overview:**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...
Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing

approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.
…

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

…
Each subject will be placed into one of two groups. Subjects assigned to group one will have their hands fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 7.9 µg per hand or 39 µg per hand.
…

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

3. **Section 8.B.6 Removal Efficiency Procedure**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. A 100 µL volume of the appropriate paint concentration will be applied to both hands, split as evenly as possible between the two hands (ca. 50 µL per hand). A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will

not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

4. **Section 8.C Assignment of Carrier and Amount of Active Ingredient**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

In this study, subjects will be assigned into two groups. The two groups are described below (total amount for both hands):

Group 1 100 µL of latex paint containing ca. 120 ppm BIT
Group 2 100 µL of latex paint containing ca. 600 ppm BIT

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

5. **Section 10.D Field Recovery Evaluation**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	100 µL	Approximately 120 ppm
Paint	100 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 500 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The fortification level of the field recovery samples is being reduced to match subject samples. The volume of each field fortification sample is being adjusted to match subject samples.

6. **Section 9.A.iii Inclusion Criteria**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

Inclusion Criteria

...

- Resident of Fresno County

The section will now read:

Inclusion Criteria

...

- Resident of Fresno County and the surrounding area

Justification: The criteria is being updated to be consistent with Section 9.A.i Population Base which specified that Fresno County and the surrounding area should be included in the recruiting population. This is consistent with the circulation area of the newspapers used for study advertising and will not bias the study recruiting.

7. **Section 9.B Subject Sequence Number**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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.

The section will now read:

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and a number based on their enrollment position (subject 1, subject 2, 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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 subject sequence number. Study data will be recorded by assigning each removal event position a RE number. For example the first subject to be tested will represent RE-01, etc. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their subject sequence number and their removal event (RE) number if applicable, 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.

Justification: The procedure for assigning an initial subject number, randomization position number, and removal event (RE) number is being clarified.

8. **Section 8.D Random Selection and Assignment of Subject to Groups**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

The section will now read:

...
Within each group of fourteen, the subjects will be divided into two blocks of seven subjects for scheduling purposes (AM vs. PM). The first five subjects of each block of seven will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the block of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

Justification: The procedure for randomizing subjects into groups and scheduling times is being clarified and made consistent with section 9.B.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 03/27/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 3/27/15
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Friday, March 27, 2015 12:35 PM
To: Megan Boatwright
Subject: RE: An Amendment to Protocol AEA08
Attachments: Protocol_ICD_Change_Submission_Form.docx

Hi Megan,

Thanks! Please complete the attached submission form as it is required.

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: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, March 27, 2015 3:26 PM
To: Jeffrey Atlas
Subject: An Amendment to Protocol AEA08

Dear Jeff,

Please find attached an amendment to protocol AEA08 for approval by the SAIRB. Please let me know if you have any questions or need anything else.

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

SCHULMAN
ASSOCIATES IRB

Protocol/Informed Consent Change Submission Form

SECTION 1.0: Submission Information & Instructions

1. Submission information: Please 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, email to Submissions@sairb.com or fax to (866) 596-1535.

SECTION 2.0: Study & Contact Information

1. Date: _____ **2. IRB Number:** _____

3. Sponsor: _____ **4. Protocol Number:** _____

5. The item(s) submitted for review on this form are for use at (choose one):

☐ All sites >>> Please specify the country of site locations: ☐ USA ☐ Canada

☐ A single or subset of sites >>> Please list the participating site(s): _____

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: _____ Company: _____

Phone: _____ Fax: _____ Email: _____

SECTION 3.0: 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 >>> Please provide the amendment number: _____ and date: _____

☐ Revised Protocol >>> Please provide the revised protocol date: _____

NOTE: Revised protocol and amendment submissions require a rationale for the changes and a summary of changes from the previous version.

☐ Administrative Letter/Change >>> Please provide the administrative letter/change date: _____

☐ Revised Site-Specific IC >>> Please provide the rationale for all requested revisions and documentation of sponsor/CRO approval.

☐ Other >>> Please specify: _____ and 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 confined to clinic ☐ Other: _____

4. Does this submission result in the need for change(s) to the current Board approved IC template for the study?

☐ No

☐ Yes >>> Please attach requested changes via tracked changes to the MS Word version of the current Schulman approved IC.

a. The revised IC is intended to be presented to: Check all that apply. NOTE: The final determination will be made by the Board.

☐ New enrollees ☐ Current subjects ☐ Other: _____

b. Please specify one of the following regarding IC translation:

☐ No IC translation is needed.

☐ I authorize Schulman to translate the IC and the associated cost, if Schulman previously translated the document.

☐ I will obtain my own translation through a certified translator and provide for Schulman review prior to use.

NOTE: Please confirm authorization for translations with the sponsor/CRO prior to submission, if necessary.

5. Does this submission create a sub-study or extension to the protocol?

☐ No

☐ Yes >>> Please complete the *Sub-Study/Additional Research Submission Form* and **a.** and **b.**:

a. Will all Schulman approved sites be participating in the extension/sub-study?

☐ No >>> Please list the participating sites: _____

☐ Yes

b. Please complete the *Revised Compensation Form* for all sites participating in the extension/sub-study.

Protocol/Informed Consent Change Submission Form

6. Does this submission modify the study visit schedule?

☐ No

☐ Yes **>>>** Please complete the *Revised Compensation Form* for each Schulman approved site.

7. Does this submission result in the need to submit recruitment or study-related materials for Board review?

☐ No

☐ Yes **>>>** Please submit all recruitment/study 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.

8. Canada studies only: If this is an amendment submission for a Phase 1, 2 or 3 study, please provide:

☐ A copy of the No Objection Letter (NOL)/ Acknowledgement **OR** ☐ The date of submission to Health Canada: _____

NOTE: Approval cannot be granted by Schulman Associates IRB unless the NOL or Acknowledgement letter is provided.

Megan Boatwright

From: Megan Boatwright
Sent: Friday, March 27, 2015 1:05 PM
To: 'submissions@sairb.com'
Cc: Jeffrey Atlas (JAtlas@sairb.com)
Subject: Submission form and amendment #1 for protocol AEA08
Attachments: Protocol_ICD_Change_Submission_Form 032715.docx; 130503_Amendment_1 signed.pdf

To whom it may Concern,

Please find attached a Protocol Change Submission Form and the Amendment being submitted for AEATF Protocol AEA08 IRB number 201307366.

Thank you,

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

Protocol/Informed Consent Change Submission Form

SECTION 1.0: Submission Information & Instructions

1. Submission information: Please 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, email to Submissions@sairb.com or fax to (866) 596-1535.

SECTION 2.0: Study & Contact Information

1. Date: March 27, 2015 **2. IRB Number:** 201307366

3. Sponsor: AEATF **4. Protocol Number:** 130503

5. The item(s) submitted for review on this form are for use at (choose one):

☒ All sites >>> Please specify the country of site locations: ☒ USA ☐ Canada

☐ A single or subset of sites >>> Please list the participating site(s): _____

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: Megan T. Boatwright Company: Golden Pacific Laboratories, LLC

Phone: (559) 275-9091 Fax: (559) 275-1810 Email: mboatwright@gplabs.com

SECTION 3.0: 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 >>> Please provide the amendment number: 1 and date: March 27, 2015

☐ Revised Protocol >>> Please provide the revised protocol date: _____

NOTE: Revised protocol and amendment submissions require a rationale for the changes and a summary of changes from the previous version.

☐ Administrative Letter/Change >>> Please provide the administrative letter/change date: _____

☐ Revised Site-Specific IC >>> Please provide the rationale for all requested revisions and documentation of sponsor/CRO approval.

☐ Other >>> Please specify: _____ and 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 confined to clinic ☒ Other: Subjects being scheduled

4. Does this submission result in the need for change(s) to the current Board approved IC template for the study?

☒ No

☐ Yes >>> Please attach requested changes via tracked changes to the MS Word version of the current Schulman approved IC.

a. The revised IC is intended to be presented to: Check all that apply. NOTE: The final determination will be made by the Board.

☐ New enrollees ☐ Current subjects ☐ Other: _____

b. Please specify one of the following regarding IC translation:

☐ No IC translation is needed.

☐ I authorize Schulman to translate the IC and the associated cost, if Schulman previously translated the document.

☐ I will obtain my own translation through a certified translator and provide for Schulman review prior to use.

NOTE: Please confirm authorization for translations with the sponsor/CRO prior to submission, if necessary.

5. Does this submission create a sub-study or extension to the protocol?

☒ No

☐ Yes >>> Please complete the *Sub-Study/Additional Research Submission Form* and **a.** and **b.**:

a. Will all Schulman approved sites be participating in the extension/sub-study?

☐ No >>> Please list the participating sites: _____

☐ Yes

b. Please complete the *Revised Compensation Form* for all sites participating in the extension/sub-study.

SCHULMAN
ASSOCIATES IRB

Protocol/Informed Consent Change Submission Form

6. Does this submission modify the study visit schedule?

☒ No

☐ Yes **>>>** Please complete the *Revised Compensation Form* for each Schulman approved site.

7. Does this submission result in the need to submit recruitment or study-related materials for Board review?

☒ No

☐ Yes **>>>** Please submit all recruitment/study 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.

8. Canada studies only: If this is an amendment submission for a Phase 1, 2 or 3 study, please provide:

☐ A copy of the No Objection Letter (NOL)/ Acknowledgement **OR** ☐ The date of submission to Health Canada: _____

NOTE: Approval cannot be granted by Schulman Associates IRB unless the NOL or Acknowledgement letter is provided.

PROTOCOL AMENDMENT NO.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 6.A Risks to the Subjects**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

...The largest amount a subject will be exposed to in this study is 0.1 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.001 mg/Kg for a 70 Kg subject. This is much less than...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

2. **Section 8.A Study Design Overview:**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...
Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing

approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.
...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

...
Each subject will be placed into one of two groups. Subjects assigned to group one will have their hands fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 7.9 µg per hand or 39 µg per hand.
...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

3. **Section 8.B.6 Removal Efficiency Procedure**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. A 100 µL volume of the appropriate paint concentration will be applied to both hands, split as evenly as possible between the two hands (ca. 50 µL per hand). A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will

not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

4. **Section 8.C Assignment of Carrier and Amount of Active Ingredient**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

In this study, subjects will be assigned into two groups. The two groups are described below (total amount for both hands):

Group 1 100 µL of latex paint containing ca. 120 ppm BIT
Group 2 100 µL of latex paint containing ca. 600 ppm BIT

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

5. **Section 10.D Field Recovery Evaluation**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.
...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	100 µL	Approximately 120 ppm
Paint	100 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 500 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.
...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The fortification level of the field recovery samples is being reduced to match subject samples. The volume of each field fortification sample is being adjusted to match subject samples.

6. **Section 9.A.iii Inclusion Criteria**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

Inclusion Criteria

…

- Resident of Fresno County

The section will now read:

Inclusion Criteria

…

- Resident of Fresno County and the surrounding area

Justification: The criteria is being updated to be consistent with Section 9.A.i Population Base which specified that Fresno County and the surrounding area should be included in the recruiting population. This is consistent with the circulation area of the newspapers used for study advertising and will not bias the study recruiting.

7. **Section 9.B Subject Sequence Number**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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.

The section will now read:

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and a number based on their enrollment position (subject 1, subject 2, 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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 subject sequence number. Study data will be recorded by assigning each removal event position a RE number. For example the first subject to be tested will represent RE-01, etc. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their subject sequence number and their removal event (RE) number if applicable, 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.

Justification: The procedure for assigning an initial subject number, randomization position number, and removal event (RE) number is being clarified.

8. **Section 8.D Random Selection and Assignment of Subject to Groups**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

The section will now read:

...
Within each group of fourteen, the subjects will be divided into two blocks of seven subjects for scheduling purposes (AM vs. PM). The first five subjects of each block of seven will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the block of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

Justification: The procedure for randomizing subjects into groups and scheduling times is being clarified and made consistent with section 9.B.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 03/27/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 3/27/15
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Friday, March 27, 2015 2:05 PM
To: Megan Boatwright
Subject: AMENDMENT/REVISED IC documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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: **AEA08 [COUNTRY:US]**
Indication: **Pesticide;**

Document Posted For:	Document Type	Posted Date
Boatwright, Megan T., B.S.	Amended Approval Letter	Mar 27, 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 Associates IRB
www.sairb.com

/larch 27, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright,BS
SUBJECT:	Updated Approval Documents
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The following item(s) were reviewed and approved by Full Board or Expedited Review on the dates listed below:

- Protocol Amendment 1 dated 03/25/2015: Expedited: 03/27/2015

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

ja

PLEASE REFERENCE IRB #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates in mm/dd/yyyy format

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Wednesday, April 29, 2015 5:46 AM
To: Megan Boatwright
Subject: Events to Report Reminder

Importance: High

NO STUDY STATUS REPORT IS DUE AT THIS TIME

Date: 29 Apr 2015
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

INVESTIGATOR RESPONSIBILITIES

As you approach the midpoint in your approval/reapproval period, we would like to remind you and your staff of your ongoing reporting responsibilities.

Please review the document entitled Event(s) that Investigators Have to Report to the IRB for specific information regarding research events that Principal Investigators (PIs)/Qualified Investigators (QIs) must report to the IRB. Schulman requires investigators report these events to the Board within ten (10) business days of discovery, except as otherwise noted.

REMINDER: It is the Investigator's responsibility to ensure subjects are being consented using the most recent, approved informed consent document.

Thank you for your assistance and cooperation.
SCHULMAN Associates IRB, Inc.
Ongoing Review Team
ongoingreview@sairb.com
www.sairb.com

Megan Boatwright

From:	Megan Boatwright
Sent:	Tuesday, July 14, 2015 9:26 AM
To:	submissions@sairb.com
Cc:	Jeffrey Atlas (JAtlas@sairb.com)
Subject:	Submission Forma nf Amendment #2 for Protocol AEA08
Attachments:	Protocol_ICD_Change_Submission_Form 071515.docx; GPL Study 130503 Amend 2 signed.pdf

To whom it may Concern,

Please find attached a Protocol Change Submission Form and Amendment #2 submitted for AEATF Protocol AEA08, IRB number 201307366. Please don't hesitate to contact me if anything else is needed or if there are questions.

Thank you,

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

Protocol/Informed Consent Change Submission Form

SECTION 1.0: Submission Information & Instructions

1. Submission information: Please 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, email to Submissions@sairb.com or fax to (866) 596-1535.

SECTION 2.0: Study & Contact Information

1. Date: July 14, 2015 **2. IRB Number:** 201307366

3. Sponsor: AEATF **4. Protocol Number:** 130503

5. The item(s) submitted for review on this form are for use at (choose one):

☒ All sites >>> Please specify the country of site locations: ☒ USA ☐ Canada

☐ A single or subset of sites >>> Please list the participating site(s): _____

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: Megan T. Boatwright Company: Golden Pacific Laboratories, LLC

Phone: (559) 275-9091 Fax: (559) 275-1810 Email: mboatwright@gplabs.com

SECTION 3.0: 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 >>> Please provide the amendment number: 2 and date: June 15, 2015

☐ Revised Protocol >>> Please provide the revised protocol date: _____

NOTE: Revised protocol and amendment submissions require a rationale for the changes and a summary of changes from the previous version.

☐ Administrative Letter/Change >>> Please provide the administrative letter/change date: _____

☐ Revised Site-Specific IC >>> Please provide the rationale for all requested revisions and documentation of sponsor/CRO approval.

☐ Other >>> Please specify: _____ and 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 confined to clinic ☒ Other: Study Completed

4. Does this submission result in the need for change(s) to the current Board approved IC template for the study?

☒ No

☐ Yes >>> Please attach requested changes via tracked changes to the MS Word version of the current Schulman approved IC.

a. The revised IC is intended to be presented to: Check all that apply. NOTE: The final determination will be made by the Board.

☐ New enrollees ☐ Current subjects ☐ Other: _____

b. Please specify one of the following regarding IC translation:

☐ No IC translation is needed.

☐ I authorize Schulman to translate the IC and the associated cost, if Schulman previously translated the document.

☐ I will obtain my own translation through a certified translator and provide for Schulman review prior to use.

NOTE: Please confirm authorization for translations with the sponsor/CRO prior to submission, if necessary.

5. Does this submission create a sub-study or extension to the protocol?

☒ No

☐ Yes >>> Please complete the *Sub-Study/Additional Research Submission Form* and **a.** and **b.**:

a. Will all Schulman approved sites be participating in the extension/sub-study?

☐ No >>> Please list the participating sites: _____

☐ Yes

b. Please complete the *Revised Compensation Form* **for all sites participating in the extension/sub-study.**

Protocol/Informed Consent Change Submission Form

6. Does this submission modify the study visit schedule?

☒ No

☐ Yes **>>>** Please complete the *Revised Compensation Form* for each Schulman approved site.

7. Does this submission result in the need to submit recruitment or study-related materials for Board review?

☒ No

☐ Yes **>>>** Please submit all recruitment/study 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.

8. Canada studies only: If this is an amendment submission for a Phase 1, 2 or 3 study, please provide:

☐ A copy of the No Objection Letter (NOL)/ Acknowledgement **OR** ☐ The date of submission to Health Canada: _____

NOTE: Approval cannot be granted by Schulman Associates IRB unless the NOL or Acknowledgement letter is provided.

PROTOCOL AMENDMENT NO.: 2
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 12.B. Analytical Method**

Effective Date: March 30, 2015

Description of Amendment (including justification):

The section currently reads:

...The method (GPL-MTH-*079*) includes the use of isotopically labeled BIT internal standard to increase accuracy...

...Hand wipe samples will be analyzed following the method documented in 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)....

...The latex paint test substances will be analyzed following GPL-MTH-*079*....

The section is being amended to document the correct method number and title of the method. The method number and title are:

GPL Analytical Method GPL-MTH-*081* entitled, "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"

Justification: To correct typographical errors of the method number and analyte name in the method title.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 06/15/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Hasmukh Shah 06/15/15
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Wednesday, July 15, 2015 2:39 PM
To: Megan Boatwright
Subject: AMENDMENT/REVISED IC documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

IRB documents have been posted and are available via Schulman Associates 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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Boatwright, Megan T., B.S.	Amended Approval Letter	Jul 15, 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 Associates IRB
www.sairb.com

July 15, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright, BS
SUBJECT:	Updated Approval Documents
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The following item(s) were reviewed and approved by Full Board or Expedited Review on the dates listed below:

- Protocol Amendment No.:2 dated 06/15/2015: Expedited: 07/15/2015

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

ja

PLEASE REFERENCE IRB #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

All dates in mm/dd/yyyy format

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Monday, September 14, 2015 5:41 AM
To: Megan Boatwright
Subject: Periodic Report Due for AEA08 (1st Reminder)

Importance: High

1st REMINDER

Date: Sep 14, 2015
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

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 **Rush Review Fee of $150.00 per site, or $250.00 for a single-site study**.

Failure to submit a report will be considered a compliance issue requiring presentation to the full board and subject to an **Incomplete Document Fee of $200**.

Thank you

Ongoing Review
SCHULMAN Associates IRB, Inc.
www.sairb.com

ongoingreview@sairb.com

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Wednesday, September 30, 2015 6:34 AM
To: Megan Boatwright
Subject: Periodic Report Due for AEA08 (2nd Reminder)

Importance: High

2nd REMINDER

Date: Sep 30, 2015
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

PERIODIC REVIEW DUE

IRB approval expires in approximately 6 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 **Rush Review Fee of $150.00 per site, or $250.00 for a single-site study**.

Failure to submit a report will be considered a compliance issue requiring presentation to the full board and subject to an **Incomplete Document Fee of $200**.

Thank you

Ongoing Review
SCHULMAN Associates IRB, Inc.
www.sairb.com

ongoingreview@sairb.com

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Monday, October 12, 2015 6:02 AM
To: Megan Boatwright
Subject: Periodic Report Due for AEA08, PI: Megan T. Boatwright, B.S. (3rd Reminder)

Importance: High

3rd REMINDER

Date: Oct 12, 2015
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

PERIODIC REVIEW DUE

IRB approval expires in approximately 4 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 **Rush Review Fee of $150.00 per site, or $250.00 for a single-site study**.

Failure to submit a report will be considered a compliance issue requiring presentation to the full board and subject to an **Incomplete Document Fee of $200**.

