UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE: March 17, 2011

SUBJECT: Science Review of the AEATF II Wipe Human Exposure Monitoring Study (Trigger Spray & Wipe and Ready-to-Use Wipes Scenarios).

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This memorandum presents the EPA/OPP Antimicrobials Division (AD) science review of the human exposure wipe study submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II). One wipe study was submitted that contains two exposure scenarios: Ready-to-Use (RTU) Wipes and Trigger Spray & Wipe. The dermal and inhalation exposure data as represented in this review are acceptable and, subject to the considerations described below, are recommended for use for pesticide handler exposure assessments.

EXECUTIVE SUMMARY

This document represents the USEPA, Office of Pesticides Program, Antimicrobials Division (AD) review of the Antimicrobial Exposure Assessment Task Force II (AEATF II) wipe study. The wipe study investigators monitored inhalation and dermal exposures to 18 workers wiping surfaces using ready-to-use (RTU) wipes and 18 workers using trigger sprayers & wipes. EPA confirms that the data meet the study design objective outlined in the AEATF II Governing Document and are considered the most reliable data for assessing exposures from wiping surfaces. The reader is referred to Section 3.0 for a discussion on the data limitations and use of the data as surrogate.

EPA intends to use these AEATF II wipe datasets instead of the Chemical Manufacturers Association (CMA) dataset to assess exposure for persons using an antimicrobial product while wiping surfaces. The exposure data in the AEATF II wipe scenarios represent RTU wipes and the application of a trigger spray and subsequent wipe only. The scenarios do not cover the pouring of the concentrate to prepare the RTU wipes (hence the wipes are defined as "ready-to-use") or pouring the concentrate to prepare a diluted solution to add to the trigger pump sprayer; open pouring of the concentrate will be measured in a future study. If pesticide products are used with open pouring of concentrates (rather than as ready-to-use wipes or with automatic dispensers to fill spray bottles), estimates of dermal and inhalation exposures from the future pour study will be combined with wipe exposures from this study when assessing exposures and risks from pesticide products applied by wiping.

Select summary statistics for the "unit exposures" normalized to pounds active ingredient handled are presented in Table 1 for inhalation exposure as well as for 3 clothing configurations. Each worker wore both inner and outer whole body dosimeters (WBD) that were sectioned and analyzed separately for each body part (e.g., lower leg, upper leg, lower arm, upper arm, etc). Therefore, the analyses of residues on the dosimeters worn by each individual worker allow for the estimation of exposure for the following 3 clothing configurations:

(1) long pants, long-sleeved shirt, and no gloves;
(2) long pants, short-sleeved shirt, and no gloves; and
(3) short pants, short-sleeved shirt, and no gloves.

For comparison, results from the earlier CMA study for wiping are also presented. The summary statistics reported in Table 1 for the AEATF II data are estimated using the lognormal mixed model while the CMA results are empirical estimates.

Table 1. Unit Exposures: Wiping Scenarios				
Exposure Route	**Clothing**	**CMA[a]**	**AEATF II[b, c] (n=18)**	
		Arithmetic Mean	**Arithmetic Mean[d]**	**95th Percentile[e]**
Ready-to-use (RTU) Wipes				
Dermal (mg/lb ai)	Long pants/long-sleeves, shoes/socks, no gloves	Not Available	2380 (1150, 5160)	5990 (2280, 16200)
	Long pants/short-sleeves, shoes/socks, no gloves		2580 (1400, 4920)	6190 (2780, 14100)
	Short pants/short-sleeves, shoes/socks, no gloves		2740 (1580, 4870)	6500 (3170, 13500)
Inhalation	Breathing Zone (mg/m^3/lb ai)		0.31 (0.13, 0.81)	1.13 (0.41, 3.09)
	Breathing Zone (mg/lb ai) [f]		0.48 (0.24, 1.06)	1.67 (0.70, 3.97)
Trigger Spray & Wipe				
Dermal (mg/lb ai)	Long pants/long-sleeves, shoes/socks, no gloves	2870 ± 4220 (n=6) (some workers short-sleeves and some long-sleeves) Not available	1050 (749, 1490)	2420 (1500.5, 3892.5)
	Long pants/short-sleeves, shoes/socks, no gloves		1530 (1160, 2050)	3220 (2148.2, 4835.4)
	Short pants/short-sleeves, shoes/socks, no gloves	Not Available	1740 (1220, 2500)	3640 (2270, 5840)
Inhalation	Breathing Zone (mg/m^3/lb ai)	12.2 ± 22.4 (n=8) (7 non-detects)	11.6 (4.8, 29.9)	37.5 (13.0, 110)
	Breathing Zone (mg/lb ai) [f]	67.3 ± 71.6 (n=6)	18.5 (8.53, 42.3)	53.8 (20.5, 144)

[a] CMA data: Mean ± std. Inhalation LOQ varied among samples. Task of using trigger pump spray and wiping restroom and dental fixtures.

[b] AEATF II dermal unit exposures reflect method removal efficiencies of 90.3% for hands and 58.8% for face/neck measurements. The percent of average dermal exposure representing the hands for the long pants, long sleeved scenario for the RTU and Trigger Spray & Wipe are 98% and 92%, respectively.

[c] Lower and upper 95% confidence intervals reported in "( )"; statistics are estimated using a variance component model accounting for correlation between measurements conducted within the same field study (i.e., measurements collected during the same time and at the same location). Additional model estimates (e.g., empirical and simple random sample assumptions) are described in Appendices A and B.

[d] Arithmetic Mean (AM) = GM * $\exp\{0.5*(\ln GSD)^2\}$

[e] 95th percentile = GM * $GSD^{1.645}$

[f] Inhalation (mg/lb ai) = (air conc (mg/m^3) / lb ai) * breathing rate (1 m^3/hour) * wipe duration (hours/day)

The following important points with respect to these data are noted:

- The AEATF II data and associated unit exposures are considered superior to the existing wipe dataset (i.e., CMA data). AEATF II efforts represented a well-designed, concerted process to collect reliable exposure data in a way that takes advantage of and incorporates a more robust statistical design, better analytical methods, and improved data handling techniques.

- The AEATF II study report containing dermal and inhalation exposure results are considered scientifically complete. No additional monitoring data are required at this time.

- The data are applicable for assessment of exposure to non-volatile pesticides. The cutoff for volatility is reviewed on a case-by-case basis (rule of thumb is that <E-4 mmHg @ 20° C is considered non-volatile).