Thank you

Ongoing Review
SCHULMAN Associates IRB, Inc.
www.sairb.com

1

ongoingreview@sairb.com

Megan Boatwright

From:	Megan Boatwright
Sent:	Monday, October 12, 2015 9:09 AM
To:	'Submissions@sairb.com'
Cc:	Jeffrey Atlas (JAtlas@sairb.com)
Subject:	Protocol/ Informed Consent Change Form
Attachments:	Protocol_ICD_Change_Submission_Form - Deviation 1.docx; 140503 protocol deviation 1 - signed.pdf

To whom it may concern,

Please find attached a Protocol Change Submission Form and the signed Deviation #1 submitted for AEATF Protocol AEA08, IRB number 201307366. Please don't hesitate to contact me if anything is needed or if there are questions.

Thank you,

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

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: October 12, 2015

2. IRB No.: 201307366

3. Sponsor: AEATF II

4. Protocol No.: AEA08

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: Megan T. Boatwright

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: Megan T. Boatwright Company: Golden Pacific Laboratories, LLC

Phone: (559) 275-9091 Email: mboatwright@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: September 22, 2015 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: Study Completed - draft report in progress

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

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.

PROTOCOL Deviation No.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 9.A.ii. Recruitment of Surrogate Workers**

Effective Date: March 9, 2015

Description of Deviation (including justification):

The Protocol states, "SAIRB approved recruiting advertisements 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 recruitment period will be opened for 2 weeks following the first publication."

All three newspapers were contacted and sent the advertisement on March 5, 2015. The Fresno Bee and Vida en el Valle provided quotes, proofs, and ran the advertisements without any issues. California Advocate responded with a quote, size of space, and confirmation there was space available in the publications of March 9th and 16th, but never provided a proof. Although GPL attempted to contact the newspaper multiple times, the California Advocate staff did not follow up and the advertisement was not published in this newspaper.

Justification: Staff at the California Advocate did not respond to requests to publish the advertisement and GPL could not accomplish this task.

Effect on Study: Recruitment proceeded through the Fresno Bee and Vida en el Valle advertisements which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled during the initial two week period without using the California Advocate. This deviation is not expected to impact the results of the study.

APPROVALS:

STUDY DIRECTOR: Megan T Boatwright 09/25/15
Megan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 09/22/2015
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Jeffrey Atlas <JAtlas@sairb.com>
Sent: Monday, October 12, 2015 9:36 AM
To: Megan Boatwright
Cc: Submissions
Subject: RE: Protocol/ Informed Consent Change Form

Hi Megan,

Please note that all protocol deviations must be submitted through our e-submission portal for review. Please proceed with the submission via the portal and you will receive an acknowledgement email containing the details of the submission.

Thank you.

Best Regards,

Jeff Atlas

Jeff Atlas, BS-HSA | 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: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, October 12, 2015 12:09 PM
To: Submissions <submissions@sairb.com>
Cc: Jeffrey Atlas <JAtlas@sairb.com>
Subject: Protocol/ Informed Consent Change Form

To whom it may concern,

Please find attached a Protocol Change Submission Form and the signed Deviation #1 submitted for AEATF Protocol AEA08, IRB number 201307366. Please don't hesitate to contact me if anything is needed or if there are questions.

Thank you,

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

Single Site Study Periodic and Continuing Review Report

Schulman IRB, Inc | sairb.com | 513.761.4100

Contact Information			
Name of User:	MeganT. Boatwright		
Title:	Principal Investigator		
Phone:	(559) 275-9091	**Fax:**	(559) 275-1810
E-mail:	mboatwright@gplabs.com		
Country:	US		

Study Information	
IRB Number:	201307366
Protocol Number:	AEA08
Sponsor:	AEATF II
PI/QI Name:	Megan T. Boatwright
[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		
Since initial approval have you consented any subjects?			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?		03/10/2015
What was the date of the most recent study visit?		04/09/2015
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)	0
	# transferred from your site (include these subjects in Number of Withdrawals in the following question)	0
Please complete the following information for all subjects consented for this study at your site:		
	Number of consented subjects	40
	Number of Screen Failures	1
	Number of Subjects Withdrawn	13
	Number of Subjects who Completed the Study	26
	Number of Subjects still Active in the Study	0
Have any subjects been withdrawn since your last report to Schulman?		Yes

Initials:	RL	Number:	6
Reason:	No show		
Initials:	JJ	Number:	4
Reason:	could not confirm participation		
Initials:	SB	Number:	24
Reason:	could not reach to schedule		
Initials:	SS	Number:	28
Reason:	could not participate due to new job		
Initials:	KL	Number:	23
Reason:	could not reach to schedule		
Initials:	RL	Number:	9
Reason:	Could not participate due to new job		
Initials:	SC	Number:	16
Reason:	moved no forwarding number		
Initials:	SM	Number:	30
Reason:	subject not needed		
Initials:	JL	Number:	5
Reason:	subject not needed		
Initials:	BC	Number:	40
Reason:	subject not needed		
Initials:	TJ	Number:	27
Reason:	subject not needed		
Initials:	DP	Number:	37
Reason:	subject not needed		
Initials:	WN	Number:	17
Reason:	subjected not needed		

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	Yes
	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?	
	Addition of Sub-Investigator(s):	No
	If "Yes", was 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:	130503 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
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:	CDPR		
Physician/Investigator:	Megan T Boatwright	Audit End Date:	04/09/2015
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:	cdpr review report.pdf
Pending Charges / Complaints:	
PI Issues:	

Financial Interest Information	
Since your last report, 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
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:	04/09/2015
	Study Closure:	01/31/2016
Consented Subjects	Enrolled:	
	Active:	
	Withdrawn:	
Please provide a reason for the withdrawals (if applicable):		

Enrolled Subjects	Males:	21
	Females:	19
	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 contiuning 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)?	
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:	10/12/2015 04:31:24 PM ET
Acknowledgement Number:	201307366_10122015163124

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 12, 2015 12:24 PM
To: Megan Boatwright
Subject: eSubmission System - Document Submission Confirmation

Importance: High

Megan,

The following documents have been successfully submitted via Schulman IRB **eSubmission** system:

Submission Type: Amendments or ICD Revisions (Single-Site Protocols)
Document Types Checked: Submission Form
Other
Additional Document Types Listed: Protocol Deviation
Additional Instructions:

List of Uploaded Files
(1) 140503 protocol deviation 1 - signed.pdf (1369.9 KB)
(2) Protocol_ICD_Change_Submission_Form - Deviation 1.docx (58.8 KB)

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone 5592759091
Email: mboatwright@gplabs.com

SCHULMAN Associates IRB, Inc.
www.sairb.com

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, October 12, 2015 1:32 PM
To: Megan Boatwright
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:

File Type	File Name	Description
Informed Consent	130503 icf.pdf	
Audit Documentation	cdpr review report.pdf	

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Acknowledgement #: 201307366_10122015163124
Form ID: OR1504209
IRB Number: 201307366
Investigator: Megan T. Boatwright
Sponsor: AEATF II
Protocol Number: AEA08
Submitted Date/Time: Oct 12 2015 4:31PM

SCHULMAN Associates IRB, Inc.
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[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From:	Schulman Ongoing Review <OngoingReviewFollowUp@sairb.com>
Sent:	Thursday, October 15, 2015 9:14 AM
To:	Megan Boatwright
Cc:	dcorrea@sairb.com
Subject:	Immediate Action Required:Periodic/Continuing Review Report Follow Up, Protocol#: AEA08,PI: Megan T. Boatwright, B.S.,IRB#: 201307366
Importance:	High

Additional Information is Needed: **Request #1**

Protocol#: **AEA08**
Sponsor: **Antimicrobial Exposure Assessment Task Force II (AEATF II)**
IRB#: **201307366**
PI Name: **Megan T. Boatwright, B.S.**

Findings: (1) There was a reportable item of non-compliance with the protocol, Board requirements or regulations noted in the study file since your last report, therefore this item should be marked "Yes". Please confirm

(2) Please submit a copy of the last Informed Consent signed by a Non-English speaking subject.

(3) It was noted that subject race and ethnicity information was not provided. Please confirm whether this information is collected from subjects or not.

Please reply to this email WITHIN 3 BUSINESS DAYS. If you are unable to provide a response via email, please fax your reply to (866) 657-7917.This information is required to process your Periodic/Continuing Review report.Your report cannot be processed until **ALL** follow up is resolved.

Approval Expires: Nov 12 2015

*As indicated by our fee schedule, the Incomplete Document Fee of $200 will be charged to the responsible party if the required follow up is not received by the 3rd Request.

Thank You,

Ongoing Review Team - Danielle Correa
SCHULMAN Associates IRB

Megan Boatwright

From: Megan Boatwright
Sent: Thursday, October 15, 2015 10:02 AM
To: 'OngoingReviewFollowUp@sairb.com'
Cc: dcorrea@sairb.com
Subject: RE: Immediate Action Required:Periodic/Continuing Review Report Follow Up, Protocol#: AEA08,PI: Megan T. Boatwright, B.S.,IRB#: 201307366
Attachments: spanish icf 130503.pdf

To whom it may concern,

Since our last review, yes we have submitted a protocol deviation on October 12, 2015, documenting that the California Advocate did not publish the ad per the protocol (item 1). Please find attached one of the Spanish Inform Consents as requested in item two. As for item three, we did not ask for subject's ethnicity or race, therefore the information is not available.

Please let meknow if you need anything else.

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: Schulman Ongoing Review [mailto:OngoingReviewFollowUp@sairb.com]
Sent: Thursday, October 15, 2015 9:14 AM
To: Megan Boatwright
Cc: dcorrea@sairb.com
Subject: Immediate Action Required:Periodic/Continuing Review Report Follow Up, Protocol#: AEA08,PI: Megan T. Boatwright, B.S.,IRB#: 201307366
Importance: High

Additional Information is Needed: **Request #1**

Protocol#: **AEA08**
Sponsor: **Antimicrobial Exposure Assessment Task Force II (AEATF II)**
IRB#: **201307366**
PI Name: **Megan T. Boatwright, B.S.**

Findings: (1) There was a reportable item of non-compliance with the protocol, Board requirements or regulations

noted in the study file since your last report, therefore this item should be marked "Yes". Please confirm

(2) Please submit a copy of the last Informed Consent signed by a Non-English speaking subject.

(3) It was noted that subject race and ethnicity information was not provided. Please confirm whether this information is collected from subjects or not.

Please reply to this email WITHIN 3 BUSINESS DAYS. If you are unable to provide a response via email, please fax your reply to (866) 657-7917.This information is required to process your Periodic/Continuing Review report.Your report cannot be processed until **ALL** follow up is resolved.

Approval Expires: Nov 12 2015

*As indicated by our fee schedule, the Incomplete Document Fee of $200 will be charged to the responsible party if the required follow up is not received by the 3rd Request.

Thank You,

Ongoing Review Team - Danielle Correa
SCHULMAN Associates IRB

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE CONSENTIMIENTO INFORMADO

Título del estudio: (Protocolo AEA08) Determinación de la eficacia para la eliminación de 1,2-benzisotiazol-3(2H)-ona (BIT) de la superficie de las manos mediante el procedimiento de limpieza y lavado con alcohol isopropílico y agua

Investigadora principal:
Megan T. Boatwright, B.S.
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091 o 949-939-3585

Asociados de investigación en el campo:
Natan R. Chavez (inglés y español)
Asociado de investigación en el campo (Field Research Associate)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Thomas F. Moate (inglés)
Asociado de investigación en el campo (Field Research Associate)
Gerente general (General Manager)
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722
Teléfono: 559-275-9091

Localización del campo:
Golden Pacific Laboratories, LLC
4720 W. Jennifer Avenue, Suite 105
Fresno, CA 93722

Patrocinador: Antimicrobial Exposure Assessment Task Force II (AEATF II).

Número de teléfono durante las 24 horas: 559-917-1736 (Megan Boatwright)

Le pedimos que piense acerca de participar en un estudio de investigación. Su participación es voluntaria. En este formulario de consentimiento informado se explica el estudio.

Puede llevarse una copia de este formulario a su casa para pensar al respecto y hablar con amigos y familiares antes de decidir si desea participar o no en el estudio. Si tiene cualquier pregunta, o si no comprende cualquier cosa de este documento, pida a alguno de nosotros que se lo expliquemos. Si prefiere hablar en español, solicítelo. Podemos explicarle el estudio en inglés o en español.

Schulman Associates Institutional Review Board, Inc. (Schulman) ha aprobado la información contenida en este documento de consentimiento y ha dado la aprobación para que el médico del estudio lleve a cabo el estudio. Un comité de revisión institucional (IRB, *institutional review board*) es un comité independiente establecido para ayudar a proteger los derechos de los sujetos de investigación. Esto no significa que el IRB haya aprobado su participación en el estudio. Usted mismo debe reflexionar sobre la información incluida en este documento de consentimiento y decidir si desea participar en el estudio.

Objetivo de este estudio

Este estudio es realizado por Golden Pacific Laboratories. No gustaría saber cuánta sustancia química es eliminada de la superficie de sus palmas cuando se aplica en cada mano una pequeña cantidad de pintura de látex para interiores que contiene la sustancia química y se deja allí durante 45 minutos. Mediremos cuánta sustancia química puede ser eliminada de sus manos enjuagando y restregando las manos con una toallita de gasa mojada con una solución de alcohol isopropílico (también llamado isopropanol o IPA) y agua. Esta información se comunicará a la Agencia de Protección Ambiental de Estados Unidos (EPA, *U.S. Environmental Protection Agency*). La EPA usará la información para evaluar a cuánta sustancia química están expuestas las personas cuando pintan.

En este estudio, la pintura será la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura que se vende en muchas tiendas. El producto se usa para pintar paredes, techos, puertas y rebordes dentro de viviendas y negocios. Contiene una pequeña cantidad de una sustancia química llamada BIT, que ayuda a impedir el crecimiento de las bacterias en la lata de pintura.

Este estudio es pagado por un grupo de empresas que fabrican productos para disminuir la cantidad de mohos y bacterias. Se llaman Grupo de Trabajo para la Evaluación de la Exposición a los Antimicrobianos II (AEATF, *Antimicrobial Exposure Assessment Task Force II*). Estos productos están registrados por la EPA como plaguicidas.

Megan Boatwright, Thomas Moate y Natan Chavez trabajan con Golden Pacific Laboratories. Megan Boatwright es la persona que está a cargo del estudio. Thomas Moate y Natan Chavez están además capacitados para explicarle el estudio y

responder cualquier pregunta que usted pueda tener. Natan Chavez habla español. Será el principal investigador hispanoparlante (que habla español).

Producto de prueba
El producto de prueba es la pintura de látex para interiores Sherwin-Williams. Es un producto para pintura de uso común. Este producto se usa para pintar paredes, techos, puertas y rebordes en viviendas y negocios. El producto de prueba contiene un plaguicida conocido como BIT, que contribuye a impedir el crecimiento de las bacterias. Usted recibirá una copia de la etiqueta del producto, es decir, de la pintura. Además, si lo desea, le proporcionaremos la hoja de datos de seguridad del material o "MSDS" de la pintura y de la sustancia química BIT.

Selección de sujetos
Para participar en este estudio usted debe estar sano y ser mayor de 18 años. Debe tener la capacidad de leer y hablar en inglés o en español. Tendrá que demostrar su edad mediante una identificación con fotografía emitida por el gobierno, por ejemplo, un permiso de conducir o un pasaporte. Usted debe desear participar en este estudio. Debe estar dispuesto a firmar este consentimiento, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental, y una hoja de trabajo sobre los requisitos. Se le pedirá que proporcione cierta información personal, 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 empresas que pagan la investigación, de American Chemistry Council o de un fabricante de pinturas. No podrá participar si está embarazada o amamantando; si ha tenido reacciones alérgicas o de hipersensibilidad al jabón, el alcohol isopropílico, los productos para pintura, el BIT u otros productos basados en sustancias químicas; si tiene psoriasis, eccema, llagas o cortes abiertos en la piel; si tiene diabetes grave; si tiene el sistema inmunitario inhibido, por ejemplo, por un trasplante de órgano o por quimioterapia activa, o si ha tenido problemas cardíacos o para respirar.

En este estudio participarán veinte personas, y se seleccionarán ocho personas como suplentes por si alguna persona no puede participar el día de la prueba.

Llevaremos a cabo el estudio en Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105, en Fresno. Usted podrá participar en el estudio una sola vez. Si es suplente un día y no es seleccionado, podrá participar en el estudio otro día.

Inscripción en el estudio
Usted se reunirá en el día de hoy con la investigadora principal, Megan Boatwright, o con el gerente general del laboratorio, Thomas Moate, o, si lo prefiere, con un

investigador que hable español. Esas personas le informarán más acerca de lo que se espera durante el estudio y qué se espera de usted. También responderán las preguntas que pueda tener sobre el estudio. Usted puede decidir hoy mismo si desea participar en el estudio o puede llevarse este formulario a su casa para hablar al respecto con sus familiares y amigos antes de tomar la decisión.

Le haremos preguntas sobre su salud general. Le preguntaremos su nombre y edad, y si tiene algún problema de piel en las manos. Si decidimos que reúne los requisitos para participar, y si usted decide que desea participar en el estudio, le pediremos que firme este consentimiento informado, que incluye el formulario de la Declaración de derechos de los sujetos en investigación experimental.

Si lo inscribimos en el estudio le pediremos que acuda al centro de estudio cierto día y a una hora determinada. Lo llamaremos el día anterior para recordárselo y para asegurarnos de que aún desea participar en el estudio.

Procedimientos del estudio

1. Si es seleccionado como uno de los sujetos, acudirá a este lugar en Fresno: Golden Pacific Laboratories, cuya dirección es 4720 W. Jennifer Ave., Suite 105; irá en el momento en que se le haya indicado y se encontrará con el equipo del estudio.

2. Megan Boatwright y el equipo de investigación revisarán con usted y otros participantes qué sucederá y usted tendrá otra oportunidad para hacer preguntas. Le recordaremos que podrá cambiar de idea acerca de la participación en el estudio en cualquier momento, antes o después del comienzo del estudio. Todo lo que tendrá que hacer será decirnos que ha cambiado de idea. No sufrirá sanciones de ningún tipo si decide retirarse del estudio.

3. Debido a que es importante que usted NO participe en el estudio si está embarazada, el día del estudio cada voluntaria mujer pasará a un área privada y se le entregará un kit para prueba de embarazo en orina como los que se pueden comprar en las farmacias. Una investigadora mujer le explicará cómo se usa el kit y responderá las preguntas. Después de que se haga usted misma la prueba, le preguntaremos si desea permanecer en el estudio. Si decide no hacerlo, no le preguntaremos por qué, y los resultados de la prueba no quedarán anotados. Se le pagará $100 por acudir al centro de la prueba, y luego usted será libre de retirarse. Si desea permanecer en el estudio, una investigadora mujer capacitada comprobará nuevamente los resultados con usted. Ninguna otra persona, aparte de usted y esa investigadora, verá los resultados, pero haremos una nota de que la prueba se realizó.

4. Antes de comenzar la prueba, se lavará las manos con jabón Ivory y agua, y se las secará con toallas de papel. Le revisaremos las manos para asegurarnos de que no tenga cortes, raspaduras ni ninguna alteración que pudiera aumentar el riesgo de problemas de la piel durante la prueba.

5. Le pediremos que se siente en una silla y se asegure de estar cómodo. Le pediremos que ponga las manos sobre una superficie acolchada, en la mesa, con las palmas hacia arriba. Le pondremos una pequeña cantidad de pintura en la palma de cada mano, y luego le pediremos que mantenga las palmas hacia arriba sobre la mesa durante 45 minutos. Después de 45 minutos le restregaremos las manos con esponjas de gasa mojadas con una mezcla de alcohol isopropílico y agua, se las enjuagaremos con la misma mezcla y guardaremos el agua del enjuague.

6. Cuando hayamos tomado la muestra de la toallita de mano, usted volverá a lavarse las manos con agua y jabón. Le revisaremos las manos antes de que se retire para observar si hay enrojecimiento u otros signos de irritación. Le pagaremos $100 en efectivo y podrá retirarse.

Riesgos
Si participa en este estudio, estará expuesto a unas pocas clases de riesgos:

1. Riesgo de una reacción a la pintura de látex o al componente plaguicida (BIT) presente en la pintura. El contacto directo con la pintura puede causar comezón o irritación pasajeras de la piel, y respirar el vapor puede producir tos e irritación de la garganta. Se usará una cantidad de pintura muy pequeña, menos de una cucharadita, para que estos riesgos sean mínimos. Además, podría presentar una reacción alérgica a la pintura, sentir mareos o dolor de cabeza. Si ha tenido anteriormente una reacción alérgica a un producto para pintura, recuerde que nos debe informar eso. Si nota enrojecimiento o comezón, siente mareos, tiene dolor de cabeza, o siente alguna otra molestia, infórmelo a un investigador.

2. Riesgo de irritación de la piel por la mezcla de alcohol isopropílico y agua, y las toallitas. El alcohol isopropílico diluido que se usa para restregar y enjuagar sus manos puede arder si usted tiene algún corte o raspadura en las manos que fuera demasiado pequeño como para ser visto antes del comienzo del estudio.

3. Si usted es mujer, podría sorprenderse el día de la investigación al enterarse de que está embarazada. Ninguna persona, aparte de usted, sabrá si la prueba indica que está embarazada, y los resultados no quedarán anotados.

Riesgos desconocidos / imprevisibles
La participación en este estudio puede plantear otros riesgos de los que no tenemos conocimiento o que no podemos predecir. Si aprendemos algo nuevo que pudiera influir en su decisión de participar, lo compartiremos inmediatamente con usted.

Lesiones relacionadas con la investigación
Si usted sufre un daño o se enferma mientras participa en este estudio, se le dará atención en una institución médica cercana. Si fuera necesario, lo llevaremos hasta allí. El AEATF pagará el tratamiento médico razonable y apropiado de una lesión o enfermedad relacionada con el estudio que no sea pagada por su seguro ni el seguro de un tercero que le dé a usted cobertura. La investigadora principal, en consulta con el profesional médico del centro, decidirá si usted presenta una lesión o enfermedad que se deba a su participación en el estudio. Si en las 24 horas siguientes a su participación en el estudio sufre una reacción en la piel u otro efecto adverso que usted considere relacionado con su participación en el estudio, debe buscar tratamiento médico y llamar a la investigadora principal, Megan Boatwright, a Golden Pacific Laboratories (559-275-9091 o 559-917-1736), lo antes posible. Ningún expediente médico será parte del estudio.

Al firmar este formulario, usted no renuncia a ninguno de sus derechos legales.

Alternativas a la participación
Si decide participar en este estudio, será porque usted lo desea. No habrá ningún beneficio directo para usted si participa, y no se verá perjudicado de ningún modo si decide no participar. La decisión depende de usted.

Beneficios
Usted no obtendrá ningún beneficio directo por participar en este estudio. Lo que aprendamos en este estudio ayudará a garantizar que los productos para pintura como la pintura de látex Sherwin-Williams se puedan usar de manera segura. Esto puede ser un beneficio indirecto para usted y otras personas cuando pinten. Las personas que pagan el estudio también se beneficiarán con ese conocimiento, ya que necesitan realizar este estudio para mantener en el mercado sus productos antimicrobianos para pintura.

Preguntas sobre este estudio
Si tiene preguntas, puede hacerlas en cualquier momento; antes, durante o después del estudio. Simplemente hágaselas a Megan Boatwright o a cualquier otro integrante del equipo de investigación.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a

Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Costos y pago
La participación en este estudio no tendrá ningún costo. Al final de cada entrevista de consentimiento informado, se le pagará $20 en efectivo por su tiempo y las molestias de acudir a nuestro consultorio. Si es seleccionado para el estudio y acude al centro de estudio asignado, se le pagará $100 en efectivo cuando haya finalizado su día, ya sea que se le haya hecho la prueba o no.

Confidencialidad
Para este estudio le asignaremos un número de identificación especial, y anotaremos e informaremos todos los datos con ese número. Conservaremos solamente un registro que relacione su nombre con ese número de identificación, y lo guardaremos separado del resto de los datos, en un armario bajo llave. No lo identificaremos a usted por su nombre ni de ningún otro modo en los informes del estudio. Posiblemente tomemos fotografías o grabemos videos del estudio, pero los modificaremos para que usted no pueda ser identificado. Las fotografías o videos modificados se podrán usar para capacitar a otros investigadores, presentar el estudio a las personas que lo pagan o para su publicación en revistas científicas.

Restringiremos el acceso a los expedientes de este estudio; solo accederán a ellos unas pocas personas. Sin embargo, podrán revisar todos los expedientes del estudio las personas que pagan el estudio, los organismos del gobierno que revisan los informes y SAIRB, Inc., que se ocupa de cuidar la seguridad de los participantes. Por ese motivo, no podemos garantizar completamente la confidencialidad. Usted podrá obtener una copia de sus expedientes si se la solicita a la investigadora principal.

Derecho a retirarse
Usted puede retirarse del estudio en cualquier momento y por cualquier motivo. Simplemente, dígaselo a cualquier integrante del equipo de investigación. Si decide no participar en este estudio o retirarse de él, no sufrirá ninguna sanción ni perderá ningún beneficio.

Motivos para ser retirado del estudio
Megan Boatwright, la investigadora principal a cargo de este estudio, puede retirarlo del estudio incluso si usted quisiera permanecer en él. Puede retirarlo si, por ejemplo:

- Ella considera que permanecer en el estudio podría implicar un riesgo para usted.
- Usted no cumple las instrucciones de los investigadores.
- El estudio se interrumpe por otros motivos.

Si usted es retirado del estudio o si el estudio completo se interrumpe, aun así se le pagará por su tiempo y molestias.

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

FORMULARIO DE DECLARACIÓN DE DERECHOS DE LOS SUJETOS EN INVESTIGACIÓN EXPERIMENTAL

Los derechos que se exponen a continuación son los derechos de toda persona a quien se invite a participar en un estudio de investigación. Como sujeto de investigación experimental, tengo los siguientes derechos:

1. Ser informado acerca del objetivo del estudio;
2. Ser informado acerca de qué me sucederá y si alguno de los procedimientos, plaguicidas o dispositivos es diferente o no de los que se usarían en la práctica habitual;
3. Ser informado acerca de los riesgos, efectos secundarios o molestias frecuentes y/o importantes de las cosas que me sucederán durante el estudio;
4. Ser informado acerca de si puedo esperar algún beneficio de la participación y, si lo hubiera, cuál podría ser el beneficio;
5. Ser informado acerca de las alternativas a la participación en el estudio;
6. Se me permita hacer cualquier pregunta concerniente al estudio tanto antes de aceptar participar como durante el transcurso del estudio;
7. Ser informado acerca de qué tipo de tratamiento médico está disponible si surgen complicaciones;
8. Negarme completamente a participar o cambiar de idea acerca de la participación después de que el estudio haya comenzado. Esta decisión no influirá en mi situación respecto a mi empleador;
9. Recibir una copia de este formulario de consentimiento firmado y fechado, y
10. Estar libre de presiones cuando considere si deseo participar o no en el estudio.

Si tiene alguna pregunta sobre sus derechos como sujeto de una investigación y/o inquietudes o quejas respecto a este estudio de investigación, debe escribir a Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, o llamar sin cargo al 1-888-557-2472 durante el horario de oficina, de lunes a viernes de 8:00 a. m. a 6:00 p. m. hora del este de los EE. UU.

Si tiene otras preguntas, debe hacérselas a la investigadora principal o a los investigadores del estudio

Contactos telefónicos:

Investigadora principal: Megan Boatwright (559) 275-9091

Personal del estudio: Thomas Moate o Natan Chavez (559) 275-9091

Aprobado por Schulman
IRB #201307366
FECHA: 6 de febrero de 2015

Consentimiento y firma

He leído este formulario de consentimiento informado y la Declaración de derechos de los sujetos en investigación experimental, se han respondido todas mis preguntas en un lenguaje que comprendo bien. Doy mi consentimiento voluntariamente para participar en este estudio como sujeto de investigación. No renuncio a ningún derecho legal al firmar este formulario. Recibiré mi copia de este formulario con todas las firmas.

Fecha/hora: 12:10 03/19/15 _____ 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: 03/19/15 12:10PM _____ Spanish Speaking Researcher's Signature

Natan Chavez
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: 03/19/15 12:10 PM _____
Megan Boatwright
Principal Investigator, Golden Pacific Laboratories, LLC

Copy of consent form given to subject: (DATE) 03/19/15 BY (INITIALS) mtb

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Thursday, October 22, 2015 4:00 PM
To: Megan Boatwright
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Boatwright, Megan T., B.S.	Re-Approval Letter	Oct 22, 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 Associates IRB
www.sairb.com

REAPPROVED: 10/22/2015
EXPIRATION DATE: 10/21/2016

October 22, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") -- Board 3
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Reapproval
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

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 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 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 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.

WebPortal/Paperless

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Wednesday, April 06, 2016 5:40 AM
To: Megan Boatwright
Subject: Events to Report Reminder

Importance: High

NO STUDY STATUS REPORT IS DUE AT THIS TIME

Date: 06 Apr 2016
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

INVESTIGATOR RESPONSIBILITIES

As you approach the midpoint in your approval/reapproval period, we would like to remind you and your staff of your ongoing reporting responsibilities.

Please review the document entitled Event(s) that Investigators Have to Report to the IRB for specific information regarding research events that Principal Investigators (PIs)/Qualified Investigators (QIs) must report to the IRB. Schulman requires investigators report these events to the Board within ten (10) business days of discovery, except as otherwise noted.

REMINDER: It is the Investigator's responsibility to ensure subjects are being consented using the most recent, approved informed consent document.

Thank you for your assistance and cooperation.
SCHULMAN IRB
Ongoing Review Team
ongoingreview@sairb.com
www.sairb.com

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Friday, August 26, 2016 7:30 PM
To: Megan Boatwright
Subject: Periodic Report Due Now for AEA08 PI: Megan T. Boatwright, B.S. (1st Reminder)

Importance: High

1st REMINDER

Date: Aug 26, 2016
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

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 **Rush Review Fee** .

Thank you

Ongoing Review
SCHULMAN IRB
www.sairb.com
ongoingreview@sairb.com

Megan Boatwright

From: Site Reminder <SiteReminderReplies@sairb.com>
Sent: Friday, September 09, 2016 7:30 PM
To: Megan Boatwright
Subject: Periodic Report Due Now for AEA08 PI: Megan T. Boatwright, B.S. (2nd Reminder)

Importance: High

2nd REMINDER

Date: Sep 09, 2016
Investigator: Megan T. Boatwright, B.S.
Sponsor: ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II (AEATF II)
Protocol: AEA08
IRB#: 201307366

PERIODIC REVIEW DUE

IRB approval expires in approximately 6 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 **Rush Review Fee** .

Thank you

Ongoing Review
SCHULMAN IRB
www.sairb.com
ongoingreview@sairb.com

Single Site Study Periodic and Continuing Review Report

Schulman IRB | sairb.com | 513.761.4100

Contact Information	
Name of User:	Megan Boatwright
Title:	Laboratory Manager
Phone:	5592759091
E-mail:	mboatwright@gplabs.com
Country:	US

Study Information	
IRB Number:	201307366
Protocol Number:	AEA08
Sponsor:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PI/QI Name:	Boatwright, Megan T., B.S.
[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:	Site/Investigator	**Documentation For:**	Single Site and Protocol Review
Report Type:	Periodic/Continuing Review		
Have any subjects been consented at your site 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?		03/10/2015
What was the date of the most recent study visit?		04/09/2015
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	40
	Number of Screen Failures	0
	Number of Subjects Withdrawn	20
	Number of Subjects who Completed the Study	20
	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
	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:	spanish icf 130503.pdf
	130503 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
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?	No
If "Yes", please list all audits 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	
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
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:	04/09/2015	
	Study Closure:	01/31/2017	
Consented Subjects	Enrolled:		
	Active:		
	Withdrawn:		
Please provide a reason for the withdrawals (if applicable):			
Enrolled Subjects	Males:	22	
	Females:	18	
	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)?			
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:	09/12/2016 03:14:52 PM ET
Acknowledgement Number:	201307366_09122016151452

Schulman

eSubmission™ 2.0
Secure electronic submission system
Developed and Hosted by Schulman - Tested, Trusted, Secure

eSubmission™ 2.0 Setup

- Getting Started Tips
- How-To Video Tutorials
- Collaboration Instructions
- Share Your Work
- User Profile
- Common Attachments
- Study Contacts
- Manage Sites
- Let Schulman Import For You
- FAQ
- New Template

Start New Form

- Initial Submission
- Study Status Report
- Recruitment/Study Materials
- Subject Safety

My Forms

- Initial Submission Templates (0)
- Started Forms (1)
- Submitted Forms (3)

Collaboration Tools

- New Sponsor Template
- Sponsor Invites Sites
- Sponsor Templates (0)
- Site Forms to Complete (0)
- Site Forms Submitted (0)

Single Site Study Periodic and Continuing Review Report Form Submission Receipt:

PLEASE NOTE: Do not use the browser "Back" button to complete another submission.

This form has been submitted successfully. Print this receipt.
You will receive a confirmation e-mail within 15 minutes. If you do not receive this e-mail confirmation, please contact Technical Support.

You may access a copy of your submission via the PDF or ZIP file below. Click on the blue link to open the file, then print your submission or send an electronic copy via email. You may also access your submission anytime by returning to **eSubmission™ 2.0** and clicking on **Submitted Forms** on the left side of the screen under **My Forms**.

User Information:

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Form ID: OR1620745
Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II)
Protocol Number: AEA08
Investigator: Boatwright, Megan T., B.S.

Form:

Single Site Study Periodic and Continuing Review Report Form (AEA08) PDF (Schulman Submission Format)

Single Site Study Periodic and Continuing Review Report Form and all uploaded files (ZIP)

Comments:

File(s) Uploaded:

File Type	File Name	File Description
Informed Consent	spanish icf 130503.pdf	
Informed Consent	130503 icf.pdf	

Monday
September 12, 2016

3:15 PM EST

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Monday, September 12, 2016 12:15 PM
To: Megan Boatwright
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:

File Type	File Name	Description
Informed Consent	130503 icf.pdf	
Informed Consent	spanish icf 130503.pdf	

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Acknowledgement #: 201307366_09122016151452
Form ID: OR1620745
IRB Number: 201307366
Investigator: Boatwright, Megan T., B.S.
Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II)
Protocol Number: AEA08
Submitted Date/Time: Sep 12 2016 3:14PM

SCHULMAN IRB
www.sairb.com

[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From: Megan Boatwright
Sent: Monday, September 12, 2016 12:59 PM
To: 'ongoingreview@sairb.com'
Subject: Corrections to Single Site Study Periodic and Continuing Review Report (201307366)

To whom it may concern,

I just submitted my Single Site Study Periodic and Continuing Review Report for IRB Number 201307366, Protocol number AEA08. It has come to my attention that the number of males vs. females is different from the number submitted last year. I have counted twice and both times counted 22 males and 18 females. Also I did not fill out the number of subjects that consented, failed, withdrew, completed or are still active correctly. Looking back over last year's submission on October 12, 2015 it reminded me of what you were truly asking. The answer should have been the same as last year: 26 completed, 1 failed screening due to cut on hand, and 13 withdrawn for various reasons. Please let me know if you have any questions.

Thank you for your time,

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: Mary Goodwin <mgoodwin@sairb.com>
Sent: Monday, September 12, 2016 1:19 PM
To: Megan Boatwright
Subject: RE: Corrections to Single Site Study Periodic and Continuing Review Report (201307366)

Megan,
I'll match your email up with the report you submitted as an explanation for the discrepancy.

Thanks for letting us know. If we have any other questions, we'll let you know.

Regards,
Mary Goodwin

Mary Goodwin | Manager, Ongoing Review
Schulman IRB
4445 Lake Forest Drive, Suite 300 | Cincinnati, OH 45242
***Office*:** 513-761-4100 ext. 178 | mgoodwin@sairb.com

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, September 12, 2016 3:59 PM
To: Ongoing Review <OngoingReview@sairb.com>
Subject: Corrections to Single Site Study Periodic and Continuing Review Report (201307366)

To whom it may concern,

I just submitted my Single Site Study Periodic and Continuing Review Report for IRB Number 201307366, Protocol number AEA08. It has come to my attention that the number of males vs. females is different from the number submitted last year. I have counted twice and both times counted 22 males and 18 females. Also I did not fill out the number of subjects that consented, failed, withdrew, completed or are still active correctly. Looking back over last year's submission on October 12, 2015 it reminded me of what you were truly asking. The answer should have been the same as last year: 26 completed, 1 failed screening due to cut on hand, and 13 withdrawn for various reasons. Please let me know if you have any questions.

Thank you for your time,

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: Schulman Technical Support <alertreply@sairb.com>
Sent: Tuesday, September 27, 2016 4:01 PM
To: Megan Boatwright
Subject: CONTINUING/PERIODIC REVIEW documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Boatwright, Megan T., B.S.	Re-Approval Letter	Sep 27, 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.

SCHULMAN IRB
www.sairb.com

REAPPROVED: 09/27/2016
EXPIRATION DATE: 09/26/2017

September 27, 2016

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Reapproval
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

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.

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WebPortal/Paperless

Schulman IRB

Protocol/Informed Consent Change Form

Submission information: Use this form to submit changes to the protocol (e.g. amendment, administrative change) or informed consent document (IC) for Board review. Please note, that no subject related activities, unless related to subject safety, will occur prior to receiving the approval letter and informed consent from Schulman.

2. Submission instructions: Submit via Secure eSubmission or email to Submissions@sairb.com.

SECTION 1.0: Study & Contact Information

1. Date: March 14, 2017

2. IRB No.: 201307366

3. Sponsor: AEATF

4. Protocol No.: 130503

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: MEgan T. Boatwright

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: Megan T. Boatwright Company: Golden Pacific Laboratories, LLC

Phone: (559) 275-9091 Email: mboatwright@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: February 28, 2017 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: Study Finished - draft report in progress

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

Schulman IRB

Protocol/Informed Consent Change Form

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.**

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 and Study Related Materials Submission Form

Note: Board review of recruitment and study-related materials will be sent under separate cover.

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Megan Boatwright | mboatwright@gplabs.com

Return to eSubmission™ 2.0 | Logout

Study Change
- Form Requirements
- Study Profile
- Protocol/Informed Consent Information
- Sub-Study
- Subject Compensation / Reimbursement
- Form Summary

Study Change Form › Form Summary

Study Amendments Submission

Review completed form information including all attachments prior to submission.
Note: Answers cannot be changed after the form is submitted. To change an answer, click the 'Back' button below.

Print Preview Only

Form Information

I am submitting this report as a:
CRO

What type of change are you submitting?
Protocol/Amendment

The selected changes:
Apply to protocol only

Does your research involve Humanitarian Use Device (HUD)?
No

Study Profile

Protocol #: AEA08
Sponsor: AEATF II
IRB #: 201307366
Investigator:

Enrollment: What is the status of study enrollment?
Enrollment closed

Subject Status: What is the status of study subjects?
No subjects active

Protocol/Informed Consent

Protocol Amendment/Revised Protocol: Amendment/Revision date: 02/28/2017
Amendment/Revision number: 2

Please attach the summary of changes:
Summary included within the revised protocol

IC Changes: Does this submission result in the need for change(s) to the current Schulman approved IC template for the study?
No

Protocol Extension: Does this submission create an extension to the protocol?
No

Sub-Study

Sub-Study: (or additional reasearch) Does this Study involve a sub-study and/or additional research activities that affect a subset of subjects?
No

Subject Compensation/Reimbursement

Compensation: Does this submission modify the study subject compensation/reimbursement?
No

Please enter any additional submission comments:

Attached Documents:

File Name	File Description	File Type
130503 protocol deviation 2 - signed.pdf	Protocol Deviation 2 AEA08	Revised Study Document

Print Preview Only

< Back | Submit

Tuesday
March 14, 2017
5:16 PM EST

Cincinnati, OH | 513.761.4100
Research Triangle Park, NC | 919.257.4900

Contact Technical Support

Megan Boatwright

rom: Schulman Technical Support <alertreply@sairb.com>
Sent: Tuesday, March 14, 2017 2:17 PM
To: Megan Boatwright
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: Study Amendments Submission
Submission Form: Study Amendments Submission Form.pdf (Schulman Submission Format)
Submission Comments:

List of Uploaded Files:

File Type	File Name	Description
Revised Study Document	130503 protocol deviation 2 - signed.pdf	Protocol Deviation 2 AEA08

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Acknowledgement #: 201307366_03142017171702
Form ID: AMD1701037
IRB Number: 201307366
Sponsor: AEATF II
Protocol Number: AEA08
Submitted Date/Time: Mar 14 2017 5:16PM

SCHULMAN IRB
www.sairb.com

[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Tuesday, May 23, 2017 11:06 AM
To: Megan Boatwright
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:	Noncompliance Issue/Deviation Submission Acknowledgement
Submission Form:	Noncompliance Issue/Deviation Submission Acknowledgement Form.pdf (Schulman Submission Format)
Submission Comments:	Words of the deviation follow: PROTOCOL Deviation No.: 3 GPL Study # 130503 Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure 1. Page 25 and 105 and Amendment 1 Item 5 – Field Recovery Evaluation Dates of Occurrence: April 7, 2015 and April 9, 2015 Description of Deviation (including justification): The Protocol states on page 25 and in Amendment 1 Item "Duplicate control matrix samples will also be prepared." However, on page 105 in Appendix I: Field Sample Identification Codes, only one code for a control matrix sample is provided. During the conduct of the study only one control matrix sample was prepared at each fortification event. Reason for Deviation: Contradiction within the protocol text and list of Field Sample Identification Codes, which was unnoticed. Effect on Study: There is no effect on the study since control samples showed no residues, therefore a duplicate control sample was not needed to verify any questionable results. APPROVALS: STUDY DIRECTOR: Mégan T. Boatwright Date Golden Pacific Laboratories, LLC SPONSOR REPRESENTATIVE: Has Shah, Ph.D. Date Sponsor Representative Signed version available upon request.