- **Ready to use wipes.** Although the statistical analysis does not provide evidence of direct proportionality (1:1) between dermal exposure and pounds of active ingredient (ai) handled (i.e., slope ≠ 1 in Table 10 below), the analysis does show that dermal exposure tends to increase with pounds of ai handled (AaiH) as described in Section 2.4 below. Inhalation exposure, however, is not proportional to AaiH (slope is negative).

- **Trigger spray and wipe**. Although the statistical analysis does not provide evidence of direct proportionality (1:1) between dermal exposure and AaiH (i.e., slope ≠ 1 in Table 11 below), the analysis does show that dermal exposure tends to increase with AaiH as described in Section 2.4 below. Inhalation exposure also slightly tends to increase with AaiH (i.e., slope = 0.25).

To assess the risks resulting from wiping exposures, EPA will combine appropriate unit exposure (UE) values with chemical-specific inputs (maximum labeled application rates, dermal absorption rates, and toxicological endpoints of concern) and default inputs (high end area treated or volume applied) in the standard pesticide handler exposure algorithm: Potential exposure = UE (mg/lb ai or mg/m^3/lb ai) x absorption (%) if applicable x maximum label rate (lb ai/gallon) x volume (gallons)

1.0 Background

The AEATF II is developing a database representing inhalation and dermal exposure during a number of antimicrobial handler scenarios. A scenario is defined as a pesticide handling task based on activity (e.g., application) and equipment type (e.g., ready-to-use wipes, mop & bucket, pressure treatment of wood facilities, painting). The AEATF II is monitoring both inner and outer dosimeters which will allow the EPA to estimate exposures to various clothing configurations (e.g., long pants, long-sleeved shirt or long pants, short-sleeved shirt or short pants, short-sleeved shirts, plus shoes, socks, and no gloves).

1.1 Wipe Scenarios Defined

Ready-to-Use (RTU) Wipes. The RTU wipe scenario in this study is defined as wiping various horizontal and vertical surfaces such as tile walls, counter tops, sinks, faucets, elevator doors, railings, shelves, etc. Wiping motions included up & down, side-to-side, and circular motions as the workers worked as they would normally do. The RTU wipes are pre-treated (pre-treatment of wipes not monitored for exposure). Subjects wore whole body dosimeters (WBD) underneath long-sleeved shirts, long pants, and no gloves. The conditions under which the study participants handle the pesticide as they are monitored are referred to as the scenario. Both inner and outer dosimeters were worn by the monitored study participants, and both inner and outer dosimeters were analyzed for residues.

Trigger Spray and Rag Wipe. The trigger spray and wipe scenario in this study is defined as using a 32 ounce trigger spray bottle to spray surfaces and subsequently wipe them. Workers cleaned various horizontal and vertical surfaces such as walls, toilets & stall walls, hand railings, shelves including underneath shelves, counter tops, etc using up & down, side-to-side, and circular motions as the workers worked as they would normally do. Subjects wore WBD underneath long-sleeved shirts, long pants, and no gloves. The conditions under which the study participants handle the pesticide as they are monitored are referred to as the scenario. Both inner and outer dosimeters were worn by the monitored study participants, and both inner and outer dosimeters were analyzed for residues. This scenario is defined to exclude pouring the antimicrobial product into the spray bottles. Antimicrobial products may be added to spray bottles in various ways, including open pouring from no-glug containers, open pouring from typical glug containers, packaged as ready-to-use, or automated dispensers. Open pouring a pesticide concentrate will be monitored in a future AEATF II study.

1.2 Study Objective

The AEATF II's study objective is to monitor inhalation and dermal exposures to be used as inputs in exposure algorithms to predict future exposures to persons wiping surfaces with either RTU wipes or trigger spray & wipe/rag. Dermal and inhalation exposure monitoring was conducted while study participants wiped various surfaces (walls, bathrooms, etc) for use in exposure assessments, as "unit exposures".

"Unit exposure" (UE) is defined as the expected external chemical exposure an individual may receive (i.e., "to-the-skin" or "in the breathing zone") per weight-unit of chemical handled

and is the default data format used in pesticide handler exposure assessments. Mathematically, unit exposures are expressed as "handler" exposure normalized by the amount active ingredient handled by participants in scenario-specific exposure studies (e.g., mg exposure/lb ai handled). EPA uses these UEs generically to estimate exposure for other chemicals having the same or different application rates.

Criteria for determining when a scenario is considered complete and operative have been developed (Christian 2007). Outlined in the AEATF II Governing Document, the criteria can be briefly summarized as follows:

- The AEATF II's objective for this study design is to be 95% confident that key statistics of normalized dermal exposure are accurate within 3-fold. Specifically, the upper and lower 95% confidence limits should be no more than 3-fold (K=3) higher or lower than the estimates for each the geometric mean, arithmetic mean, and 95th percentile dermal unit exposures. To meet this objective AEATF II proposed an experimental design with a 3 cluster by 6 monitoring events (MEs).

- EPA also plans to use the data to evaluate the presumption of proportionality between exposure and amount of active ingredient handled. EPA used a log-log regression test to distinguish complete proportionality (slope = 1) from complete independence (slope = 0), with 80% statistical power, achieved when the width of the 95th confidence interval of the regression slope is 1.4 or less.

1.3 Protocol Modifications, Amendments, and Deviations

1.3.1 Protocol Modifications Subsequent to EPA/HSRB Review

EPA required two science-based modifications to the protocol (EPA 2008). The EPA review of the protocol noted that the type of wipe to be used in the Trigger Spray & Wipe scenario was not specified. The protocol was modified to identify the wipe as cotton rags. EPA also required a residue removal efficiency study to address the efficiency of the hand wash and face/neck wipes. The AEATF II responded by purchasing an existing study conducted to assess the removal efficiency (Boatwright 2007, MRID 47214801).