List of Uploaded Files:

Submitting User Information

Company:	Golden Pacific Laboratories, LLC
Name:	Megan Boatwright
Phone:	5592759091
Email:	mboatwright@gplabs.com

Acknowledgement #:	201307366_05232017140659
Form ID:	SN1712645
IRB Number:	201307366

Investigator:	Megan Boatwright
Sponsor:	AEATF II
Protocol Number:	AEA08
Submitted Date/Time:	May 23 2017 2:05PM

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[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Tuesday, May 23, 2017 12:14 PM
To: Megan Boatwright
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 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	130503 english icf.pdf	
Informed Consent	130503 spanish icf.pdf	

Submitting User Information

Company: Golden Pacific Laboratories, LLC
Name: Megan Boatwright
Phone: 5592759091
Email: mboatwright@gplabs.com

Acknowledgement #: 201307366_05232017151530
Form ID: OR1711434
IRB Number: 201307366
Investigator: Megan Boatwright
Sponsor: AEATF II
Protocol Number: AEA08
Submitted Date/Time: May 23 2017 3:14PM

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[This message is auto generated by Schulman eSubmission™ 2.0 system. Please do not reply.]

Megan Boatwright

'om: Mary Holtman <MHoltman@sairb.com>
Sent: Thursday, May 25, 2017 1:56 PM
To: Megan Boatwright
Subject: Protocol AEA08 - Dr. Boatwright (201307366)

Hi Megan,

Please see below for a finding noted during review of your Final Report.

The finding listed here does not require action unless the information is inaccurate. This is solely for your records.

As indicated by your previous report, the date the first subject was consented at your site should be 03/10/2015.

Thank you,

Mary Holtman | Ongoing Review Coordinator II
Schulman IRB
Cincinnati, OH| Research Triangle Park, NC
***Office*:** 513-761-4100 x5199 | ***Fax*:** 866-657-7917| mholtman@sairb.com
Visit us at http://www.sairb.com

Megan Boatwright

From: Schulman Technical Support <alertreply@sairb.com>
Sent: Thursday, May 25, 2017 4:00 PM
To: Megan Boatwright
Subject: CLOSURE documents posted for Protocol AEA08 [Country:US]

Importance: High

Megan,

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:	**AEA08 [COUNTRY:US]**
Indication:	**Pesticide;**

Document Posted For:	**Document Type**	**Posted Date**
Boatwright, Megan T., B.S.	Closure Letter	May 25, 2017

★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.

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SCHULMAN IRB
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STUDY CLOSURE: 05/25/2017

May 25, 2017

FROM:	Schulman IRB ("Schulman" or the "Board")
TO:	Megan T. Boatwright, B.S.
SUBJECT:	Study Closure
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

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 G.

CORRESPONDENCE WITH CDPR

Table of Content

Date	Page Range	Document(s)
7 April 15	1274	TLouie→MBoatwright notification that a letter from CDPR with approval for Amendment 1 was available
	1275-1276	Approval Letter dated April 6, 2015
20 April 15	1277	TLouie→MBoatwright notification that a letter from CDPR summarizing observations of study monitoring was available
	1278	CDPR Letter dated April 20, 2015
	1279-1282	Observations of Studies Involving Human Subjects Form for 130503
5 April 17	1283	MBoatwright→DRichmond transmittal of Protocol Amendment 2, Protocol Deviations 1 and 2 for completeness of records although not required by protocol
	1284	Protocol Amendment 2
	1285	Protocol Deviation 1
	1286	Protocol Deviation 2

Megan Boatwright

From: Megan Boatwright
Sent: Monday, November 04, 2013 10:41 AM
To: drichmond@cdpr.ca.gov
Cc: Rob Testman (rtestman@gplabs.com)
Subject: Removal Efficiency Protocol for Review
Attachments: Protocol 130503 BIT Removal Effeciency 01Nov2013 Draft.docx

Dear Don,

Please find attached the removal efficiency protocol involving human subjects that will be conducted in California here at our facility for your review and comments. We will be submitting this protocol for IRB review. Please let me know if you have any questions or need anything else.

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

***DRAFT* PROTOCOL**

01 November 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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

April 2014

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 77

TABLE OF CONTENTS

List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No:	AEA08
GPL Study No:	130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	April 2014
Proposed Experimental Termination Date:	June 2014
Proposed Final Report Issue Date:	August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8F.1	Sample Identification	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.1	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

Sponsor:

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:

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

Field Research Associates:	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
Quality Assurance Unit:	Margaret A. Hamelin Golden Pacific Laboratories, LLC 4720 W. Jennifer Ave., Suite 105 Fresno, CA 93722 Phone: (559) 275-9091 E-mail: mhamelin@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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated by testing BIT in solvent will better enable extrapolation of the BIT in paint data to other antimicrobial active ingredients. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. 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.

The test substances in this study are latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 µg/mL and 3.9 mg/mL. The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface protection, therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 10 subjects at one of two concentrations (5 subjects each). A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. Hand exposure will be measured by scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs their hands together. The gauze pads will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in IPA or latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The data generated by testing BIT in solvent will better enable extrapolation of the paint data to other antimicrobial active ingredients. The primary objective of this study is to determine the removal efficiency of BIT in latex paint, and in IPA from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to extrapolate data from existing human hand removal efficiency studies. In this study, at least 20 subjects (5 for each scenario) will be monitored in order to capture the expected variation in skin differences, concentration, and paint or solvent as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions

(Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT. Even if all of the applied BIT were absorbed this would represent about 0.009 mg/Kg for a 50 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting absorbtion.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used on the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to 30 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is

quite low. 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint or solvent from human skin is not available. Removal efficiency studies which have been conducted with other actives do not provide for interpretation of BIT removal, or the removal of any actives in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substances for this study are the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing 1,2-benzisothiazoline-3-one (BIT) and BIT prepared in isopropyl alcohol (IPA). BIT is the active ingredient selected for measurement in the proposed paint

applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

B. Test Substance Identification – BIT in Solvent

The reference substance 1,2-Benzisothiazol-3(2H)-one (BIT) will be prepared at approximately 786 µg/mL and 3.9 mg/mL using isopropyl alcohol (HPLC grade) as the dilution solvent.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be recorded in the raw data
Purity:	to be recorded in the raw data
Date Received:	to be recorded in the raw data
Expiration Date:	to be recorded in the raw data

C. 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.

BIT in solvent will be used as a second test substance in order to provide comparative removal efficiency information between a paint matrix and solvent. This information will be used to improve extrapolation of data for other actives which may have removal efficiency data in solvent to a paint matrix.

The analytical method for the determination of BIT in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

D. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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.

E. Calibration of Application Equipment

BIT in paint or solvent will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

F. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint or IPA.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of four groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 786 µg/mL in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/mL in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tube. The glass capillary tube will be placed into a glass test tube and retained for analysis.

The paint or solution will be left on the hands to dry for 45 minutes. Each hand will then be washed by scrubbing with a gauze wipe soaked in 50% IPA / 50% distilled water solution and rinsed with the same solution. The solution and gauze wipe will be collected as a single sample for each hand, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. Either a 500 µL volume of the appropriate paint concentration or a 100 µL volume of the appropriate solvent concentration will be applied. A glass capillary tube will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread

closer than 2 cm from any edge of the palmar surface. The capillary tube from each subject will be placed into a glass test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects 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.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into four groups. Two groups will receive BIT applied in paint, and two groups will receive BIT applied in IPA. The four groups are described below:

Group 1	500 µL of latex paint containing ca. 120 ppm BIT
Group 2	500 µL of latex paint containing ca. 600 ppm BIT
Group 3	100 µL of ~ 786 µg/mL fortification solution of BIT in IPA
Group 4	100 µL of ~ 3.9 mg/mL fortification solution of BIT in IPA

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four groups, each corresponding to one of the four test substance/concentration combinations. The first set of seven subjects will be placed into Group 1, the second set of seven subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4.

Within each group of seven, the first five subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the group of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into four groups, subjects from the first group will be scheduled into the study. No more than two groups will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., five subjects for each of four groups). As described above, an additional eight subjects (two per cluster) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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 ask the subject if he/she is taking any medication and 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects

have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- Consider their self to be in good health

- 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

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 or sensitivities 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)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer an 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. If a monitoring event is terminated early due to medical reasons any samples from the subject will not be analyzed.

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with

water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

B. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

C. 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 (hand wipe/wash solutions containing gauze wipes) will take place on each day of the study. Field fortification solutions of BIT in latex paint or in solvent will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the hand wash samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm
IPA	100 µL	Approximately 786 µg/mL
IPA	100 µL	Approximately 3.9 mg/mL

On each study day, samples will be fortified as shown above in duplicate. Duplicate control hand wash samples will also be prepared.

Hand wash samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL-LH:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
LH = Left Hand
Additional designations are as follows:
S = Solvent
H = High Concentration Level
RH = Right Hand

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at $\leq$ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze wipes is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The IPA test substances will be analyzed by diluting to an appropriate concentration with 50% acetonitrile /50% water, vialing with internal standard, and analyzing by HPLC/MS/MS. The capillary pipets used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the capillary tubes used during application will be subtracted from the amount applied to determine a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the QAU. The QAU will report to the President of

Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).
2. A detailed summary of the amount of test substance applied to each subject hand.
3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.

13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

_____

Has Shah, Ph.D. Date
Sponsor's Representative

_____

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

_____

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

_____

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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 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/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/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)(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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

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.

3/2013 www.sherwin-williams.com 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

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:

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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint or rubbing (isopropyl) alcohol containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. 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) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 BIT in rubbing alcohol. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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; 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. 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 your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands with gauze pads wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe sample, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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. 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 have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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.

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

Megan Boatwright, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*

6. Name			
7. Address			
8. City, ST, Zip			
9. Telephone(s)			
10. Age in years =	11. DOB:	12. Sex M F	
13. Resident in Fresno County? Yes No			
14. Preferred Language: English Spanish	15. Reads: English Spanish		
16. Are you pregnant? NA Yes No	17. Are you nursing a baby? NA Yes No		
18. Do you consider your general health good? Yes No			
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? Yes No			
20. 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 AND BIT REFERENCE SUBSTANCE

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

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.

SIGMA-ALDRICH

sigma-aldrich.com

Material Safety Data Sheet

Version 4.2
Revision Date 10/05/2012
Print Date 05/30/2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Supplier	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052
Emergency Phone # (For both supplier and manufacturer)	:	(314) 776-6555
Preparation Information	:	Sigma-Aldrich Corporation Product Safety - Americas Region 1-800-521-8956

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

GHS Classification
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Serious eye damage (Category 1)
Skin sensitization (Category 1)
Acute aquatic toxicity (Category 1)

GHS Label elements, including precautionary statements

Pictogram

Signal word: Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary statement(s)

P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

HMIS Classification

Health hazard:	2
Flammability:	0
Physical hazards:	0

NFPA Rating

Health hazard:	2
Fire:	0
Reactivity Hazard:	0

Potential Health Effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.
Ingestion	Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula : C_7H_5NOS

Molecular Weight : 151.19 g/mol

Component		Concentration
1,2-Benzisothiazolin-3-one		
CAS-No.	2634-33-5	-
EC-No.	220-120-9	
Index-No.	613-088-00-6	

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	crystalline
Colour	light yellow

Safety data

pH	no data available
Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Autoignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Vapour pressure	no data available
Density	no data available
Water solubility	no data available

Partition coefficient: n-octanol/water	no data available
Relative vapour density	no data available
Odour	no data available
Odour Threshold	no data available
Evaporation rate	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
no data available

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides
Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50
LD50 Oral - rat - 1,020 mg/kg

Inhalation LC50
no data available

Dermal LD50
no data available

Other information on acute toxicity
no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
May cause allergic skin reaction.

Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects
no data available

Additional Information
RTECS: DE4620000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint or rubbing alcohol on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 5/30/2013

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 removal efficiency 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 removed from the palms of your hand when paint or rubbing alcohol containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint or rubbing alcohol on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze wipe. We will collect the wash water and gauze wipe. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Hand	Target BIT Concentration
AEA08-RE-01-PL-LH	1	Left	120 ppm
AEA08-RE-01-PL-RH	1	Right	120 ppm
AEA08-RE-02-PL-LH	2	Left	120 ppm
AEA08-RE-02-PL-RH	2	Right	120 ppm
AEA08-RE-03-PL-LH	3	Left	120 ppm
AEA08-RE-03-PL-RH	3	Right	120 ppm
AEA08-RE-04-PL-LH	4	Left	120 ppm
AEA08-RE-04-PL-RH	4	Right	120 ppm
AEA08-RE-05-PL-LH	5	Left	120 ppm
AEA08-RE-05-PL-RH	5	Right	120 ppm
AEA08-RE-06-PH-LH	6	Left	600 ppm
AEA08-RE-06-PH-RH	6	Right	600 ppm
AEA08-RE-07-PH-LH	7	Left	600 ppm
AEA08-RE-07-PH-RH	7	Right	600 ppm
AEA08-RE-08-PH-LH	8	Left	600 ppm
AEA08-RE-08-PH-RH	8	Right	600 ppm
AEA08-RE-09-PH-LH	9	Left	600 ppm
AEA08-RE-09-PH-RH	9	Right	600 ppm
AEA08-RE-10-PH-LH	10	Left	600 ppm
AEA08-RE-10-PH-RH	10	Right	600 ppm
AEA08-RE-11-SL-LH	11	Left	786 µg/mL
AEA08-RE-11-SL-RH	11	Right	786 µg/mL
AEA08-RE-12-SL-LH	12	Left	786 µg/mL
AEA08-RE-12-SL-RH	12	Right	786 µg/mL
AEA08-RE-13-SL-LH	13	Left	786 µg/mL
AEA08-RE-13-SL-RH	13	Right	786 µg/mL
AEA08-RE-14-SL-LH	14	Left	786 µg/mL
AEA08-RE-14-SL-RH	14	Right	786 µg/mL
AEA08-RE-15-SL-LH	15	Left	786 µg/mL
AEA08-RE-15-SL-RH	15	Right	786 µg/mL
AEA08-RE-16-SH-LH	16	Left	3.9 mg/mL
AEA08-RE-16-SH-RH	16	Right	3.9 mg/mL
AEA08-RE-17-SH-LH	17	Left	3.9 mg/mL
AEA08-RE-17-SH-RH	17	Right	3.9 mg/mL
AEA08-RE-18-SH-LH	18	Left	3.9 mg/mL
AEA08-RE-18-SH-RH	18	Right	3.9 mg/mL
AEA08-RE-19-SH-LH	19	Left	3.9 mg/mL
AEA08-RE-19-PH-RH	19	Right	3.9 mg/mL
AEA08-RE-20-PH-LH	20	Left	3.9 mg/mL
AEA08-RE-20-PH-RH	20	Right	3.9 mg/mL

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-S-01-C	Control	None
AEA08-FF-S-01-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-01-H2	High Fortified with Solvent	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg
AEA08-FF-S-02-C	Control	None
AEA08-FF-S-02-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-02-H2	High Fortified with Solvent	390 µg

Megan Boatwright

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Monday, November 04, 2013 1:02 PM
To: Megan Boatwright
Subject: RE: Removal Efficiency Protocol for Review

Megan,

I will send this protocol for review either later today or tomorrow.

Don

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, November 04, 2013 10:42 AM
To: Richmond, Don@CDPR
Cc: Robert Testman
Subject: Removal Efficiency Protocol for Review

Dear Don,

Please find attached the removal efficiency protocol involving human subjects that will be conducted in California here at our facility for your review and comments. We will be submitting this protocol for IRB review. Please let me know if you have any questions or need anything else.

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: 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

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:	Escobar, Olga@CDPR <Olga.Escobar@cdpr.ca.gov>
Sent:	Thursday, December 19, 2013 2:33 PM
To:	Megan Boatwright
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 "Determination of Removal.... "
Attachments:	ny12-19a.pdf

Ms. Boatwright:

Attached please find the correspondence to you from Nino Yanga concerning protocol for the study "Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure.

Please feel free to 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

Megan Boatwright
Golden Pacific Laboratories, LLC (GPL)
4720 West Jennifer Avenue, Suite 105
Fresno, CA 93722

Dear Ms. Boatwright:

On November 4, 2013, the Department of Pesticide Regulation (DPR) received the protocol for the study **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure."** 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 the *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

- The terms gauze sponges, gauze pads, and gauze wipes are used interchangeably throughout the protocol. We suggest using the same term consistently throughout the protocol.
- Clarify the amount of paint applied to the hands of each subject. *Section 6A, Risks to Subjects, page 11, paragraph 1* states" The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint..." Se*ction 8, Study Design, Overview, page 15, paragraph 3* states "Subjects assigned to group 1 will have each hand fortified with a 500µL volume of paint..." Per section 8A, the total exposure to the paint is 1.0 ml. *Section 8B, Removal Proficiency Procedure # 6* specifies the amount being applied, but does not state whether the amount is per hand or the combined amount for both hands.
- Clarify the number of samples per subject. Se*ction 8, Study Design, Overview, page 15, paragraph 5* indicates **two** samples per subject. This section states "The solution and gauze will be collected as a single sample for each hand..." On the other hand, *Section 8B, Removal Proficiency Procedure # 8* indicates **one** sample per subject. This section states "The subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges... The researchers will then rinse with the same solvent while the subject rubs their hands together."
- The protocol should address the possibility that a subject may withdraw before the end of the and under what circumstances the researchers would collect and analyze the samples.
- *Section 2, Summary; Section 8A, Study Design, Overview*; and *Section 8B, Removal Efficiency Procedure # 5* states the subjects will wash their hands with Ivory soap and water, and dry their hands using paper towels. The US EPA's Reregistration Eligibility Document for BIT states that BIT is used as an antimicrobial in Pulp and Paper Mill Systems and is commonly found in many consumer products including soap. This raises the possibility that the Ivory soap and paper towels used in the study could contain BIT, and that their use could leave measurable residues on the skin. Consider analyzing the soap and paper towels for the presence of BIT prior to use in the study.
- *Section 3, Rationale and Objective of the Study*. The study objective is to determine the removal efficiency of BIT from the hands. The study involves applying BIT in latex paint or

in isopropyl alcohol to the palms of research subjects. Because the "thick-skinned palmar surface of the hands will be exposed," subjects are expected to have limited absorption of BIT, and thus reduced dermal exposure (*Section 6A, Risks to Subjects, page 11, lines 9-11*). The removal of BIT from the palms may be significantly greater than from the back of the hands which have thinner skin than the palms. For this reason, the protocol may actually underestimate exposure because it will overestimate the removal efficiency of washing. Therefore, we suggest that this section include a discussion of why the palmar surface was selected over the thinner dorsal surface of the hand, or why not treat both the dorsal and palmar surfaces, since dermal characteristics may have an impact on the results.

- *Section 4, Rationale for Use of Human Subjects – page 9*. The protocol states "The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing the task." 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 5, Oversight of Ethical Conduct – page 10,* and *Section 19, Protocol Changes*.
  - 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 6A, Risks to the Subjects – page 11, line 6*. The referenced default body weight of 50 kg is low. U.S. EPA and DPR both use a default body weight value of 70 kg (EPA Exposure Factors Handbook). Consider revising the default body weight to 70 kg.
- Discrepancy in duration of exposure. *Section 6A, Risks to Subject – page 11, paragraph 2, line 23* states "exposure to one of the test substances will be limited to 30 minutes." *Section 8A, Study Design Overview – page 15, paragraph 5* states "The paint or solution will be left on the hands to dry for 45 minutes." The ICF Study Procedures # 5 also list the duration of exposure as 45 minutes. Revise this section to indicate exposure will be limited to 45 minutes.
- *Section 6A, Risks to the Subjects – page 11, paragraph 4*. "The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is quite low." Specify the potential damage that would be caused by the release of positive pregnancy findings. Alternatively, consider using a different word for "damage" in the sentence which probably refers to the consequences following the unintentional release of the positive pregnancy findings.
- *Section 7D, Test Substance, Safety Precautions – page 14*. 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 8B, Removal Proficiency Procedure # 8 – page 17*. 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 8B, Removal Proficiency Procedures # 8 – page 17.* 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 9Aii, Recruitment of Surrogate Workers – page 19, paragraph 4, line 6.* During the recruitment meeting, the investigator will ask the potential subjects some questions on the Subject Self-Reporting Demographic Form. Five questions deal with prior history of medical conditions that would exclude the subject from participating in the study. These medical conditions are listed in the exclusion criteria in Section 9Aiii. In addition to these questions, the protocol states "The investigator will ask the subject if he/she is taking any medication." There is no exclusion for subjects taking medication. If there are medications that would exclude the subject from participation, the list of medications should be included in the exclusion criteria. The protocol should explain why this question is being asked.
- *Section 9Aii, Recruitment of Surrogate Workers – page 20, 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, Recruitment of Surrogate Workers – page 21, paragraph 4.* 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 Sequence Number – page 23, paragraph 3; and Section 13A, Field Records – page 30.* Clarify storage of records. Section 9A 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 24.* 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, Field Recovery Evaluation – page 25.* To ensure there is no background contamination, include field blanks of the gauze wipes and the rinse solution.
- *Section 12B, Analytical Methods – page 28.* It is unclear from the analytical methods whether dried latex paint is soluble in isopropyl alcohol (the solvent used to clean the hands) and if the BIT can be separated from the latex paint matrix once it is dried. This information may be known, but not included in the protocol.

Informed Consent Form (ICF)

- 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.
- *Protocol section 9b, Subject Sequence Number, page 2* 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 Procedures 5 – page 45*. The procedure as written may not describe how the subjects will hold their hands during the application and drying period and may lead to concern about how to hold the hands upright for 45 minutes during the drying period. Suggest revising the second sentence from "We will ask you to place your hands upright on the table in front of you" to "We will ask you to place your hands on a padded surface on the table with your palms facing up."

II. Exposure Assessment

- None

III. Human Subject Protection/Ethical Considerations

Protocol

- None

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.
- *Risks 1 – page 45.* In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.

IV. Editorial Comments

Protocol

- Define acronyms when first used: QAU (page 31) and PR 2011-3 (page 32).
- *Section 2, Summary – page 8, paragraph 2, line 18*. Revise sentence to "...subjects rub their hands together."
- *Section 6A, Risks to the Subjects – page 10*. The Reregistration Eligibility Decision document is referenced as EPA, 2006a. Revise to EPA, 2005 as listed in *Section 22, References*.
- *Section 6D, Alternative Data Sources – page 12, lines 3 & 4; Section 7C, Alternative Data Sources – page 14, line 4.* Suggest replacing "actives" with "active ingredients."
- *Section 9Aii, Subject Recruitment – page 19, paragraph 4*. Revise form name to Subject Self-Reporting Demographic Form

- *Section 22, page 35.* The following references are not cited in the text of the protocol: AEATF II (2012, 2008); Gijsbers et al (2004); Popendorf et al (1992); and Ross et al (2008).

Informed Consent Form (ICF)

- *Questions about this Study – page 46, paragraph 1.* Suggest revising the sentence to: "If you have any questions, you may ask Megan Boatwright or any other member of the research team at any time – before, during, or after the study."
- *Questions about the Study – page 46, paragraph.* Revise the name of the IRB to Schulman Associates Institutional Review Board.

Experimental Subject's Bill of Rights

- *Page 48.* 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

rom:	Megan Boatwright
Sent:	Friday, January 24, 2014 3:49 PM
To:	'drichmond@cdpr.ca.gov'
Cc:	Rob Testman (rtestman@gplabs.com)
Subject:	Response to DPR Reviewof Protocol for the study "Determination of Removal.... "
Attachments:	CDPR letter 23Jan2014 - Response to review (130503).pdf; Protocol 130503 BIT Removal Effeciency 23Jan2014 Draft 4.docx

Hi Don,

Attached is a letter with responses to the CDPR comments on the removal efficiency 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.

Best Regards,

Megan

Megan T. Boatwright
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mboatwright@gplabs.com

Golden Pacific
LABORATORIES

January 23, 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 **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure."** 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 (559) 275-9091 or mboatwright@gplabs.com.

Sincerely,

Megan Boatwright

Megan T. Boatwright
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
The terms gauze sponges, gauze pads, and gauze wipes are used interchangeably throughout the protocol. We suggest using the same term consistently throughout the protocol.	Gauze sponge(s) is the correct term.	All references were changed to sponge(s) to make it consistent throughout the protocol.
Clarify the amount of paint applied to the hands of each subject. *Section 6A, Risks to Subjects, page 11, paragraph 1* states" The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint..." Se*ction 8, Study Design, Overview, page 15, paragraph 3* states "Subjects assigned to group 1 will have each hand fortified with a 500µL volume of paint..." Per section 8A, the total exposure to the paint is 1.0 ml. *Section 8B, Removal Proficiency Procedure # 6* specifies the amount being applied, but does not state whether the amount is per hand or the combined amount for both hands.	Section 6A and 8B will be updated to clarify the volumes are per hand as already done in section 8A.	Section 6A and 8B were changed to clarify the volumes are per hand.
Clarify the number of samples per subject. Se*ction 8, Study Design, Overview, page 15, paragraph 5* indicates **two** samples per subject. This section states "The solution and gauze will be collected as a single sample for each hand..." On the other hand, *Section 8B, Removal Proficiency Procedure # 8* indicates **one** sample per subject. This section states "The subjects will hold their hands over a stainless steel bowl while researchers scrub the hands with 2 gauze sponges... The researchers will then rinse with the same solvent while the subject rubs their hands together."	Section 8B Procedure #8 is wrong.	Section 8B Procedure #8 was changed to reflect collection per hand creating two samples.

CA DPR Comments	GPL Response	Protocol Modifications
The protocol should address the possibility that a subject may withdraw before the end of the and under what circumstances the researchers would collect and analyze the samples.	If a subject withdraws at any time prior to the 45 minutes, the samples will not be collected. The subject will be allowed to wash up and leave.	Statement added to section 9D Stop Criteria and Medical Management.
Section 2, Summary; Section 8A, Study Design, Overview; and *Section 8B, Removal Efficiency Procedure # 5* states the subjects will wash their hands with Ivory soap and water, and dry their hands using paper towels. The US EPA's Reregistration Eligibility Document for BIT states that BIT is used as an antimicrobial in Pulp and Paper Mill Systems and is commonly found in many consumer products including soap. This raises the possibility that the Ivory soap and paper towels used in the study could contain BIT, and that their use could leave measurable residues on the skin. Consider analyzing the soap and paper towels for the presence of BIT prior to use in the study.	During set up and preparation of the study the soap and towels will be screened for presence of BIT.	N/A

CA DPR Comments	GPL Response	Protocol Modifications
Section 3, Rationale and Objective of the Study. The study objective is to determine the removal efficiency of BIT from the hands. The study involves applying BIT in latex paint or surface of the hands will be exposed," subjects are expected to have limited absorption of BIT, and thus reduced dermal exposure (*Section 6A, Risks to Subjects, page 11, lines 9-11*). The removal of BIT from the palms may be significantly greater than from the back of the hands which have thinner skin than the palms. For this reason, the protocol may actually underestimate exposure because it will overestimate the removal efficiency of washing. Therefore, we suggest that this section include a discussion of why the palmar surface was selected over the thinner dorsal surface of the hand, or why not treat both the dorsal and palmar surfaces, since dermal characteristics may have an impact on the results.	Although paint can get on the backside of hands during painting activities, the majority of exposure is expected on the palmer side of the hand (fingers and palm). In addition, applying liquid paint to the backside of hands would increase risk of loss due to drips and run off. The palmar surface was thus considered more representative and more likely to produce reliable data.	N/A
Section 4, Rationale for Use of Human Subjects – page 9. The protocol states "The low toxicity of the test materials and low dermal penetration of BIT should mean that there is little incremental risk associated with performing the task." 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 regarding low dermal penetration will be deleted.	Modified Section 4 to remove reference to low penetration.

CA DPR Comments	GPL Response	Protocol Modifications
Section 5, Oversight of Ethical Conduct – page 10, and *Section 19, Protocol Changes.* - 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.	Both sections have existing statements covering the fact. Last paragraph of Section 5 and first paragraph of section 19	N/A
Section 6A, Risks to the Subjects – page 11, line 6. The referenced default body weight of 50 kg is low. U.S. EPA and DPR both use a default body weight value of 70 kg (EPA Exposure Factors Handbook). Consider revising the default body weight to 70 kg.	Section will be changed to reflect the default weight of CDPR and the EPA.	Section 6A was changed to a weight of 70 Kg and the calculated mg/Kg was recalculated and updated.
Discrepancy in duration of exposure. *Section 6A, Risks to Subject – page 11, paragraph 2, line 23* states "exposure to one of the test substances will be limited to 30 minutes." *Section 8A, Study Design Overview – page 15, paragraph 5* states "The paint or solution will be left on the hands to dry for 45 minutes." The ICF Study Procedures # 5 also list the duration of exposure as 45 minutes. Revise this section to indicate exposure will be limited to 45 minutes.	Typographical error in section 6A.	Section 6A corrected to correct time of 45 minutes.

CA DPR Comments	GPL Response	Protocol Modifications
Section 6A, Risks to the Subjects – page 11, paragraph 4. "The potential damage caused by release of positive pregnancy findings is very high, but the likelihood of this happening is quite low." Specify the potential damage that would be caused by the release of positive pregnancy findings. Alternatively, consider using a different word for "damage" in the sentence which probably refers to the consequences following the unintentional release of the positive pregnancy findings.	Sentence will be removed since issue was addressed in previous paragraph.	Deleted sentence from protocol.
Section 7D, Test Substance, Safety Precautions – page 14. 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 8B, Removal Proficiency Procedure # 8 – page 17. 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.	Procedure will be described with more detail.	Section 8B Procedure #8 was modified to add more details of how the procedure is done.

CA DPR Comments	GPL Response	Protocol Modifications
Section 8B, Removal Proficiency Procedures # 8 – page 17. 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 substance from the hands is a more complex system than dissolving neat compound. 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
Section 9Aii, Recruitment of Surrogate Workers – page 19, paragraph 4, line 6. During the recruitment meeting, the investigator will ask the potential subjects some questions on the Subject Self-Reporting Demographic Form. Five questions deal with prior history of medical conditions that would exclude the subject from participating in the study. These medical conditions are listed in the exclusion criteria in Section 9Aiii. In addition to these questions, the protocol states "The investigator will ask the subject if he/she is taking any medication." There is no exclusion for subjects taking medication. If there are medications that would exclude the subject from participation, the list of medications should be included in the exclusion criteria. The protocol should explain why this question is being asked.	The line about medicine was accidentally left in and will be removed from the protocol.	Line stating "The investigator will ask the subject if he/she is taking any medication and answer any questions" was deleted.

CA DPR Comments	GPL Response	Protocol Modifications
Section 9Aii, Recruitment of Surrogate Workers – page 20, 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.	Sentence will be updated to reflect this fact.	Section 9Aii sentence was updated to verify age not identity.
Section 9Aii, Recruitment of Surrogate Workers – page 21, paragraph 4. 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
Section 9B, Subject Sequence Number – page 23, paragraph 3; and Section 13A, Field Records – page 30. Clarify storage of records. Section 9A 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.

CA DPR Comments	GPL Response	Protocol Modifications
Section 9D, Stop Criteria and Medical Management – page 24. 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 sentence 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."
Section 10C, Field Recovery Evaluation – page 25. To ensure there is no background contamination, include field blanks of the gauze wipes and the rinse solution.	The duplicate control samples are collected and analyzed for that purpose.	Section was edited to better describe procedure.
Section 12B, Analytical Method – page 28. It is unclear from the analytical method whether dried latex paint is soluble in isopropyl alcohol (the solvent used to clean the hands) and if the BIT can be separated from the latex paint matrix once it is dried. This information may be known, but not included in the protocol.	Pre-study activities have demonstrated that BIT can be extracted from dried paint with solvent/water mixtures, including IPA/water.	N/A
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.	Will be added to Informed Consent form (ICF).	Added to ICF Consent Signature page.
Protocol section 9b, Subject Sequence Number, page 2 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.	Will add language to ICF.	Added the following language to ICF: "You may obtain a copy of your own records from the Principal Investigator upon request."

CA DPR Comments	GPL Response	Protocol Modifications
Study Procedures 5 – page 45. The procedure as written may not describe how the subjects will hold their hands during the application and drying period and may lead to concern about how to hold the hands upright for 45 minutes during the drying period. Suggest revising the second sentence from "We will ask you to place your hands upright on the table in front of you" to "We will ask you to place your hands on a padded surface on the table with your palms facing up."	Wording could be clearer so protocol will be edited.	Wording was edited as suggested by DPR.
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).
Risks 1 – page 45. In addition to the potential symptoms listed in this section, add headache and dizziness, which are indicated on the paint label.	Potential symptoms described on label will be added.	Risk 1 updated to include allergic reaction, dizziness and headache.
EDITORIAL COMMENTS Define acronyms when first used: QAU (page 31) and PR 2011-3 (page 32).	QAU will be defined at first use, however will not be changing PR 2011-3 since this is how the guideline is written/ referenced when not citing the entire title.	Protocol edited accordingly on page 31.
Section 2, Summary – page 8, paragraph 2, line 18. Revise sentence to "...subjects rub their hands together."	Description incorrect.	Sentence was edited to reflect correct actions.
Section 6A, Risks to the Subjects – page 10. The Reregistration Eligibility Decision document is referenced as EPA, 2006a. Revise to EPA, 2005 as listed in *Section 22, References.*	Dates do not agree, reference will be verified and corrected accordingly.	Updated text to 2005

CA DPR Comments	GPL Response	Protocol Modifications
Section *6D, Alternative Data Sources – page 12, lines 3 & 4; Section 7C, Alternative Data Sources – page 14, line 4.* Suggest replacing "actives" with "active ingredients."	Actives is slang and incomplete; will be replaced in all places with active ingredients.	Word "actives" was replaced with phase active ingredients.
Section 9Aii, Subject Recruitment – page 19, paragraph 4. Revise form name to Subject Self-Reporting Demographic Form	Missing Subject in title of form to keep consistency.	Section 9Aii was edited to add Subject to form title for consistency.
Section 22, page 35. The following references are not cited in the text of the protocol: AEATF II (2012, 2008); Gijsbers et al (2004); Popendorf et al (1992); and Ross et al (2008).	References verified if needed or not and removed accordingly.	Three references were removed, the others were kept.
Questions about this Study – page 46, paragraph 1. Suggest revising the sentence to: "If you have any questions, you may ask Megan Boatwright or any other member of the research team at any time – before, during, or after the study."	Wording is more complex than the ICF is supposed to be.	NA
Questions about the Study – page 46, paragraph. Revise the name of the IRB to Schulman Associates Institutional Review Board.	Typographic error.	Independent corrected to Institutional
Experimental Subject's Bill of Rights • Page 48. Revise the name of the IRB to Schulman Associates Institutional Review Board.	Typographic error.	Independent corrected to Institutional

***DRAFT* PROTOCOL**

~~01 November 2013~~23 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

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Proposed Experimental Start Date

April 2014

Testing Facility/ Study Location

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

Sponsor Study Identification

AEA08

GPL Study Number

130503

Total Number of Pages: 77

TABLE OF CONTENTS

List of Appendices

1. GENERAL INFORMATION

Study Title

Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Sponsor Study No: AEA08
GPL Study No: 130503

Objective

This study is being conducted to determine the removal efficiency of BIT from the hands due to dermal exposure associated with the use of latex paint containing BIT.

Proposed Experimental Start Date:	April 2014
Proposed Experimental Termination Date:	June 2014
Proposed Final Report Issue Date:	August 2014

Applicable Guidelines

This study is based upon the U.S. Environmental Protection Agency's (EPA) guidance documents for dermal exposure measurements under Series 875: Occupational and Residential Exposure Test Guidelines (875.1000, 875.1200 and 875.1600) and the OECD guidelines (OECD, 1997).

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 will 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. Not all citations for a particular 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
7E.1	Test and Reference Substances Analysis	7.0
8B.3	Hand Wash Samples	10.0
8C.2	Dermal Face/Neck Wipe Samples	10.0
8F.1	Sample Identification	10.0
10B.1	Packing, Handling and Shipping of Samples	10.0
10C.1	Worker and Study Observations	10.0
11A.1	Pregnancy Testing and Nursing Status	10.0
11B.1	Heat Stress	9.0
11C.1	Emergency Procedures	9.0
11F.0	Adverse Events Reporting to IRB	9.0

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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 produced by this study will allow the interpretation of results from a separate study measuring exposure of consumer painters who apply latex paint containing BIT. The data generated by testing BIT in solvent will better enable extrapolation of the BIT in paint data to other antimicrobial active ingredients. The data generated from these studies will be used by the EPA in assessing potential exposure and risks to users of paint containing antimicrobial products and will be used in developing exposure assessments and human health risk analyses. 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.

The test substances in this study are latex paint containing two concentrations of 1,2-benzisothiazoline-3-one (BIT), CAS No. 2634-33-5, and IPA containing BIT at two concentrations. The BIT in IPA will be tested with concentrations of approximately 786 µg/mL and 3.9 mg/mL. The latex paint will be tested with BIT concentrations of approximately 120 ppm and 600 ppm (mg/kg). The EPA does not require registration of paint making no claim of surface ~~protection,~~protection; therefore no EPA registration number is available for the paint. The BIT is added commercially using registered products such as Mergal® BIT20 (EPA Reg. No 5383-121). A copy of the product label for Mergal® BIT20 is attached as Appendix A. The paint test substance will be supplied in commercially available 1 gallon to 5 gallon paint cans, and is expected to have a BIT concentration of approximately 120 ppm as manufactured. Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher BIT concentration of approximately 600 ppm. The product label for the paint is provided in Appendix B.

All study participants will be adult subjects capable of 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. Twenty eight (28) qualified subjects will be recruited to participate in the study; twenty will participate in the study while eight will serve as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels. The subjects will be seated around a table with their hands resting on a padded surface. Latex paint containing BIT will be applied to the palmar surfaces of each hand of 10 subjects at one of two concentrations (5 subjects each). A small volume of solvent (IPA) containing BIT will be applied to the palmar surfaces of each hand of 10 other subjects at one of two concentrations (5 subjects each). After forty-five (45) minutes the surface of the hands will be cleaned using the hand wipe and wash procedure. Hand exposure will be measured by scrubbing the hands with gauze sponges soaked with a solution of 50% isopropyl alcohol/ 50% distilled water until all dried paint is loosened or removed, then rinsing with the same solvent while the subject rubs their ~~hands~~ fingers to their palm~~together~~. The gauze ~~pads~~ sponges will be added to the rinse solvent for extraction. The results from these subjects will allow accurate calculation of removal efficiency from the skin for BIT in IPA or latex paint, and correction of data from monitoring events (MEs) for this factor.

The study will be conducted at GPL in the conference room, having adequate facilities to support the study (working HVAC, working restrooms, seating, etc.).

The hand wipe/wash solutions will be analyzed for residues of BIT using a validated analytical method.

3. RATIONALE AND OBJECTIVE OF THE STUDY

The hands, along with ones clothes, are the most likely part of the body to be exposed to paint while painting walls, ceilings, doors and trim. It is important to determine the removal efficiency of the anti-microbial on the hands using the same wipe/wash procedure to be used during AEATF painter exposure monitoring studies. The data generated by testing BIT in solvent will better enable extrapolation of the paint data to other antimicrobial active ingredients. The primary objective of this study is to determine the removal efficiency of BIT in latex paint, and in IPA from human hands.

4. RATIONALE FOR USE OF HUMAN SUBJECTS

Human subjects are required in this study because they will normally be exposed to the antimicrobial chemicals when performing painting activities. In-vitro models are unlikely to capture the variability of performing the wipe/wash procedure on human subjects, and will reduce the ability to extrapolate data from existing human hand removal efficiency studies. In this study, at least 20 subjects (5 for each scenario) will be monitored in order to capture the expected variation in skin differences, concentration, and paint or solvent as a carrier of the BIT. Data is not available from other studies to allow accurate estimation of the dermal removal efficiency of BIT using the study techniques. The low toxicity of the test materials ~~and low dermal penetration of BIT~~ should mean that there is little incremental risk associated with performing this task.