The HSRB provided written discussion on a number of concerns including:

- ***Sampling size and replication of ME*** – The HSRB questioned whether or not the sampling size of 3 clusters by 6 MEs per cluster would provide an accuracy goal of k=3. Based on EPA's statistical review provided in Section 2.4 below, the sampling size as designed is sufficient to meet the accuracy goal. The HSRB also discussed the need for repeat measurements or in lieu of repeat measurements the need for a discussion on the limitations of the study design. EPA acknowledges that ideally, the sample design would benefit from a large sample size that includes multiple replicates from each worker. However, EPA also recognizes that the repeat measures is as a trade-off for overall sample size (resource issue). Sampling the same worker twice (or 3X, 4X....) would have provided information on the within-worker variability (e.g., do some workers consistently

experience high or low exposures day-after-day while others are highly variable?). Such information would be useful, especially because worker assessments generally represent longitudinal (multi-day) exposures. But any gain in characterization of within-worker variability information would result in a loss in characterization of between-worker variability and, given a fixed sample size, in accuracy (the fold relative accuracy or "K" factor as discussed in the AEATF II Governing Document). With respect to the K-factor, because of the inherent correlation, sampling workers multiple times reduces "effective" sample size - which, due to the relationship between sample size, variability, and accuracy -- would have made the K-factor unacceptably larger. Thus, if EPA wanted both within-worker variability information and a K=3, the AEATF II would need to increase the total number of workers monitored not only in this study but for the other planned scenarios as well. Thus, the trade-off becomes the number of pesticide exposure scenarios that could be monitored by the AEATF II.

Alternatively, EPA could have accepted a larger K-factor if within-worker variability was more desirable. Instead, because assumptions can be made for within-worker variability in order to model longitudinal exposures from the collected 1-day exposures, EPA elects to continue to utilize the 3-fold K factor as its accuracy benchmark In summary, given the fixed sample size, EPA has chosen the larger "effective" sample size/smaller K-factor and between-worker variability, while sacrificing more concrete information on within-worker variability.

- ***ME duration*** – The HSRB noted that the durations of the MEs should be longer. The AEATF II responded by increasing the proposed 30 to 120 minute range of monitoring to 30 to 210 minutes of wiping activities. The justification of the wipe sampling time is cited in the AEATF II's Supplement 2 report submitted previously for the mop study (MRID 482102-01). MRID 482102-01 provides wiping durations from time and motion-based estimates for wiping on a per room basis from the International Sanitary Supply Association (ISSA) as 8.51 minutes/room. The theoretical maximum of 25 rooms/day cleaned was also provided in MRID 482102-01 and cited below: : "*…information from the following sources: 1) the American Hospital Association (http://www.aha.org/aha_app/index.jsp), the American Society for Health Care Environmental Services (http://www.ashes.org/ashes_app/index.jsp), and the U.S. EPA's Environmental Best Practices for Health Care Facilities (JCAHO Environment of Care Standards 1.3,2.3,4.0, November 2005) indicates that a single individual at a hospital would typically clean from 15 to 20 hospital patient rooms per day during a standard 6.5 hour shift. ….JohnsonDiversey Inc. feels that the lower typical range could be less than 15 rooms per day. Consequently, depending on the degree of conservatism desired, 20-25 rooms/day would appear to be a reasonable upper bound for these professional applicators.*" The maximum wiping duration was thus increased to 210 minutes (i.e., 8.51 minutes/room x 25 rooms = 212.75 minutes, rounded to 210 minutes). This change to the protocol was discussed and accepted by the Joint Regulatory Committee (JRC).

- ***Amount active ingredient handled (AaiH)*** – The HSRB noted that the AaiH instead of exposure duration should be used to differentiate among MEs. Other protocols (e.g., aerosol can spray) have been modified to use the amount handled instead of exposure duration to differentiate among MEs. However, for the wipe study, the information

above on wiping duration was determined by the JRC to be the best information available on the task of wiping. Individual workers were given the ability to choose to use the appropriate amount of RTU wipes or diluted treatment solution in the Trigger Spray & Wipe as they would normally do. This approach was judged by EPA to lead to the most relevant information on how much active ingredient would be used by workers working as they normally would do.

- ***Proportionality between exposure and AaiH*** – The HSRB indicated in their written protocol review comments that they wanted to see a discussion of proportionality and regressions with the completed data. EPA reviewed the data and presents the analysis of proportionality in Section 2.4 below and Appendices A and B. In brief, the statistical analysis compared pounds of active ingredient to wiping duration and other relevant variables as the possible normalization variables.

    - **RTU Wipes:** Although the statistical analysis does not provide evidence of direct proportionality (1:1) between dermal exposure and pounds of active ingredient (ai) handled (i.e., slope ≠ 1 in Table 10 below), the analysis does show that dermal exposure tends to increase with pounds of ai handled (AaiH) as described in Section 2.4 below. Inhalation exposure, however, is not proportional to AaiH (estimated slope is negative). The statistical analysis also suggests that the dermal exposure is proportional to the wiping duration (see Appendix A). The statistical analysis does not distinguish whether inhalation exposure is proportional to or independent of the wiping duration.

    - **Trigger spray and wipe**. Although the statistical analysis does not provide evidence of direct proportionality (1:1) between dermal exposure and AaiH (i.e., slope ≠ 1 in Table 11 below), the analysis does show that dermal exposure tends to increase with AaiH as described in Section 2.4 below. Inhalation exposure also slightly tends to increase with AaiH (i.e., estimated slope = 0.25). The statistical analysis shows even less support for proportionality between dermal or inhalation exposure and the wiping duration (see Appendix B).

  The basis for the exposure extrapolation by AaiH is explained by the following:

  $$Exposure = K(AiaH)^{slope}$$

  If slope = 0 then exposure is independent of the AaiH. If slope = 1 then exposure is directly proportional (1:1) to AaiH. If slope is positive, not zero and not 1 then the exposure tends to increase with the AiaH but not proportionally, so that, for example, doubling the AiaH will not tend to double the exposure. If the slope confidence interval excludes both 1 and 0 then the statistical evidence rejects both proportionality and independence and shows that the exposure tends to increase with the AiaH but not proportionally (see Tables 10 and 11 for results of proportionality test). This implies that using the normalized exposure results to estimate exposures for different pesticides or different concentrations is an approximation that tends to overestimate exposure at the high end of AaiH. Section 2.4 below also provides the threshold of AaiH where exposure

based on estimated AaiH lower than the threshold results in an under-estimate of exposure and estimated AaiH higher than the threshold results in an over-estimate of exposure (i.e., protective of human health).

- ***Monitoring equipment*** – The HSRB indicated that they wanted to see better descriptions of the equipment used to measure light levels, air temperature, and relative humidity. Better descriptions of these monitoring devices within the protocol are not apparent. However, the environmental conditions (e.g., temperature & humidity) do not appear to have been a factor that would have hampered the workers in their performance of their wiping activities. This wipe study was conducted during the same time period as the previously reviewed AEATF II mop study (but not on the same days). Therefore, the "lessons learned" (e.g., impact of the room size, ventilation, etc on air concentrations) from the previous HSRB review of the mop study could not be incorporated into this study as the wipe study was completed prior to the HSRB comments on the mop study.