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 found in paint, adhesives, caulking, ink and many other consumer products, 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, a copy of the product labels (Appendices A and B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), the latex paint and BIT reference 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 RED for BIT summarizing its risk assessment conclusions

(Appendix H). The documents utilized with subjects (Appendices B, C, D, E, F, G) will be available in English and Spanish. Following approval by SAIRB, the Study Protocol, approved Informed Consent Form 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. Deviations will be reported in writing by letter, fax or email as soon as possible following the change. 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.

Using the best existing data available to EPA from the Pesticide Handlers Exposure Database (PHED; EPA, 1998) the Agency estimated risk to individuals applying BIT in paint in the Reregistration Eligibility Decision document (EPA, 2006a). 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 routes assuming an absorbed dermal dose of 0.13 mg/Kg/day, and determined the dermal margin of exposure (MOE) was 3.7x greater than the target MOE. The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.~~009~~006 mg/Kg for a ~~50~~70 Kg subject. This is much less than the dermal exposure assumed by EPA for residential painters. Thus, the subjects involved in this study will have a greater MOE than the targeted MOE. Subjects' exposure will be further reduced since only the thick-skinned palmar surface of the hands will be exposed to BIT potentially limiting ~~absorbtion~~absorption.

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, cleaning products, ink, adhesives, caulking, and paint. The EPA has re-registered BIT and issued a RED (EPA, 2005). Additionally, the safety of latex paint has been established through long term household and professional use of the product. Any subject with a known allergic reaction to latex paint or rubbing alcohol will be excluded from participating. At high concentration, BIT can produce dermal irritation, but this is not commonly seen at dilutions used in this study. Latex paint can cause dermal irritation but subjects with known allergies will be excluded. Significant risks associated with paint or solvent ingestion by subjects is very unlikely and would require gross intentional mishandling by subjects. Actual chemical risk during the study is lower than when conducting painting activities at home. Irritation due to rubbing (isopropyl) alcohol used on the hands can occur if the subjects have existing abrasions or skin conditions that reduce barrier properties of the skin, (e.g., eczema or psoriasis), however subjects with these conditions will be excluded from the study. Subjects' actual duration of exposure to one of the test substances will be limited to ~~30~~45 minutes. Subjects will be closely observed by a study staff member. The protocol and Informed Consent will be reviewed by an IRB prior to enrolling subjects.

Females of child-bearing age may be surprised by the outcome of the required pregnancy test.

The likelihood of exposure to low levels of BIT in this study is very high. Exposure to rubbing alcohol is uniformly high, but the low toxicity coupled with exclusion of subjects with prior abrasions or skin conditions reduces risk to low levels. ~~The potential damage caused by release of positive~~

~~pregnancy findings is very high, but the likelihood of this happening is quite low.~~ 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.

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. Society may benefit from continued ability to use antimicrobials that improve the quality of life. Measuring removal efficiency in this research study will produce reliable data about the dermal 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. 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, bacteria 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. Alternative Data Sources

Data demonstrating removal efficiency of BIT in paint or solvent from human skin is not available. Removal efficiency studies which have been conducted with other active ingrediaents do not provide for interpretation of BIT removal, or the removal of any ~~actives~~ active ingredients in a latex paint matrix. This is critical information for appropriate risk assessment. The use of in-vitro models may not produce accurate data due to the complex interactions of temperature, moisture, and movement of skin which can impact both the drying and removal characteristics of the test substance.

7. TEST SUBSTANCE

The test substances for this study are the formulated product, Sherwin-Williams latex paint (referred to as SW latex paint in this protocol), containing

1,2-benzisothiazoline-3-one (BIT) and BIT prepared in isopropyl alcohol (IPA). BIT is the active ingredient selected for measurement in the proposed paint applicator exposure studies, based on its stability, abundance in the formulation, and sensitivity of its analytical method. GLP purity analysis (content of active ingredient in each test substance concentration) will be performed by the testing facility prior to its use in the study. Retained samples from each lot of test substance used in the study will be archived at GPL.

A. Test Substance Identification - BIT in Paint

Product Name:	Sherwin-Williams Latex Paint A86W00151
Manufacturer:	Sherwin-Williams Paint Co. (Cleveland, OH)
EPA Reg. No.:	N/A
Active Ingredient:	BIT
CAS Number:	[2634-33-5] – BIT
Composition:	ca. 120 ppm (mg/kg) and 600 ppm BIT in latex paint
Lot No.:	to be recorded in the raw data

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 a second BIT concentration of approximately 600 ppm.

B. Test Substance Identification – BIT in Solvent

The reference substance 1,2-Benzisothiazol-3(2H)-one (BIT) will be prepared at approximately 786 µg/mL and 3.9 mg/mL using isopropyl alcohol (HPLC grade) as the dilution solvent.

Name:	1,2-Benzisothiazol-3(2H)-one (BIT)
CAS Number:	[2634-33-5]
Active Ingredient:	BIT
Lot Number:	to be recorded in the raw data
Purity:	to be recorded in the raw data
Date Received:	to be recorded in the raw data
Expiration Date:	to be recorded in the raw data

C. 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.

BIT in solvent will be used as a second test substance in order to provide comparative removal efficiency information between a paint matrix and solvent. This information will be used to improve extrapolation of data for other active ingredients which may have removal efficiency data in solvent to a paint matrix.

The analytical method for the determination of BIT in hand wipe/wash samples at very low concentrations will be validated (GPL Study 130478) prior to its use in this study. The validation study will also evaluate the freezer storage stability of BIT in hand wipe/wash samples. The limit of quantitation (LOQ) for hand wipe/wash samples is 1.0 ng/mL.

D. Safety Precautions

Copies of the Materials Safety Data Sheets (MSDS) for SW latex paint and BIT and the SW latex paint 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 paint product label (English or Spanish, as requested) will be provided to each subject, and each subject will be made aware of the MSDS and copies in the preferred language will be provided upon request. Label safety cautions will be explained to the subjects involved in the study.

Test substance on the skin will be removed and following completion of collection, each subject will wash their hands thoroughly with soap and water. The Principal Investigator or designee 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.

E. Calibration of Application Equipment

BIT in paint or solvent will be applied to hands using positive displacement micropipettes, which are sent out annually to the factory for calibration. The testing facility will verify the amount of test substance delivered by the micropipettes by weighing at least 5 aliquots to determine accuracy and precision of delivery. The Study Director will be informed of the verification results prior to use of the micropipettes with the subjects.

F. Test Substance Storage

The test substance will be stored at room temperature. Storage will be at Golden Pacific Laboratories.

8. STUDY DESIGN

A. Overview

This study will measure the removal efficiency of BIT from the palmar surface of hands after treatment with BIT in paint or IPA.

Twenty-eight (28) qualified subjects (see Section 9.a.iii for Inclusion/Exclusion Criteria) will be recruited for the study; of these 20 will be selected to participate in the study and 8 will be retained as alternates. Both the left hand and the right hand of each subject will be used during the study. The subjects will first wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands with clean paper towels.

Each subject will be placed into one of four groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing approximately 600 ppm BIT. Subjects assigned to group three will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 786 µg/mL in isopropyl alcohol (IPA). Subjects assigned to group four will have each hand fortified with a 100 µL of a fortification solution of BIT targeted to be at a concentration of 3.9 mg/mL in isopropyl alcohol (IPA). Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.

The subjects will be seated during application and drying periods with their hands placed on a padded surface on a table. The appropriate volume of the assigned carrier and test substance will be aliquoted onto the palmar side of the hand using a positive displacement pipette and spread over the palmar surface with a glass capillary tube. The glass capillary tube will be placed into a glass test tube and retained for analysis.

The paint or solution will be left on the hands to dry for 45 minutes. Each hand will then be washed by scrubbing with a gauze ~~wipe~~ sponge soaked in 50% IPA / 50% distilled water solution and rinsed with the same solution. The solution and gauze ~~wipe~~ sponge will be collected as a single sample for each hand, extracted and analyzed.

Procedures for the assignment of subjects into groups are described in the following sections (8.C and 8.D). Procedures for the recruitment, selection, compensation, and possible withdrawal of subjects are described in Section 9.

B. Removal Efficiency Procedure

The removal efficiency procedure will be conducted at Golden Pacific Laboratory's office in Fresno County, California. Monitoring of each subject is expected to take a maximum of 1.5 to 2 hours on a single day. This includes discussion with the study director prior to initiation, and all study procedures.

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. The Principal Investigator or on-site health professional will check subject's hands for any cracking, bleeding, sores, or other disqualifying skin problems.

4. 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. In the case of a positive test the subject will not participate in the study, but will be paid $100 for her inconvenience and will be free to go. A note indicating that the pregnancy test was performed in accordance with SOP AEATF II-11A.1 will be made in the raw data for each female subject.

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

6. The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, e~~E~~ither a 500 µL volume of the appropriate paint concentration or a 100 µL volume of the appropriate solvent concentration will be applied. A glass capillary tube will be used to spread the test substance across the center of the palmar surface, but test

substance will not be spread closer than 2 cm from any edge of the palmar surface. The capillary tube from each subject will be placed into a glass test tube and stored frozen prior to analysis.

7. The subjects will be asked to sit quietly with their hands resting on a padded surface on a table for 45 minutes. A television or similar entertainment will be provided. Study personnel will continuously be present to monitor and respond to any subject requests. On-site medical personnel will be available to assist with any subject concerns.

8. After 45 minutes the subjects will hold their hand~~s~~ over a stainless steel bowl while researchers scrub the hand~~s~~ with ~~2~~ a gauze sponge~~s~~ (J&J Mirasorb 4-ply each) ~~stacked together~~. The gauze sponge~~s~~ 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 the hand with the same solvent ~~while the subject rubs their hands together~~by pouring the solvent ~~e~~over the hand and having the subject rub their fingers and palm together. The total volume of IPA/water solution used will be ~~500~~ 250 mL. The used gauze sponge~~s~~ will be added to the hand wash solution ~~containers~~collected in the stainless steel bowl and saved with the rinse solution for analysis. The procedure will then be repeated for the second hand producing a second sample.

9. The subjects will be asked to again wash their hands with soap and water, and dry them with paper towels.

10. 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.

C. Assignment of Carrier and Amount of Active Ingredient

In this study, subjects will be assigned into four groups. Two groups will receive BIT applied in paint, and two groups will receive BIT applied in IPA. The four groups are described below (amounts per hand):

Group 1	500 µL of latex paint containing ca. 120 ppm BIT
Group 2	500 µL of latex paint containing ca. 600 ppm BIT
Group 3	100 µL of ~ 786 µg/mL fortification solution of BIT in IPA
Group 4	100 µL of ~ 3.9 mg/mL fortification solution of BIT in IPA

D. Random Selection and Assignment of Subject to Groups

The total number of qualified subjects will each be assigned a unique and consecutive number, starting at RE-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 28 numbers in the generated randomized list will determine the participating subjects, while the remaining subjects will be held as alternates, their order for potential entry into the study being determined by the randomization process. The 28 subjects for the groups will be split into four groups, each corresponding to one of the four test substance/concentration combinations. The first set of seven subjects will be placed into Group 1, the second set of seven subjects will be placed into Group 2, the third set of seven subjects will be placed into Group 3, and the fourth set of seven subjects will be placed into Group 4.

Within each group of seven, the first five subjects will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the group of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.

Once the subjects have been randomized into four groups, subjects from the first group will be scheduled into the study. No more than two groups will be monitored in one day. The randomization process will prevent bias.

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

Twenty-eight subjects are required for this study to participate in determining the removal efficiency. This includes the planned 20 participants needed for the target design (i.e., five subjects for each of four groups). As described above, an additional eight subjects (two per cluster) are included as insurance against subject withdrawal or other failure to complete the assigned palmar application (see 8.D).

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

SAIRB approved recruiting advertisements (appendix F) 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 Spanish language weekly 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 2 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 SAIRB approved script (Appendix G). 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 ask the subject if he/she is taking any medication and 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 SAIRB approved Informed Consent including the Experimental Subject's Bill of Rights Form (Appendix C) and answer their 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 B), 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,~~age for inclusion in the study and review the package of information provided for completeness against the protocol's inclusion/exclusion criteria. 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. Volunteers who lack proper identification will not be enrolled in the study. No other action will be taken.

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 randomized. The random order will be used to accept participants into the study and assign participants to specific groups.

The recruitment process will terminate when at the end of the 2 week recruitment time period a minimum of 28 subjects have been recruited for the study, that is, have agreed to participate and signed the Informed Consent including the Experimental Subject's Bill of Rights Form. If fewer than 28 subjects have been recruited during the 2 weeks open recruitment period, the enrollment period will be extended in 7 days increments, until at least 28 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. 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 as verified by a government issued photo ID
- Consider their self to be in good health
- 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

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 or sensitivities 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)
- 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.

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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

After 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. The Principal Investigator or on-site health professional will discuss the symptoms of skin reactions with the subjects prior to participation in the study. Subjects will be instructed to inform the Principal Investigator or research staff immediately if they feel ill, suffer a~~n~~ 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 research personnel 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 skin reaction during the study period, research staff will immediately request the on-site health professional to evaluate the skin reaction. If appropriate, 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 or on-site health professional will be contacted for further 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. Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.

If a monitoring event is terminated early due to medical reasons or the subject withdraws for any reason, ~~any~~ samples from the subject will not be collected. ~~not be analyzed~~ Research staff will assist the subject in gently washing exposed skin with clean water and mild soap.~~.~~

Study personnel will be instructed to inform the Principal Investigator immediately of any skin reactions, 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 is treated for medical reasons, 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

A. Preparation of the Surface of the Hands

Prior to applying a test substance to the hand and performing the hand wipe and wash, a standard procedure will be used to clean the hands. All subjects will wash their hands with liquid Ivory soap, rinse their hands with water and dry their hands using clean paper towels at least 5 minutes before the test substance application. The palmar surface of subject's hands will not come in contact with any surface between washing and completion of the monitoring event. Each subject will sit in the climate-controlled room prior to the application and until the hand-wiping procedure is completed.

B. Environmental Monitoring

Air temperature and relative humidity of the room for the duration of the 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.

C. 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 (hand wipe/wash solutions containing gauze ~~wipes~~sponges) will take place on each day of the study. Field fortification solutions of BIT in latex paint or in solvent will be prepared at the appropriate concentrations, or aliquots of the study test substances may be used.

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.

An aliquot of each field fortification solution will be added to the ~~hand wash~~matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm
IPA	100 µL	Approximately 786 µg/mL
IPA	100 µL	Approximately 3.9 mg/mL

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix~~hand wash~~ samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

~~Hand wash~~Field fortification samples will be fortified and will remain at ambient temperature for at least 1 hour before being placed into frozen storage. Samples will then be maintained in frozen storage until analyzed.

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 AEA08-RE-01-PL-LH:

AEA08 = Task Force Study Number
RE = Removal Efficiency
01 = Subject 01
P = Paint
L = Low Concentration
LH = Left Hand
Additional designations are as follows:
S = Solvent
H = High Concentration Level
RH = Right Hand

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. Shipping

Samples will not be shipped.

C. Storage

All samples will be placed into frozen storage within 1 hour of collection. The samples will be stored in a freezer maintained at ≤ -10°C until analyzed.

12. ANALYTICAL PROCEDURES

Removal efficiency samples and field recovery samples will be analyzed according to the analytical method specified in Section 12.B. of this protocol. The methodology will be validated for use in the relevant matrix before the start of this study.

A. Reference Substance, Fortification Solution, and Internal Standard

i. Reference Substance

The reference substance for this study is the 1,2-Benzisothiazol-3(2H)-one (BIT) used by the analytical laboratory to add BIT to the test substances, prepare calibration standards (HPLC/MS/MS) and prepare fortification solutions used to fortify field and 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 was obtained from Troy Chemical Company. Receipt of the reference substance was 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 provided by 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 the study samples will be conducted at Golden Pacific Laboratories using HPLC/MS/MS. The HPLC/MS/MS method will be validated by GPL and is extremely sensitive and selective, allowing for very low detection limits. The limit of quantification (LOQ) for the hand wash solutions containing gauze ~~wipes~~ sponges is 1.0 ng/mL. 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 method will be followed as rigidly as possible. No changes are permitted without prior approval of the Principal Investigator. All data will be measured against a standard curve (five point minimum, one of which will be at <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 at the beginning of each run.

Each analytical set will include two laboratory fortified samples, and a control. The fortification levels will bracket the expected levels in the field samples.

Hand wipe samples will be analyzed following the method documented in 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).

An aliquot of the hand wash sample will be transferred to a chromatography vial, an equal amount of internal standard solution will be added, and analyzed using HPLC/MS/MS. Samples may require dilution using 50% acetonitrile /50% water, prior to vialing and analysis.

The latex paint test substances will be analyzed following GPL-MTH-079. The IPA test substances will be analyzed by diluting to an appropriate concentration with 50% acetonitrile /50% water, vialing with internal standard, and analyzing by HPLC/MS/MS. The capillary pipets used in dosing will be analyzed using the method for latex paint, with modifications as necessary approved by the Principal Investigator.

Field fortification samples will be analyzed along with the corresponding study samples from the same test day.

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. Sample Quantification

Chromatographic quantification (using HPLC/MS/MS) will be achieved using an internal standard and a standard curve obtained from peak areas from 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.

Determined concentrations in study samples will be corrected for the average recovery of corresponding field fortification samples analyzed in the same analytical set, as long as the average field fortification recovery is <100%.

D. Data Analysis

At the end of the study, a complete report will be prepared. The results of the study will include (1) the application amount of the test substance and BIT on the palm of the hand, (2) the amount of BIT found in the wipe solution samples and (3) the percent of BIT that can be removed from the surface of the skin. Residues of BIT found on the capillary tubes used during application will be subtracted from the amount applied to determine

a corrected amount applied. Percent removal efficiency will be calculated as the amount of compound removed from the skin by the wipe/wash procedure, divided by the corrected total amount of compound applied to the skin times 100.

Statistical procedures planned for use in this study include the calculation of means of replicate analyses and the standard deviations. Linear regression may be used in generation of calibration curves. All statistical techniques used will be fully described in the final report.

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. Temperature and relative humidity in the testing area each day of monitoring;
4. Subjects' Self-Reporting Demographic Forms, Informed Consent including Experimental Subject's Bill of Rights Form, maintained apart from other raw data in a secure archive marked confidential;
5. Test substance temperature records;
6. Sample information (including inventory, chain of custody);
7. 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, facility records will be maintained and archived at GPL. True copies of certain facility records will be included with the raw data such as:

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 paint label (Appendix B), the Informed Consent including Experimental Subject's Bill of Rights Form (Appendix C), the Subject Self-Reporting Demographic Form (Appendix D), paint MSDS and BIT reference substance MSDS (Appendix E), as well as all recruiting materials, such as newspaper advertisements (Appendix F), interview scripts (Appendix G), and an executive summary of EPA's REDs for BIT summarizing their risk assessment conclusions (Appendix H). 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.

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.

B. Statistical Methods

Proposed calculations are limited to the calculations specified in Section 12.D.

16. QUALITY ASSURANCE

This study will be conducted according to FIFRA GLP Standards (40 CFR 160). The facility will be inspected by the Quality Assurance Unit (QAU). The QAU will report to the President of Golden Pacific Laboratory. The QAU will review the protocol prior to study initiation. Different phases of the study and 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 sample extracts 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 monitoring period(s).

2. A detailed summary of the amount of test substance applied to each subject hand.
3. A detailed summary of the length of time each subject was monitored (application and removal times).
4. A complete description of collection, handling and storage of field samples.
5. Results of analysis.
6. A detailed description of the methods.
7. Example calculations.
8. A summary of the recovery data.
9. Representative chromatograms of control, treated, fortified samples and calibration standards.
10. A typical standard curve.
11. The signed protocol, including all amendments and deviations.
12. All correspondence between the IRB and Principal Investigator, including information sent to the IRB to support the protocol.
13. A copy of the IRB approval documentation and a copy of the approved Informed Consent Form.
14. Any adverse findings and the nature and magnitude of every event.
15. All correspondence with Cal DPR regarding Section 6710.

19. PROTOCOL CHANGES

Protocol changes (amendments and deviations) shall be reported to the SAIRB 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. Protocol amendments will be signed by the Principal Investigator and reported to the Sponsor Representative.

B. Deviations

Unplanned changes (deviations) which occur during conduct of the study cannot, by definition, be reviewed and approved by the IRB prior to implementation. Protocol deviations will be signed by the Principal Investigator and reported to the Sponsor Representative. Deviations relating to human subjects will be reported to SAIRB and CDPR in writing by letter, fax or email as soon as possible following the change.

21. PROTOCOL APPROVALS

Has Shah, Ph.D. Date
Sponsor's Representative

Megan T Boatwright, B.S. Date
Study Director/ Principal Investigator
Golden Pacific Laboratories, LLC

Robert J. Testman, M.B.A. Date
Testing Facility Management
Golden Pacific Laboratories, LLC

Protocol reviewed by:

Margaret A. Hamelin, B.S. Date
Quality Assurance
Golden Pacific Laboratories, LLC

22. REFERENCES

AEATF II (Antimicrobial Exposure Assessment Task Force II). 2012. 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 MERGAL® BIT20

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes, on skin or 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. Also consider pulmonary edema, 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:
1,2-Benzisothiazolin-3(2H)-One ..... % Weight 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, NJ 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. Usage rates will vary depending upon the specific product and conditions. Typical usage rates for industrial and institutional products to control growth of bacteria and fungi. Suggested rate is 0.05-0.25% w/w of *Mergal* BIT 20 in the finished product. For example, use 0.5-2.5 lbs. of *Mergal* BIT 20 per 100 gallons 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 aqueous and fatty foods. Use of *Mergal* BIT 20 must not exceed 0.31 mg/in.² (0.0166 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 regulations in 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 STERILIZATION (c)(4)(ix)

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-0.01-0.15% 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 B: LABEL FOR SHERWIN WILLIAMS LATEX PAINT

SHERWIN WILLIAMS.

101.02

SUPERPAINT®

Interior Latex
Flat
A86-100 Series

As of 12/01/2012 Complies with:			
OTC	Yes	LEED09 CI	Yes
SCAQMD	Yes	LEED09 NC	Yes
CARB	Yes	LEED09 CS	Yes
CARB SCM2007	Yes	LEED09 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 SCR/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

APPENDIX C: INFORMED CONSENT INCLUDING SUBJECT'S BILL OF RIGHTS FORM

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

Principal Investigator:
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:
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 (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

Sponsor: Antimicrobial Exposure Assessment Task Force II (AEATF II).

24-Hour Phone Number: 559-917-1736 (Megan Boatwright)

We're asking you to think about being in a research study. 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 is removed from the surface of your palm when a small amount of interior latex paint or rubbing (isopropyl) alcohol containing the chemical is applied to each of your hands and allowed to sit for 45 minutes. We will measure how much chemical can be removed from your hands by rinsing and scrubbing your hand with a gauze ~~wipe~~ sponge soaked with a solution of isopropyl alcohol (IPA) and water. 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 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 is paying for this study. They are called the Antimicrobial Exposure Assessment Task Force II. These products are registered by the EPA as pesticides.

Megan Boatwright, Thomas Moate and Natan Chavez are with Golden Pacific Laboratories. Megan Boatwright is in charge of the study. Thomas Moate 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 BIT in rubbing alcohol. You will be given a copy of the product label for the paint. We will also give you the Material Safety Data Sheet or "MSDS" for the paint and the BIT chemical, 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 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; 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.

Twenty people will be in this study, and eight people will be selected as alternates in case anyone can't participate on the day of the test.

We will do the study at Golden Pacific Laboratories at 4720 W. Jennifer Ave., Suite 105, in Fresno. You can be in the study only once. If you are an 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, 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 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.

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.

Study Procedure

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.

2. Megan Boatwright 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 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.

4. Before the test begins you will wash your hands 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. We will ask you to be seated in a chair and make sure you are comfortable. We will ask you to place your hands ~~upright on the table in front of you~~on a padded surface on the table with your palms facing up. We will place a small amount of paint or rubbing alcohol on the palm of each of your hands, and then ask you to keep your hands upright on the table for 45 minutes. After 45 minutes we will scrub your hands one at a time with gauze ~~pads~~ sponges wet with a rubbing alcohol and water mixture, rinse them with the same mixture, and save the rinse water.

6. When we have collected the hand wipe samples, you will wash your hands again with soap and water. 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 few kinds of risks:

1. Risk of a reaction to the latex paint. Direct contact with the paint can cause temporary itching 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 might also have an allergic reaction to the paint, feel dizzy, or develop 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, have a headache, or if you have any other discomfort, tell a researcher.

2. Risk of skin irritation from the rubbing alcohol and water mixture, and wipes. The diluted rubbing alcohol used to scrub and rinse your hands may sting if you have any cuts or abrasions on your hands that were too small to see before the study started.

3. 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, Megan Boatwright, 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. 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 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 Megan Boatwright 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.

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, the Principal Investigator in charge of this study, can remove you from this study even if you would like to stay in it. She might remove you if, for example:

- She thinks staying in the study could put you at risk.
- You fail to follow the instructions of the researchers.
- The study is stopped 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~~* 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: Megan Boatwright (559) 275-9091

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: _____ _____
Megan Boatwright
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 AEA08: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using Isopropyl Alcohol/ Water Wipe and Wash Procedure

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*				
6. Name				
7. Address				
8. City, ST, Zip				
9. Telephone(s)				
10. Age in years =	11. DOB:	12. Sex M F		
13. Resident in Fresno County? Yes No				
14. Preferred Language: English Spanish	15. Reads: English Spanish			
16. Are you pregnant? NA Yes No	17. Are you nursing a baby? NA Yes No			
18. Do you consider your general health good? Yes No				
19. Are you bothered by house paint smell or house paint on your skin more than family or friends? Yes No				
20. 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 AND BIT REFERENCE SUBSTANCE

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.

SIGMA-ALDRICH

sigma-aldrich.com

Material Safety Data Sheet

Version 4.2
Revision Date 10/05/2012
Print Date 05/30/2013

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	1,2-Benzisothiazol-3(2*H*)-one
Product Number	:	561487
Brand	:	Aldrich
Supplier	:	Sigma-Aldrich 3050 Spruce Street SAINT LOUIS MO 63103 USA
Telephone	:	+1 800-325-5832
Fax	:	+1 800-325-5052
Emergency Phone # (For both supplier and manufacturer)	:	(314) 776-6555
Preparation Information	:	Sigma-Aldrich Corporation Product Safety - Americas Region 1-800-521-8956

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazards
Harmful by ingestion., Skin sensitiser, Irritant

GHS Classification
Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Serious eye damage (Category 1)
Skin sensitization (Category 1)
Acute aquatic toxicity (Category 1)

GHS Label elements, including precautionary statements

Pictogram

Signal word Danger

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Precautionary statement(s)

P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

HMIS Classification

Health hazard:	2
Flammability:	0
Physical hazards:	0

NFPA Rating

Health hazard:	2
Fire:	0
Reactivity Hazard:	0

Potential Health Effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.
Ingestion	Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula : C_7H_5NOS

Molecular Weight : 151.19 g/mol

Component		Concentration
1,2-Benzisothiazolin-3-one		
CAS-No.	2634-33-5	-
EC-No.	220-120-9	
Index-No.	613-088-00-6	

4. FIRST AID MEASURES

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIREFIGHTING MEASURES

Conditions of flammability
Not flammable or combustible.

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Hazardous combustion products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage
Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	crystalline
Colour	light yellow

Safety data

pH	no data available
Melting point/freezing point	Melting point/range: 154 - 158 °C (309 - 316 °F) - lit.
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Autoignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Vapour pressure	no data available
Density	no data available
Water solubility	no data available

Partition coefficient: n-octanol/water	no data available
Relative vapour density	no data available
Odour	no data available
Odour Threshold	no data available
Evaporation rate	no data available

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
no data available

Conditions to avoid
no data available

Materials to avoid
Strong oxidizing agents

Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Sulphur oxides
Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral LD50
LD50 Oral - rat - 1,020 mg/kg

Inhalation LC50
no data available

Dermal LD50
no data available

Other information on acute toxicity
no data available

Skin corrosion/irritation
no data available

Serious eye damage/eye irritation
no data available

Respiratory or skin sensitization
May cause allergic skin reaction.

Germ cell mutagenicity
no data available

Carcinogenicity

IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Teratogenicity

no data available

Specific target organ toxicity - single exposure (Globally Harmonized System)
no data available

Specific target organ toxicity - repeated exposure (Globally Harmonized System)
no data available

Aspiration hazard
no data available

Potential health effects

Inhalation	May be harmful if inhaled. Causes respiratory tract irritation.
Ingestion	Harmful if swallowed.
Skin	Harmful if absorbed through skin. Causes skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects
no data available

Additional Information
RTECS: DE4620000

12. ECOLOGICAL INFORMATION

Toxicity

Toxicity to fish	LC50 - Oncorhynchus mykiss (rainbow trout) - 0.8 mg/l - 96.0 h
Toxicity to daphnia and other aquatic invertebrates	EC50 - Daphnia magna (Water flea) - 4.4 mg/l - 48 h

Persistence and degradability
no data available

Bioaccumulative potential
no data available

Mobility in soil
no data available

PBT and vPvB assessment
no data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life.

13. DISPOSAL CONSIDERATIONS

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (1,2-Benzisothiazolin-3-one)
Marine pollutant: Marine pollutant

IATA
UN number: 3077 Class: 9 Packing group: III
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (1,2-Benzisothiazolin-3-one)

Further information
EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.

15. REGULATORY INFORMATION

OSHA Hazards
Harmful by ingestion., Skin sensitiser. Irritant

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

New Jersey Right To Know Components

	CAS-No.	Revision Date
1,2-Benzisothiazolin-3-one	2634-33-5	

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

APPENDIX F: NEWSPAPER ADVERTISEMENTS SOLICITING RESEARCH SUBJECTS

VOLUNTEER SUBJECTS WANTED

Seeking volunteers for a research study evaluating exposure to an anti-microbial in paint or rubbing alcohol on surface of hands. Volunteers will be compensated a total of up to $120 for their inconvenience.

Please contact Megan Boatwright (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: 5/30/2013

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 removal efficiency 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 removed from the palms of your hand when paint or rubbing alcohol containing the chemical BIT is put on your hands and dried for 45 minutes. We will measure how much of the chemical is in the hand wash solution used to clean your hands.

The test product will be SHERWIN-WILLIAMS LATEX PAINT. It is used to paint interior surfaces such as walls and moldings.

The study itself will take about an hour and a half to two hours of your time. We will ask you to come to the laboratory, sit in a chair with your hands palm side up on a table. We will put paint or rubbing alcohol on the palms of your hands. You will sit there for 45 minutes while it dries. We will then clean your hands with rubbing alcohol and water and scrub the hands with a gauze ~~wipe~~sponge. We will collect the wash water and gauze ~~wipe~~sponge. Then we will pay you and you are free to go.

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, Megan Boatwright. 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 Megan Boatwright 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:
vii

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

All samples will be labeled with the study number and date of collection in addition to the sample identification code.

Hand Wipe Samples

Sample Identification	Subject Number	Hand	Target BIT Concentration
AEA08-RE-01-PL-LH	1	Left	120 ppm
AEA08-RE-01-PL-RH	1	Right	120 ppm
AEA08-RE-02-PL-LH	2	Left	120 ppm
AEA08-RE-02-PL-RH	2	Right	120 ppm
AEA08-RE-03-PL-LH	3	Left	120 ppm
AEA08-RE-03-PL-RH	3	Right	120 ppm
AEA08-RE-04-PL-LH	4	Left	120 ppm
AEA08-RE-04-PL-RH	4	Right	120 ppm
AEA08-RE-05-PL-LH	5	Left	120 ppm
AEA08-RE-05-PL-RH	5	Right	120 ppm
AEA08-RE-06-PH-LH	6	Left	600 ppm
AEA08-RE-06-PH-RH	6	Right	600 ppm
AEA08-RE-07-PH-LH	7	Left	600 ppm
AEA08-RE-07-PH-RH	7	Right	600 ppm
AEA08-RE-08-PH-LH	8	Left	600 ppm
AEA08-RE-08-PH-RH	8	Right	600 ppm
AEA08-RE-09-PH-LH	9	Left	600 ppm
AEA08-RE-09-PH-RH	9	Right	600 ppm
AEA08-RE-10-PH-LH	10	Left	600 ppm
AEA08-RE-10-PH-RH	10	Right	600 ppm
AEA08-RE-11-SL-LH	11	Left	786 µg/mL
AEA08-RE-11-SL-RH	11	Right	786 µg/mL
AEA08-RE-12-SL-LH	12	Left	786 µg/mL
AEA08-RE-12-SL-RH	12	Right	786 µg/mL
AEA08-RE-13-SL-LH	13	Left	786 µg/mL
AEA08-RE-13-SL-RH	13	Right	786 µg/mL
AEA08-RE-14-SL-LH	14	Left	786 µg/mL
AEA08-RE-14-SL-RH	14	Right	786 µg/mL
AEA08-RE-15-SL-LH	15	Left	786 µg/mL
AEA08-RE-15-SL-RH	15	Right	786 µg/mL
AEA08-RE-16-SH-LH	16	Left	3.9 mg/mL
AEA08-RE-16-SH-RH	16	Right	3.9 mg/mL
AEA08-RE-17-SH-LH	17	Left	3.9 mg/mL
AEA08-RE-17-SH-RH	17	Right	3.9 mg/mL
AEA08-RE-18-SH-LH	18	Left	3.9 mg/mL
AEA08-RE-18-SH-RH	18	Right	3.9 mg/mL
AEA08-RE-19-SH-LH	19	Left	3.9 mg/mL
AEA08-RE-19-PH-RH	19	Right	3.9 mg/mL
AEA08-RE-20-PH-LH	20	Left	3.9 mg/mL
AEA08-RE-20-PH-RH	20	Right	3.9 mg/mL

Field Quality Control Samples – Fortified and Blank

Sample Identification	Sample	Target Fortification (µg BIT)
AEA08-FF-P-01-C	Control	None
AEA08-FF-P-01-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-01-H1	High Fortified with Paint	390 µg
AEA08-FF-P-01-H2	High Fortified with Paint	390 µg
AEA08-FF-S-01-C	Control	None
AEA08-FF-S-01-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-01-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-01-H2	High Fortified with Solvent	390 µg
AEA08-FF-P-02-C	Control	None
AEA08-FF-P-02-L1	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-L2	Low Fortified with Paint	78.5 µg
AEA08-FF-P-02-H1	High Fortified with Paint	390 µg
AEA08-FF-P-02-H2	High Fortified with Paint	390 µg
AEA08-FF-S-02-C	Control	None
AEA08-FF-S-02-L1	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-L2	Low Fortified with Solvent	78.5 µg
AEA08-FF-S-02-H1	High Fortified with Solvent	390 µg
AEA08-FF-S-02-H2	High Fortified with Solvent	390 µg

Megan Boatwright

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Wednesday, February 26, 2014 1:37 PM
To: Megan Boatwright
Cc: Robert Testman
Subject: DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "

Megan,

I reviewed the revisions and responses to our comments on the protocol. I found these acceptable. If EPA's HSRB requires any substantial changes, please forward the changes to me for review. Once you receive IRB approval of the protocol and the Spanish translation of the ICF and other documents are done, please submit copies of the translated documents to me. You may submit these documents when requesting final approval of the protocol.

If you have any questions, please call or email me.

Don

Don Richmond
Research Scientist II
Exposure Monitoring and Industrial Hygiene Program
Worker Health and Safety Branch
Department of Pesticide Regulation
Phone: (916) 445-4192

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, January 24, 2014 3:50 PM
To: Richmond, Don@CDPR
Cc: Robert Testman
Subject: Response to DPR Reviewof Protocol for the study "Determination of Removal.... "

Hi Don,

Attached is a letter with responses to the CDPR comments on the removal efficiency 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.

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: Robert Testman
Sent: Thursday, February 19, 2015 10:26 AM
To: Richmond, Don@CDPR; Megan Boatwright
Subject: RE: DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "

Hi Don,

We will be sending you a data CD via FedEx with the final version of the removal efficiency study protocol, a copy of the tracked changes version of the protocol, a letter to EPA which includes a table with changes made and rationale, and the final IRB approval letter. The files are too large for email so we need to send you the CD instead. I want to be sure that we send the package to the correct address, so can you provide this? We hope to run the study the week of April 6, with subjects in-house April 7 and April 9. The brush and roller study documents are still in progress. Please let us know if you have any questions.

Thanks,
Rob

From: Richmond, Don@CDPR [mailto:Don.Richmond@cdpr.ca.gov]
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If you have any questions, please call or email me.

Don

Don Richmond
Research Scientist II
Exposure Monitoring and Industrial Hygiene Program
Worker Health and Safety Branch
Department of Pesticide Regulation
Phone: (916) 445-4192

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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: Robert Testman
Sent: Monday, February 23, 2015 12:40 PM
To: Megan Boatwright
Subject: FW: DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "

Hi Megan,

I talked to Don today. Can you FedEx the CD to him?

Thanks

From: Richmond, Don@CDPR [mailto:Don.Richmond@cdpr.ca.gov]
Sent: Monday, February 23, 2015 11:55 AM
To: Robert Testman
Subject: RE: DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "

Rob,

Here is the address:

Don Richmond
Department of Pesticide Regulation
Worker Health and Safety Branch
1001 I Street, P. O. Box 4015
Sacramento, CA 95812-4015

Thanks,
Don

From: Robert Testman [mailto:rtestman@gplabs.com]
Sent: Thursday, February 19, 2015 10:26 AM
To: Richmond, Don@CDPR; Megan Boatwright
Subject: RE: DPR Review of GPL Response Letter to DPR Reviewof Protocol for the study "Determination of Removal.... "

Hi Don,

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If you have any questions, please call or email me.

Don

Don Richmond
Research Scientist II
Exposure Monitoring and Industrial Hygiene Program
Worker Health and Safety Branch
Department of Pesticide Regulation
Phone: (916) 445-4192

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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: Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent: Tuesday, March 03, 2015 4:50 PM
To: Megan Boatwright
Cc: Ting, David@OEHHA; Salocks, Charles@OEHHA; Ngai, William@OEHHA; Laribi, Ouahiba@OEHHA; Beauvais, Sheryl@CDPR; McKenzie, Jenna@CDPR; Ross, Lisa@CDPR; Richmond, Don@CDPR; Nonato, Yvette@CDPR; Yanga, Nino@CDPR
Subject: Study Protocol Approval.
Attachments: ny03-03.pdf

Ms. Boatwright:

Attached is your electronic file copy of a letter (2 pages) from the Department of Pesticide Regulation, Saturnino Yanga, Environmental Program Manager I, Worker Health and Safety Branch (WHS), dated March 3, 2015, RE: Final approval of the pesticide exposure study protocol entitled, "**Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure**."

If you have any questions about this letter, please contact in WHS – Saturnino Yanga at (916) 445-6387.

[If you need the original, signed hard copy, please notify me & WHS will send it to you. Hard copies to cc:s are also provided upon request.]

Tina Louie
Worker Health & Safety Branch
Department of Pesticide Regulation
(916) 324-0603
tlouie@cdpr.ca.gov

March 3, 2015

Ms. Megan Boatwright
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Ms. Boatwright:

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, **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure"** on March 2, 2015. This study protocol and associated consent form were reviewed and unanimously approved by the Schulman Associates Institutional Review Board of Sunrise, Florida on February 6, 2015, in accordance with 40 CFR Part 26. This study approval will expire on November 12, 2015.

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,

Saturnino Yanga, DVM, MPVM, MS
Environmental Program Manager I
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., Sr. Toxicologist, Pesticide Epidemiology Section (PES), PETB, OEHHA
William Ngai, M.D., MPH, Public Health 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
Jenna McKenzie, Ph.D., Associate Toxicologist, HHA, DPR
Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Don Richmond, Research Scientist II, WHS, DPR
Yvette Nonato, M.D., DPBRM, Research Scientist I, WHS, DPR

Megan Boatwright

From: Megan Boatwright
Sent: Friday, March 27, 2015 12:32 PM
To: 'drichmond@cdpr.ca.gov'
Subject: Amendment for Removal Efficiency Protocol 130503
Attachments: 130503_Amendment_1 signed.pdf

Dear Don,

Please find attached an amendment for the removal efficiency protocol we will be conducting at GPL in a couple weeks. Please let me know if you have any questions. I look forward to seeing you at the study.