- **October 2010 HSRB statistical suggestions –** The HSRB raised several issues concerning the statistical analysis of the completed AEATF II mop study that are also relevant to this wipe study. During the October 2010 HSRB review of the AEATF II's mop study, one or more of the Board members suggested additional statistical analysis including reviewing the quadratic model, degrees of freedom, and non-parametric bootstrap methods. Section 2.4 below and Appendices A and B explore these suggested alternatives.

1.3.2 Protocol Amendments

The study report (page 116) lists 7 protocol amendments. The amendments range from changing the building selection criteria to improving clarity in definitions/statements to adding additional steps to insure enough study participants for the study to improved efficiency of the conduct of the study. Additionally, amendments were made to address study personnel changes.

1.3.3 Protocol Deviations

A total of 23 minor deviations were noted in the study (study report pages 117-118). The deviations included, but not limited to, washing hands and face prior to the monitoring period with 50:50 IPA:water instead of only Ivory soap; light levels not monitored; break times did not follow protocol exactly; slight under-dilution of the trigger bottle spray solution in clusters 2 and 3 ($1/65^{th}$ DDAC/water instead of the target $1/64^{th}$ dilution); etc. For a detailed description of the protocol deviations the reader is referred to the study report. These deviations did not adversely affect the outcome of the study.

1.4 Material & Methods

The following is a summary of the field aspects of the study:

- ***Study Location:*** The wipe study was conducted in Fresno County, CA. Pictures and floor plans for both scenarios are provided in Appendices H (page 324) through J (page

330) of the study report. Each cluster is a different building. The buildings are an office building, a Rite Aid, and a retired teacher's memorial building. These are the same buildings used in the previously conducted AEATF II mop study; separated by time and different test subjects.

- ***Pesticide Tested:*** The test substance monitored was didecyl dimethyl ammonium chloride (DDAC), CAS number 7173-51-5. DDAC was formulated in a product known as Buckeye Sanicare Lemon Quat (EPA Reg No. 47371-131-559). This product also contained another Quat, ADBAC. DDAC and ADBAC are in Lemon Quat at 2.54% and 1.69%, respectively (total of 2.54% + 1.69% = 4.23%). There is a discrepancy on page 32 of the study report, listing the total DDAC and ADBAC concentration at 4.51% ai. Golden Pacific Laboratories (GPL) noted in a subsequent discussion that the certificate of analysis listed the total ai as 4.51% ai. GPL also noted that DDAC was determined to be at 2.58%, 2.5%, and 2.44% in clusters 1, 2, 3, respectively. The impact of the certificate of analysis listing the total ADBAC and DDAC as 4.51% is considered minor because the percent DDAC was determined for each cluster.

- ***Test System:***

    - **RTU Wipes:** The RTU wipes were prepared (solution preparation discussed in the bullets below) at least 1 week in advance of the monitoring and stored in 8.5 x 5 inch plastic cylinders. Each wipe was 8 x 7 inches with the wipes connected to each other. A photo of RTU wipes and container are presented below in Figure 1.
    - **Trigger Spray & Wipe:** The trigger bottle was a 32 ounce GRIP AND GO! (Buckeye International, product #41076000) and the rags used for wiping were cotton (Bag-o-Rags). Photos of trigger spray bottle and wipe/rag are presented below in Figure 1a.

Figure 1. RTU Wipes and Wipe Container.

Figure 1a. Trigger Spray Bottle and Wipe/Rag.

- ***Sequence of Events:*** A table listing the chronological order of key events for the study (e.g., test site selection, IIRB approval, subject recruitment, start of each monitoring events, etc) is reported on pages 121-122 of the study report.

- ***Sample Size:*** The study consisted of 3 clusters and 6 MEs per cluster (n=18) for each of the two wipe scenarios for a total of 36 MEs in the study.

- ***Treatment Solutions:***

    - **RTU Wipes:** The diluted treatment solution of Lemon Quat was prepared by the researchers for the RTU wipes in the laboratory (i.e., GPL). The Lemon Quat product was diluted with water 1:64 (0.0397% DDAC). Rolls of dry wipes (75 wipes per roll) were treated with 500 mL of the water diluted product. The treated wipes were then shaken on a shaker for 30 minutes. The nominal concentration of each wipe was 2.61 mg DDAC/wipe. The measured concentrations for the wipes were 2.34, 2.90, and 2.55 mg DDAC/wipe in clusters 1, 2, 3, respectively. The preparation of the treatment solution and RTU wipes were not part of the monitoring events.
    - **Trigger Sprayers:** The diluted treatment solution of Lemon Quat was prepared by the researchers in a 50 gallon tank. The preparation of the treatment solution was not part of the monitoring events. The 2.54% DDAC in concentrated solution was diluted 1:64 (0.0397% DDAC) in cluster 1 and 1:63 (0.0403% DDAC) in clusters 2 and 3.

- ***Duration & AaiH:*** For each of the 3 clusters (in each of the two scenarios), the MEs were randomly assigned to 1 of the 6 purposively selected wiping times. The pre-determined wiping times were:

    - 30 to <60 minutes
    - 60 to <90 minutes
    - 90 to <120 minutes
    - 120 to <150 minutes
    - 150 to <180 minutes
    - 180 to 210 minutes

    Actual wiping durations followed the predetermined sampling times closely. Individual wiping times for each of the MEs are reported in Table 2 below. The amount of DDAC handled by the 18 MEs in each scenario ranged from 0.00014 to 0.00160 lbs ai with a mean ± one standard deviation of 0.00074 ± 0.00044 lb ai for the RTU Wipes scenario and ranged from 0.00038 to 0.00474 lbs ai with a mean of 0.0014 ± 0.0010 lb ai for the trigger spray scenario. The 18 MEs in the RTU Wipes scenario used varying numbers of wipes ranging from 27 to 250 wipes per ME. The amount ai per ME for the Trigger Spray and Wipe scenario is the amount actually sprayed onto surfaces, determined by weighing the spray container before and after wiping. These data are also reported in Table 2 below. The correlation coefficients between AaiH and wiping duration were 0.8 for RTU and 0.7 for spray and wipe. Some workers used more wipes or spray solution than others. For example, in the ready-to-use wipe study, in cluster 1 subject number W16 wiped for 165 minutes and used 156 wipes (0.0008 lb ai) while subject number W17 wiped for 162 minutes yet only used 88 wipes (0.00045 lb ai).

- ***Wiping Procedures***: Appendix K on pages 333 to 351 of the study report records the observation notes taken during each ME for the RTU scenario and Appendix L pages 352 to 371 for the trigger spray scenario. The workers were instructed to wipe "*as they would normally do*". Typical wiping procedures/observations were that the workers cleaned various horizontal and vertical surfaces such as walls, counter tops, etc using up & down, side-to-side, and circular motions.

- ***Environmental Conditions*:** Environmental conditions (humidity and temperature) are reported for the MEs on pages 136 to 141 of the study report (note: humidity and/or temperature readings not available for 8 of the MEs). The humidity averaged in the 40% range. Temperatures averaged in the low 70º F range. The heating ventilation air conditioning (HVAC) system descriptions for clusters 1 and 3 are reported on page 142 of study report (not available for cluster 2 for both scenarios). Cluster 1 reports the only air changes per hour (ACH), which is 8.1 ACH. It is unclear how the ACH was measured and if it represented ACH of outside make-up air or re-circulating air. Lighting levels were not measured. The HSRB noted at the October 2011 review of the AEATF II mop study that more attention should be given by the researchers to record the environmental conditions. However, this wipe study was conducted roughly at the same time period as the mop study. Therefore, limited information is available in this study too.

2.0 Results

2.1 QA/QC Recovery Results

Controls: The non-fortified field and laboratory control samples were all less than the limit of quantification (LOQ) which indicates no background contamination. The LOQs for the various matrices are air sampling tubes 10 ng/sample, neck/face wipe 50 ng/sample, WBD sections 3 µg/sample, and hand wash 1 µg/sample.

Laboratory Recoveries: Concurrent laboratory recoveries serve both scenarios (RTU & trigger spray). Most of the individual laboratory fortified recovery values range within 70 to 120 percent. Exceptions include a few outside of the 120 percent upper bound, none below 70 percent. A summary of the overall concurrent laboratory recovery samples for each monitoring matrix by cluster is reported in the study report starting on page 76 (individual recovery values can be viewed starting on page 144). The mean recoveries in cluster 1 for all matrices range from 103 ± 15 to 113 ± 17; cluster 2 ranged from 99 ± 5 to 113 ± 6; and cluster 3 ranged from 95 ± 4 to 108 ± 6.

Field Recoveries: Field recoveries serve both scenarios (RTU & trigger spray). Most of the individual field fortified recovery values range within 70 to 120 percent. Exceptions include a few outside of the 120 percent upper bound, none below 70 percent. A summary of the overall field fortified recovery samples for each monitoring matrix by cluster is reported on page 78 of the study report (individual recovery values can be viewed starting on page 150). The mean recoveries in cluster 1 for all matrices range from 83 ± 11 to 107 ± 21; cluster 2 ranged from 93

± 10 to 109 ± 12; and cluster 3 ranged from 92 ± 9 to 103 ± 5. All exposure/field matrices were corrected for the field fortified recovery results.

2.2 Calculating Unit Exposures

Dermal Unit Exposure: Dermal exposure is measured using 100% cotton inner and outer "whole body dosimeters" (WBD). The inner WBDs were worn underneath normal work clothing (i.e., long-sleeved shirt and long pants). The normal work clothing worn over the inner WBDs were also analyzed and reported as "outer" dosimeters. In addition, dermal exposures also included hand washes (collected at the end of the day and during breaks), and face/neck wipes (also collected during the ME to wipe off sweat; see study report page 48). The inner and outer WBDs are sectioned and analyzed by body part (i.e., upper and lower arms, front and rear torso, and upper and lower legs). The inner WBD sections were only analyzed if the corresponding outer dosimeter section tested above the LOQ. One-half the LOQ was substituted for all non detected (ND) samples. If the outer dosimeter was ND then the inner dosimeter for the same body section was also considered to be ND and ½ LOQ was substituted for those WBD sections as well. The study report for total dermal exposure substituted a single ½ LOQ value for multiple ND samples. EPA has recalculated the total dermal exposure substituting ½ LOQ for each of the ND WBD sections (resulting in a minimal impact on the results). All samples are adjusted as appropriate according to recovery results from field fortification samples.

Dermal exposures to the hands and face/neck are also corrected for sampling efficiency (see study report pages 67 and 69 for equations). A removal efficiency study for hand washes and wipes was performed using the test substance, DDAC, in a previous study (Boatwright 2007, MRID 47214801). The hand wash removal efficiency for DDAC is 90.3%. The same study also performed wipes. The wipe removal efficiency is calculated as 58.8% and is used to correct the face/neck samples.

Total dermal exposure is calculated by summing exposure across all body parts for each individual monitored. The following WBD sections are summed to calculate the clothing configuration of long pants, long-sleeved shirts (plus face/neck wash and hand wash):

- inner lower and inner upper arms,
- inner front and inner rear torso, and
- inner lower and inner upper legs.

The following WBD sections are summed to calculate the clothing configuration of long pants, short-sleeved shirts (plus face/neck wash and hand wash):

- outer and inner lower arm,
- inner upper arm,
- inner front and inner rear torso, and
- inner lower and inner upper leg.

The following WBD sections are summed to calculate the clothing configuration of short pants, short-sleeved shirts (plus face/neck wash and hand wash):

- outer and inner lower arm,
- inner upper arm,
- inner front and inner rear torso,
- inner upper leg, and
- inner and outer lower leg.

Dermal unit exposures (i.e., mg/lb ai handled) are calculated by dividing the summed total exposure by the amount of active ingredient handled. The AEATF II's study report normalized the dermal exposures by milligrams (mg) of active ingredient applied. EPA recalculated the exposures and expressed the results as mg/lb ai applied. EPA prefers the normalization by pounds to coincide with the English units reported on pesticide labels (e.g., pounds, ounces).

Inhalation Exposure: Inhalation exposure is measured using a personal air sampling pump and an OSHA Versatile Sampler (OVS) tubes. The tube is attached to the worker's collar to continuously sample air from the breathing zone. The sampling pumps were run continuously, even during breaks. Collected residue, per standard practice, is adjusted for recovery from field fortification samples.

Inhalation unit exposures (i.e., mg/m^3/lb ai handled) are calculated by dividing the air concentrations by the amount of ai handled. When the need arises for the unit inhalation exposures to be in units of mg/lb ai (e.g., when assessing inhalation risks using an oral toxicological endpoint) the inhalation unit exposure is calculated as the (air conc (mg/m^3) / lb ai) * breathing rate (1 m^3/hour) * wipe duration (hours/day).