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

PROTOCOL AMENDMENT NO.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 6.A Risks to the Subjects**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...The largest amount a subject will be exposed to in this study is 0.5 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.006 mg/Kg for a 70 Kg subject. This is much less than...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

...The largest amount a subject will be exposed to in this study is 0.1 mL of latex paint (density 1.45 g/mL) containing approximately 600 ppm of BIT per hand. Even if all of the applied BIT were absorbed this would represent about 0.001 mg/Kg for a 70 Kg subject. This is much less than...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

2. **Section 8.A Study Design Overview:**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

...
Each subject will be placed into one of two groups. Subjects assigned to group one will have each hand fortified with a 500 µL volume of paint containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 500 µL volume of paint containing

approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 78.5 µg per hand or 390 µg per hand.
...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

...
Each subject will be placed into one of two groups. Subjects assigned to group one will have their hands fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 120 ppm BIT. Subjects assigned to group two will have each hand fortified with a 100 µL volume of paint split as evenly as possible between the two hands (ca. 50 µL per hand) containing approximately 600 ppm BIT. Subject hands will thus be fortified at concentrations of approximately 7.9 µg per hand or 39 µg per hand.
...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

3. **Section 8.B.6 Removal Efficiency Procedure**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. On each hand, a 500 µL volume of the appropriate paint concentration will be applied. A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

The test substance will be applied to the palmar surfaces of each hand using a positive displacement micropipette. A 100 µL volume of the appropriate paint concentration will be applied to both hands, split as evenly as possible between the two hands (ca. 50 µL per hand). A glass stirring rod with rounded annealed ends will be used to spread the test substance across the center of the palmar surface, but test substance will

not be spread closer than 2 cm from any edge of the palmar surface. The stirring rod from each subject will be placed into a test tube and stored frozen prior to analysis.

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

4. **Section 8.C Assignment of Carrier and Amount of Active Ingredient**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section currently reads:

In this study, subjects will be assigned into two groups. The two groups are described below (amounts per hand):

Group 1 500 µL of latex paint containing ca. 120 ppm BIT
Group 2 500 µL of latex paint containing ca. 600 ppm BIT

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

In this study, subjects will be assigned into two groups. The two groups are described below (total amount for both hands):

Group 1 100 µL of latex paint containing ca. 120 ppm BIT
Group 2 100 µL of latex paint containing ca. 600 ppm BIT

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The exposure to each subject will be reduced.

5. **Section 10.D Field Recovery Evaluation**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	500 µL	Approximately 120 ppm
Paint	500 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 250 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

...

The section is being amended to reflect a modified application procedure with less paint used. The section will now read:

An aliquot of each field fortification solution will be added to the matrix samples using positive displacement micropipettes to deliver the correct fortification levels listed in the table below.

Carrier of BIT	Volume	Concentration
Paint	100 µL	Approximately 120 ppm
Paint	100 µL	Approximately 600 ppm

On each study day, matrix samples will be fortified as shown above in duplicate. Duplicate control matrix samples will also be prepared. Matrix samples will be prepared by adding 500 mL of 50% IPA / 50% distilled water into the sample jars along with a gauze sponge.

...

Justification: The volume of paint to be applied per subject is being reduced to reflect a recommendation by HSRB and EPA. The fortification level of the field recovery samples is being reduced to match subject samples. The volume of each field fortification sample is being adjusted to match subject samples.

6. **Section 9.A.iii Inclusion Criteria**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

Inclusion Criteria

...

- Resident of Fresno County

The section will now read:

Inclusion Criteria

...

- Resident of Fresno County and the surrounding area

Justification: The criteria is being updated to be consistent with Section 9.A.i Population Base which specified that Fresno County and the surrounding area should be included in the recruiting population. This is consistent with the circulation area of the newspapers used for study advertising and will not bias the study recruiting.

7. **Section 9.B Subject Sequence Number**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

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 RE-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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 RE number. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their RE 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.

The section will now read:

Individuals on the primary call-in list for this study will be initially identified by only their first and last name and a number based on their enrollment position (subject 1, subject 2, 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 sequential group of seven study sequence numbers will be assigned to the first group, the second sequential group of seven will be assigned the second group, the third sequential group of seven will be assigned to the third group, and the fourth sequential group of seven will be assigned to the fourth group. Thus, allocation of subjects as primary and alternate 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 subject sequence number. Study data will be recorded by assigning each removal event position a RE number. For example the first subject to be tested will represent RE-01, etc. All subjects' names and personal identifiers provided will be kept confidential to ensure their privacy.

Records relating individual names to their subject sequence number and their removal event (RE) number if applicable, 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.

Justification: The procedure for assigning an initial subject number, randomization position number, and removal event (RE) number is being clarified.

8. **Section 8.D Random Selection and Assignment of Subject to Groups**

Effective Date: March 25, 2015

Description of Amendment (including justification):

The section reads:

...
Within each group of fourteen, the first ten subjects will be the primary subjects to have their hands treated per the scenario assignment. The last four subjects in the group of fourteen will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first ten subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

The section will now read:

...
Within each group of fourteen, the subjects will be divided into two blocks of seven subjects for scheduling purposes (AM vs. PM). The first five subjects of each block of seven will be the primary subjects to have their hands treated per the scenario assignment. The last two subjects in the block of seven will be considered as alternates and will be on hand if any subject is unable, chooses not to participate, or chooses to stop before reaching the end. If the first five subjects complete the assignment, the alternates are paid and will not participate in that group. Alternates who do not participate will be placed back in the pool of subjects. If additional subjects above the 28 initially selected are required, randomized subject 29 will be contacted followed by randomized subject 30 and so on, until all assignments are completed for the study.
...

Justification: The procedure for randomizing subjects into groups and scheduling times is being clarified and made consistent with section 9.B.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 03/27/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 3/27/15
Has Shah, Ph.D. Date
Sponsor Representative

Megan Boatwright

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Wednesday, April 01, 2015 9:35 AM
To: Megan Boatwright
Subject: RE: Amendment for Removal Efficiency Protocol 130503

Megan,

I have been off for a few days and will look at the amendment this morning. I am planning to come down to observe the study for a few hours and will be in contact with you or Rob later today or tomorrow to confirm the schedule.

Do you have IRB approval of the amendment? If you do, please send me a copy of the approval.

Thanks,
Don

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Friday, March 27, 2015 12:32 PM
To: Richmond, Don@CDPR
Subject: Amendment for Removal Efficiency Protocol 130503

Dear Don,

Please find attached an amendment for the removal efficiency protocol we will be conducting at GPL in a couple weeks. Please let me know if you have any questions. I look forward to seeing you at the study.

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: Megan Boatwright
Sent: Monday, April 06, 2015 8:02 AM
To: 'Richmond, Don@CDPR'
Cc: Rob Testman (rtestman@gplabs.com)
Subject: RE: Amendment for Removal Efficiency Protocol 130503
Attachments: 130503 amendment 1 approval irb.pdf

Good Morning Don,

Please find attached the approval letter from the IRB for Amendment 1 for the Removal Efficiency Study. We look forward to your visit on Thursday.

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
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mboatwright@gplabs.com

March 27, 2015

FROM:	Schulman Associates IRB, Inc. ("Schulman" or the "Board") – Board #3
TO:	Megan T. Boatwright,BS
SUBJECT:	Updated Approval Documents
SPONSOR:	Antimicrobial Exposure Assessment Task Force II (AEATF II)
PROTOCOL NO:	AEA08
PROTOCOL TITLE:	Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

The following item(s) were reviewed and approved by Full Board or Expedited Review on the dates listed below:

- Protocol Amendment 1 dated 03/25/2015: Expedited: 03/27/2015

Based on review of the item(s) listed above, no changes to the Informed Consent(s) were necessary.

ja

PLEASE REFERENCE IRB #201307366 ON ALL CORRESPONDENCE FOR THIS STUDY
WebPortal/Paperless

Megan Boatwright

From: Richmond, Don@CDPR <Don.Richmond@cdpr.ca.gov>
Sent: Monday, April 06, 2015 10:14 AM
To: Megan Boatwright
Subject: RE: Amendment for Removal Efficiency Protocol 130503

Megan,

Thanks for submitting the IRB approval for the amendment. You should be receiving an email with a letter from DPR either today or tomorrow on the amendment. Because the change in the protocol is not expected to cause a potential health effect to the participants, DPR does not need to approve the amendment. I will see you Thursday, probably about 8:30 am.

Don

From: Megan Boatwright [mailto:mboatwright@gplabs.com]
Sent: Monday, April 06, 2015 8:02 AM
To: Richmond, Don@CDPR
Cc: Robert Testman
Subject: RE: Amendment for Removal Efficiency Protocol 130503

Good Morning Don,

Please find attached the approval letter from the IRB for Amendment 1 for the Removal Efficiency Study. We look forward to your visit on Thursday.

Best Regards,

Megan

Megan T. Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave, Suite 105
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Tel: (559) 275-9091
Fax: (559) 275-1810
mboatwright@gplabs.com

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To: Megan Boatwright
Subject: RE: Amendment for Removal Efficiency Protocol 130503

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Do you have IRB approval of the amendment? If you do, please send me a copy of the approval.

Thanks,
Don

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Dear Don,

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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

Megan Boatwright

From: Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent: Tuesday, April 07, 2015 6:02 PM
To: Megan Boatwright
Cc: Kwok, Eric@CDPR; Ross, Lisa@CDPR; McKenzie, Jenna@CDPR; Richmond, Don@CDPR; Nonato, Yvette@CDPR; Yanga, Nino@CDPR
Subject: Protocol Amendment Letter
Attachments: ny04-06.pdf

Dear Ms. Boatwright:

Attached is your electronic file copy of a letter (2 pages), from the Department of Pesticide Regulation, Saturnino ("Nino") Yanga, Environmental Program Manager I, Worker Health and Safety Branch (WHS), dated April 6, 2015.
RE: Protocol Amendment for study AEA08, "**Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure**."

If you have any questions about this letter, please contact in WHS – Nino Yanga at (916) 445-6387.

[If you need the original, signed hardcopy, please notify me & WHS will provide it.]

Tina Louie
Worker Health & Safety Branch
Department of Pesticide Regulation
(916) 324-0603
tlouie@cdpr.ca.gov

April 6, 2015

Ms. Megan Boatwright
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Ms. Boatwright:

On March 27, 2015, the Department of Pesticide Regulation (DPR) received a protocol amendment for study AEA08, **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure"** The amendment includes a decrease in the volume of paint applied to the hands of each subject, effectively reducing the amount of exposure to the test substance. Additional changes include initial assignment of subject numbers, an increase in the recruitment area, and the procedure for randomization of subjects into groups

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). The approval has been obtained.

The Director of DPR granted approval of the protocol on March 2, 2015. Approval expires on November 12, 2015. 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 by telephone at (916) 445-4192, or by e-mail at: drichmond@cdpr.ca.gov.

Sincerely,

Saturnino "Nino" Yanga, DVM, MPVM, MS
Environmental Program Manager I
Worker Health and Safety Branch
(916) 445-6387

cc: Eric Kwok, Ph.D., D.A.B.T., Senior Toxicologist, HHA, DPR
Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Jenna McKenzie, Ph.D., Associate Toxicologist, HHA, DPR
Don Richmond, Research Scientist II, WHS, DPR
Yvette Nonato, M.D., Research Scientist I, WHS, DPR

Megan Boatwright

From: Louie, Tina@CDPR <Tina.Louie@cdpr.ca.gov>
Sent: Monday, April 20, 2015 1:27 PM
To: Megan Boatwright
Cc: Robert Testman; Ross, Lisa@CDPR; Yanga, Nino@CDPR
Subject: Pesticide Exposure Monitoring Study.
Attachments: dr04-20.pdf

Ms. Boatwright:

Attached is your electronic file copy of a letter from the Department of Pesticide Regulation, Donald Richmond, Research Scientist II, Worker Health & Safety Branch (WHS), dated April 20, 2015, RE: "Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Hand Wash Procedure."
(The cover letter is one page with a 3 page attachment; the entire document is 4 pages.)

If you have any questions about this letter, please contact in WHS – Donald Richmond at (916 445-4192.

[If you need the original, signed hard copy, please notify me, & WHS will provide it.]

Tina Louie
Worker Health & Safety Branch
Department of Pesticide Regulation
'916) 324-0603
tlouie@cdpr.ca.gov

April 20, 2015

Megan Boatwright
Golden Pacific Laboratories, LLC (GPL)
Fresno, California 93722

Dear Ms. Boatwright:

I appreciate the opportunity to have observed the pesticide exposure monitoring that you and your staff conducted as part of the study, **"Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure."**

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,

[*Original signed by D. Richmond*]

Donald M. Richmond
Research Scientist II
Worker Health and Safety Branch
9916) 445-4192

Attachment

cc: Lisa Ross, Ph.D., Environmental Program Manager II, WHS, DPR
Saturnino "Nino" Yanga, DVM, MPVM, MS, Environmental Program Manager I, WHS, DPR
Robert Testman, Golden Pacific Laboratories, LLC

Observations of Studies Involving Human Subjects

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

Study Director: Megan Boatwright Observation Date: April 9, 2015

Location: Fresno, CA

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:
I asked one participant the above four questions about the informed consent process he went through. I also asked if he had received a copy of the Informed Consent Forms. His answers were consistent with being properly consented. At the beginning of the study time, the study director asked the participants if they had any questions. None of the participants had questions.

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:
I did not observe any safety issues during the study. I did notice a definite odor of alcohol near the scrub/rinse table during the hand washing/scrubbing for each participant and the pouring of the alcohol into the sample jar. The odor quickly disappeared afterwards.

Research Staff
How many researchers are present at the study site? Five (5) including the nurse.
List below the protective equipment/clothing researchers wore while monitoring workers.
List below the protective equipment researchers wore while handling samples.

Comments:
Only three of the five study staff handled paint or alcohol solution. They wore safety glasses, nitrile gloves and lab coats while applying the paint to the hands of the participants and handling the alcohol scrub/rinse solution. The remaining study staff and an on-site nurse did not handle the paint or alcohol solution.

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:
No sample dosimetry involved – antimicrobial paint applied to the palms of the hands.

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:
Paint applied by syringe; staff had drip pan underneath if any paint dripped off the syringe. This prevented possible contamination of non-treated skin areas, etc. A second staff member spread paint with a glass stirring, wiping rod on palm to get as much paint off the rod as possible. Each stirring rod was saved in a separate vial.

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 brought into room from a separate laboratory room at the time the paint was to be applied for each participant. Staff staggered the start for the participants, starting one every 10 minutes. This allowed the study staff 10 minutes to scrub/rinse the hands of each participant at the end of the 45 minute drying period.
The scrubbing/Rinsing area was sufficiently close to facilitate removal of paint at the proper time. Paint removal was performed first on participant closest to the scrub area.

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.
None.

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.

Morning session: 7 participants, 2 serving as alternates. All 7 showed up.

The nurse checked each participant's hands and discussed two participants with the study director. One participant with a cut on one hand was paid and dismissed. The study director and nurse decided the other participant could continue in the study, but as a precaution had him serve as an alternate.

Participants washed their hands in mild soap and dried them with paper towels. They were seated around a table with beach towels on the table top for padding. Large gauze pads covered the towels. The study director asked each participant if the chair was comfortable and if the chair needed to be adjusted. After the beginning of the study, participant 5 asked for a seat adjustment. The seat was adjusted to the satisfaction of the participant. Part way through the study, participant 2 requested her head band be removed from her head for her comfort. Staff removed the headband and put it with her belongings.

After the last participant had paint applied to the hands, the alternate was paid and dismissed.

Scrub/Rinse solution: premeasured 500 ml of 50% alcohol/50% distilled water solution.

After 45 minutes, each participant moved from their seat at the table to the hand scrub/rinse area. Study staff explained the scrub/rinse procedure for each step of the process to the participants. The participants held their hands over a stainless steel bowl which was used to collect an alcohol scrub/rinse solution poured from a glass jar. Study staff used gauze pads with alcohol solution to remove all of the paint from a participant's hand. The gauze pads were placed in the stainless steel bowl after use and saved as part of the sample. The participant then washed his/her hands with additional alcohol poured on the hands. Staff poured the remainder of the alcohol solution from the glass jar over the hands as a final rinse. The participant shook or let the remaining alcohol drip from their hands into the bowl. The participants then washed their hands in mild soap and water. The nurse inspected their hands. They were paid for their participation and free to leave. Study staff poured the alcohol scrub/rinse solution from the stainless steel bowl into a glass sample jar.

Observations of Studies Involving Human Subjects

Megan Boatwright

From: Megan Boatwright
Sent: Wednesday, April 05, 2017 11:10 AM
To: Richmond, Don@CDPR (Don.Richmond@cdpr.ca.gov)
Subject: Amendments and Deviations for Removal Efficiency Study
Attachments: 130503 protocol deviation 2 - signed.pdf; 140503 protocol deviation 1 - signed.pdf; GPL Study 130503 Amend 2 signed.pdf

Dear Don,

I have attached a protocol amendment and two protocol deviations for your records pertaining to the Removal Efficiency study GPL Study # 130503, AEATF Study # AEA08. I believe per our protocol I did not need to send you the amendment or deviation 1, however I felt I rather have given you a complete picture. Amendment 2 had been sent to the IRB and after waiting for a response from them after three weeks I called to follow up and was told deviation do not get a response back from the IRB, so I have nothing to send you showing I sent it to them. Please add this to your file. Please let me know if you have any questions or need anything else.

Thank you for your time.

Best Regards,

Megan

Megan Boatwright
Laboratory Manager
Golden Pacific Laboratories, LLC
4720 W. Jennifer Ave., Suite 105
Fresno, CA 93722
Telephone: (559) 275-9091
mboatwright@gplabs.com

PROTOCOL AMENDMENT NO.: 2
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 12.B. Analytical Method**

Effective Date: March 30, 2015

Description of Amendment (including justification):

The section currently reads:

...The method (GPL-MTH-*079*) includes the use of isotopically labeled BIT internal standard to increase accuracy...

...Hand wipe samples will be analyzed following the method documented in 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)....

...The latex paint test substances will be analyzed following GPL-MTH-*079*....

The section is being amended to document the correct method number and title of the method. The method number and title are:

GPL Analytical Method GPL-MTH-*081* entitled, "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"

Justification: To correct typographical errors of the method number and analyte name in the method title.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 06/15/15
Megan Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Hamesh Shah 06/15/15
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL Deviation No.: 1
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Section 9.A.ii. Recruitment of Surrogate Workers**

Effective Date: March 9, 2015

Description of Deviation (including justification):

The Protocol states, "SAIRB approved recruiting advertisements 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 recruitment period will be opened for 2 weeks following the first publication."

All three newspapers were contacted and sent the advertisement on March 5, 2015. The Fresno Bee and Vida en el Valle provided quotes, proofs, and ran the advertisements without any issues. California Advocate responded with a quote, size of space, and confirmation there was space available in the publications of March 9th and 16th, but never provided a proof. Although GPL attempted to contact the newspaper multiple times, the California Advocate staff did not follow up and the advertisement was not published in this newspaper.

Justification: Staff at the California Advocate did not respond to requests to publish the advertisement and GPL could not accomplish this task.

Effect on Study: Recruitment proceeded through the Fresno Bee and Vida en el Valle advertisements which cover the same geographic area as the California Advocate. Sufficient subjects were enrolled during the initial two week period without using the California Advocate. This deviation is not expected to impact the results of the study.

APPROVALS:

STUDY DIRECTOR: Megan T. Boatwright 09/25/15
Megan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 09/22/2015
Has Shah, Ph.D. Date
Sponsor Representative

PROTOCOL Deviation No.: 2
GPL Study # 130503

Study Title: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/ Water Wipe and Wash Procedure

1. **Page 8 and 13 – Test Substance**

Dates of Occurrence: April 7, 2015 and April 9, 2015

Description of Deviation (including justification):

The Protocol states, "Additional BIT in a minimal volume of dipropylene glycol will be added by the testing facility to achieve a higher (second) BIT concentration of approximately 600 ppm."

In preparing the BIT solution used to increase the concentration of BIT in the paint, diethylene glycol was used instead of dipropylene glycol.

Reason for Deviation: Chemist used wrong solvent when preparing solution of BIT.

Effect on Study: There is no expected effect on the study results since the chemical properties of dipropylene glycol and diethylene glycol are similar. In this fortification solution, BIT fully dissolved into the diethylene glycol solvent.

APPROVALS:

STUDY DIRECTOR: Megan Boatwright 02/28/17
Mégan T. Boatwright Date
Golden Pacific Laboratories, LLC

SPONSOR REPRESENTATIVE: Has Shah 02/27/17
Has Shah, Ph.D. Date
Sponsor Representative