2.3 Dermal and Inhalation Exposure Results

Results -- A summary of the results of the 18 MEs for each scenario are presented in Tables 2 and 5 (long pants, long sleeved-shirts), Tables 3 and 6 (long pants, short-sleeved shirts), and Tables 4 and 6 (short pants, short-sleeved shirts). These tables report the results for each individual worker along with empirical statistical summaries of each cluster and overall exposures. The inhalation UEs are the same for each of the clothing configurations (i.e., the three clothing scenarios are from the same worker). Therefore, the inhalation exposures are only reported once (in Tables 2 and 5).

Appendices A and B provides alternative statistical models to estimate the exposure summary statistics, including:

- Empirical simple random sampling model (see Appendices A and B Table 1);
- Lognormal simple random sampling model (see Appendices A and B Tables 3 through 6); and
- Lognormal mixed model (see Appendices A and B Table 2 for a summary, and Appendices A and B Tables 3 through 6 for detailed results).

The results of the lognormal mixed model have been selected to best represent the summary statistics for the unit exposures (as reported in Table 1 above). For a detailed discussion of the

lognormal mixed model calculations and results (along with a discussion of the HSRB-suggested quadratic models) the reader is referred to Appendices A and B.

Observations -- This wipe study includes the recording of individual participant activities by observers. The study report indicates… "*There were always three to four study personnel following the subject during a given monitoring event",* with one being the *"observer".* Observations recorded during each ME are reported starting on page 333 of the study report and record the "real world" events during wiping as a worker would normally do. A review of these observations and resulting exposures did not indicate any obvious outliers in the data.

Impact of Non-detects -- Minimal exposure inside of the clothing was expected for many of the body parts sampled for the wipe pesticide application technique. Even with sensitive analytical methods for the surrogate compound, DDAC, many samples were non-detect (ND). Samples with results less than the limit of quantification (LOQ) are included in the calculation of total exposure as ½ LOQ. For the ready-to-use wipes study, all of the hand wash and face/neck samples and 12 of the 18 air samples were greater than the LOQ. Also for the ready-to-use wipes study, 81 of the 108 inner WBD sectioned body parts and 20 of the 108 outer WBD sectioned body parts were less than the LOQ or not measured (because they were inner sections corresponding to an outer section that was below the LOQ). For the trigger spray and wipe study, all of the hand wash, face/neck samples and air samples were greater than the LOQ. Also for the trigger spray and wipe study, 38 of the 108 inner WBD sectioned body parts and 2 of the 108 outer WBD sectioned body parts were less than the LOQ or not measured.

The impact of the ND samples for the short pants, short-sleeved shirt, and no glove clothing configuration for the dermal UE is minimal. The following data presentation (empirical estimates) illustrate the change in the dermal UE values when NDs were substituted with 0, ½ LOQ, and the full LOQ.

Comparison of Dermal UE (mg/lb ai) for Non-detects Equal to 0, ½ LOQ, Full LOQ				
Study	Statistic	NDs = 0	NDs = ½ LOQ	NDs = Full LOQ
RTU Wipes	Mean	2600	2620	2640
RTU Wipes	95th% tile	5620	5640	5650
Trigger Spray & Wipe	Mean	1730	1740	1740
Trigger Spray & Wipe	95th% tile	3310	3310	3320

A similar analysis was not performed for the long pants, long-sleeved shirt or the long pants, short-sleeved shirt clothing configurations but the impact of the non-detects on these clothing configurations is expected to be minimal too. This expectation is based on the higher contribution of the hand exposure to total dermal exposure for the long pants, long-sleeved shirt clothing configuration. For the ready-to-use wipes, for the long pants, long-sleeved shirt configuration, 98 percent of the total dermal exposure is attributed to the hand exposure and only 82 percent of the total dermal exposure for the short pants, short-sleeved shirt scenario is attributed to the hands. For the trigger spray and wipe study, for the long pants, long-sleeved shirt configuration, 92 percent of the total dermal exposure is attributed to the hand exposure and only 51 percent of the total dermal exposure for the short pants, short-sleeved shirt scenario is attributed to the hands.

Table 2. RTU Wipes: Summary (Empirical) of Dermal and Inhalation Results -- Long Pants, Long-sleeved Shirt and No Glove Scenario.

Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Wipes	Pounds ai Handled	Dermal Exposure (mg)	Inhalation Exposure (mg/m3)	Unit Exposures	
									Dermal (mg/lb ai)	Inhalation (mg/m3/lb ai)
1	WS-02	W45	37	1614.5	40	0.000206	0.6656	0.000048	3225.62	0.2336
	WS-08	W13	73	1509.8	27	0.000139	0.7067	0.000289	5071.69	2.0742
	WS-10	W42	104	3504.0	103	0.000531	1.3874	0.000070	2611.34	0.1308
	WS-11	W32	131	2750.8	216	0.001113	1.6163	0.000143	1451.74	0.1284
	WS-05	W17	162	1790.1	88	0.000454	2.2305	0.000224	4911.30	0.4932
	WS-01	W16	165	5029.6	156	0.000805	2.8259	0.000058	3511.84	0.0716
		Mean	**112**	**2699.8**	**105**	**0.000542**	**1.5721**	**0.000139**	**3463.92**	**0.5220**
		Std	**51**	**1378.3**	**71**	**0.000368**	**0.8500**	**0.000099**	**1379.47**	**0.7751**
2	WS-13	W37	61	557.0	37	0.000236	0.4229	0.000180	1792.87	0.7631
	WS-20	W26	90	1752.0	165	0.001056	0.9662	0.000073	914.90	0.0687
	WS-24	W29	120	2786.0	138	0.000882	1.2203	0.000146	1383.81	0.1656
	WS-21	W5	149	2663.0	131	0.000838	0.6179	0.000043	737.54	0.0516
	WS-17	W14	180	703.0	222	0.001420	1.6167	0.000200	1138.70	0.1409
	WS-14	W41	182	1603.0	250	0.001598	0.8203	0.000011	513.23	0.0068
		Mean	**130**	**1677.3**	**157**	**0.001005**	**0.9440**	**0.000109**	**1080.18**	**0.1994**
		Std	**49**	**939.8**	**75**	**0.000482**	**0.4295**	**0.000077**	**462.54**	**0.2823**
3	WS-32	W49	59	876.0	37	0.000208	0.4432	0.000035	2131.87	0.1693
	WS-28	W2	89	1110.0	71	0.000399	1.3682	0.000070	3428.86	0.1752
	WS-30	W34	119	1160.0	123	0.000692	1.0243	0.000058	1479.71	0.0842
	WS-27	W39	133	1800.0	84	0.000472	1.2331	0.000015	2613.73	0.0309
	WS-31	W52	179	1899.0	177	0.000994	0.9362	0.000029	941.58	0.0290
	WS-34	W8	201	4907.0	213	0.001197	2.5280	0.000430	2111.74	0.3592
		Mean	**130**	**1958.7**	**118**	**0.000660**	**1.2555**	**0.000106**	**2117.91**	**0.1413**
		Std	**53**	**1500.1**	**67**	**0.000377**	**0.6997**	**0.000160**	**866.69**	**0.1245**
Overall		Mean	124	2111.9	127	0.000736	1.2572	0.000118	2220.67	0.2876
		Std	49	1295.1	71	0.000437	0.6931	0.000111	1360.84	0.4841
		Median	126	1771.1	127	0.000748	1.1223	0.000070	1952.30	0.1358
		Geo Mean	113	1781.4	104	0.000594	1.0926	0.000077	1840.68	0.1290
		95th%tile	185	4925.4	226	0.001447	2.5727	0.000310	4935.36	0.9597

Table 3. RTU Wipes: Summary (Empirical) of Dermal Results -- Long Pants, Short-sleeved Shirt and No Glove Scenario.								
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Wipes	Pounds ai Handled	Dermal Exposure (mg)	Unit Exposures Dermal (mg/lb ai)
1	WS-02	W45	37	1614.5	40	0.000206	0.6896	3341.92
	WS-08	W13	73	1509.8	27	0.000139	0.7701	5526.72
	WS-10	W42	104	3504.0	103	0.000531	1.4518	2732.55
	WS-11	W32	131	2750.8	216	0.001113	1.7303	1554.13
	WS-05	W17	162	1790.1	88	0.000454	2.4105	5307.65
	WS-01	W16	165	5029.6	156	0.000805	2.8987	3602.31
		Mean	**112**	**2699.8**	**105**	**0.000542**	**1.6585**	**3677.55**
		Std	**51**	**1378.3**	**71**	**0.000368**	**0.8809**	**1522.95**
2	WS-13	W37	61	557.0	37	0.000236	0.7139	3026.47
	WS-20	W26	90	1752.0	165	0.001056	1.0222	967.93
	WS-24	W29	120	2786.0	138	0.000882	1.4383	1631.02
	WS-21	W5	149	2663.0	131	0.000838	0.9229	1101.61
	WS-17	W14	180	703.0	222	0.001420	1.7807	1254.21
	WS-14	W41	182	1603.0	250	0.001598	0.9203	575.79
		Mean	**130**	**1677.3**	**157**	**0.001005**	**1.1330**	**1426.17**
		Std	**49**	**939.8**	**75**	**0.000482**	**0.3975**	**856.85**
3	WS-32	W49	59	876.0	37	0.000208	0.4496	2162.41
	WS-28	W2	89	1110.0	71	0.000399	1.3884	3479.48
	WS-30	W34	119	1160.0	123	0.000692	1.0969	1584.58
	WS-27	W39	133	1800.0	84	0.000472	1.2461	2641.29
	WS-31	W52	179	1899.0	177	0.000994	1.0462	1052.21
	WS-34	W8	201	4907.0	213	0.001197	3.0470	2545.28
		Mean	**130**	**1958.7**	**118**	**0.000660**	**1.3790**	**2244.21**
		Std	**53**	**1500.1**	**67**	**0.000377**	**0.8780**	**852.86**
Overall		Mean	124	2111.9	127	0.000736	1.3902	2449.31
		Std	49	1295.1	71	0.000437	0.7417	1424.35
		Median	126	1771.1	127	0.000748	1.1715	2353.85
		Geo Mean	113	1781.4	104	0.000594	1.2279	2068.53
		95th%tile	185	4925.4	226	0.001447	2.9210	5340.51

Table 4. RTU Wipes: Summary (Empirical) of Dermal Results -- Short Pants, Short-sleeved Shirt and No Glove Scenario.								
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Number Wipes	Pounds ai Handled	Dermal Exposure (mg)	Unit Exposures Dermal (mg/lb ai)
1	WS-02	W45	37	1614.5	40	0.000206	0.6911	3349.19
	WS-08	W13	73	1509.8	27	0.000139	0.9411	6754.00
	WS-10	W42	104	3504.0	103	0.000531	1.4750	2776.21
	WS-11	W32	131	2750.8	216	0.001113	1.7399	1562.80
	WS-05	W17	162	1790.1	88	0.000454	2.4698	5438.22
	WS-01	W16	165	5029.6	156	0.000805	2.9026	3607.08
		Mean	**112**	**2699.8**	**105**	**0.000542**	**1.7032**	**3914.58**
		Std	**51**	**1378.3**	**71**	**0.000368**	**0.8585**	**1877.49**
2	WS-13	W37	61	557.0	37	0.000236	0.7154	3032.83
	WS-20	W26	90	1752.0	165	0.001056	1.0425	987.16
	WS-24	W29	120	2786.0	138	0.000882	2.1983	2492.84
	WS-21	W5	149	2663.0	131	0.000838	1.1079	1322.44
	WS-17	W14	180	703.0	222	0.001420	2.0777	1463.40
	WS-14	W41	182	1603.0	250	0.001598	0.9319	583.05
		Mean	**130**	**1677.3**	**157**	**0.001005**	**1.3456**	**1646.95**
		Std	**49**	**939.8**	**75**	**0.000482**	**0.6292**	**931.92**
3	WS-32	W49	59	876.0	37	0.000208	0.4540	2183.58
	WS-28	W2	89	1110.0	71	0.000399	1.3928	3490.43
	WS-30	W34	119	1160.0	123	0.000692	1.1675	1686.57
	WS-27	W39	133	1800.0	84	0.000472	1.2525	2654.85
	WS-31	W52	179	1899.0	177	0.000994	1.0657	1071.82
	WS-34	W8	201	4907.0	213	0.001197	3.2280	2696.48
		Mean	**130**	**1958.7**	**118**	**0.000660**	**1.4268**	**2297.29**
		Std	**53**	**1500.1**	**67**	**0.000377**	**0.9402**	**848.35**
Overall		Mean	124	2111.9	127	0.000736	1.4919	2619.61
		Std	49	1295.1	71	0.000437	0.7861	1570.45
		Median	126	1771.1	127	0.000748	1.2100	2573.85
		Geo Mean	113	1781.4	104	0.000594	1.3126	2211.36
		95th%tile	185	4925.4	226	0.001447	2.9514	5635.59

Table 5. Trigger Spray & Wipe: Summary (Empirical) of Dermal and Inhalation Results -- Long Pants, Long-sleeved Shirt and No Glove Scenario.

Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Pounds ai Handled	Dermal Exposure (mg)	Inhalation Exposure (mg/m3)	Unit Exposures	
								Dermal (mg/lb ai)	Inhalation (mg/m3/lb ai)
1	WS-04	W50	51	1077.4	0.000419	1.4571	0.019400	3478.65	46.3142
	WS-06	W24	70	640.0	0.000375	0.4272	0.009930	1139.85	26.4951
	WS-07	W27	93	1406.5	0.000928	2.5802	0.004130	2779.98	4.4497
	WS-09	W10	142	3243.7	0.001153	0.6361	0.011700	551.64	10.1473
	WS-12	W19	174	3628.7	0.001764	0.8415	0.023000	477.12	13.0408
	WS-03	W7	187	3186.3	0.002055	0.7894	0.017800	384.19	8.6630
		Mean	**120**	**2197.1**	**0.001116**	**1.1219**	**0.014327**	**1468.57**	**18.1850**
		Std	**56**	**1298.2**	**0.000689**	**0.7933**	**0.006975**	**1331.76**	**15.6889**
2	WS-16	W6	60	1269.0	0.000672	0.4342	0.008640	645.68	12.8493
	WS-23	W25	89	1444.0	0.000822	0.5088	0.003470	618.78	4.2197
	WS-18	W18	121	1130.0	0.001435	0.7107	0.005490	495.18	3.8252
	WS-22	W44	150	2501.0	0.002013	2.3867	0.015000	1185.74	7.4522
	WS-19	W12	180	3076.0	0.004742	2.1591	0.014100	455.30	2.9733
	WS-15	W56	209	3617.0	0.001973	1.0917	0.000859	553.28	0.4353
		Mean	**135**	**2172.8**	**0.001943**	**1.2152**	**0.007927**	**658.99**	**5.2925**
		Std	**56**	**1043.5**	**0.001481**	**0.8535**	**0.005734**	**267.87**	**4.3369**
3	WS-36	W55	59	387.0	0.000399	0.8074	0.003300	2023.28	8.2699
	WS-25	W35	60	1256.0	0.000747	0.7648	0.005560	1023.26	7.4395
	WS-35	W4	104	1072.0	0.001177	1.2772	0.005350	1084.87	4.5444
	WS-33	W1	137	2740.0	0.001307	1.0788	0.018900	825.16	14.4568
	WS-29	W40	153	421.0	0.001276	0.8842	0.004100	692.70	3.2120
	WS-26	W28	185	2047.0	0.001268	0.9754	0.005360	769.41	4.2283
		Mean	**116**	**1320.5**	**0.001029**	**0.9646**	**0.007095**	**1069.78**	**7.0251**
		Std	**51**	**926.2**	**0.000373**	**0.1908**	**0.005850**	**490.67**	**4.1344**
Overall		Mean	124	1896.8	0.001363	1.1006	0.009783	1065.78	10.1676
		Std	52	1115.4	0.001003	0.6491	0.006716	853.95	10.8404
		Median	129	1425.3	0.001222	0.8629	0.007100	731.06	7.4458
		Geo Mean	112	1547.1	0.001112	0.9554	0.007420	859.16	6.6726
		95th%tile	190	3618.8	0.002458	2.4157	0.019940	2884.78	29.4680

Table 6. Trigger Spray & Wipe: Summary (Empirical) of Dermal Results -- Long Pants, Short-sleeved Shirt and No Glove Scenario.							
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Pounds ai Handled	Dermal Exposure (mg)	Unit Exposures Dermal (mg/lb ai)
1	WS-04	W50	51	1077.4	0.000419	2.0281	4841.81
	WS-06	W24	70	640.0	0.000375	0.7222	1926.97
	WS-07	W27	93	1406.5	0.000928	2.7192	2929.74
	WS-09	W10	142	3243.7	0.001153	0.9741	844.78
	WS-12	W19	174	3628.7	0.001764	1.1855	672.17
	WS-03	W7	187	3186.3	0.002055	2.6234	1276.77
		Mean	**120**	**2197.1**	**0.001116**	**1.7088**	**2082.04**
		Std	**56**	**1298.2**	**0.000689**	**0.8656**	**1582.78**
2	WS-16	W6	60	1269.0	0.000672	0.7702	1145.37
	WS-23	W25	89	1444.0	0.000822	0.6868	835.24
	WS-18	W18	121	1130.0	0.001435	1.0797	752.28
	WS-22	W44	150	2501.0	0.002013	4.1687	2071.06
	WS-19	W12	180	3076.0	0.004742	5.9021	1244.61
	WS-15	W56	209	3617.0	0.001973	1.3197	668.83
		Mean	**135**	**2172.8**	**0.001943**	**2.3212**	**1119.57**
		Std	**56**	**1043.5**	**0.001481**	**2.1844**	**517.79**
3	WS-36	W55	59	387.0	0.000399	0.8411	2107.73
	WS-25	W35	60	1256.0	0.000747	1.2978	1736.43
	WS-35	W4	104	1072.0	0.001177	2.0282	1722.78
	WS-33	W1	137	2740.0	0.001307	1.3478	1030.92
	WS-29	W40	153	421.0	0.001276	1.3502	1057.77
	WS-26	W28	185	2047.0	0.001268	1.1904	939.02
		Mean	**116**	**1320.5**	**0.001029**	**1.3426**	**1432.44**
		Std	**51**	**926.2**	**0.000373**	**0.3865**	**485.34**
Overall		Mean	124	1896.8	0.001363	1.7908	1544.68
		Std	52	1115.4	0.001003	1.3566	1027.18
		Median	129	1425.3	0.001222	1.3087	1194.99
		Geo Mean	112	1547.1	0.001112	1.4736	1325.14
		95th%tile	190	3618.8	0.002458	4.4287	3216.55

Table 7. Trigger Spray & Wipe: Summary (Empirical) of Dermal Results -- Short Pants, Short-sleeved Shirt and No Glove Scenario.							
Cluster	Subject Order	Subject Number ID	Task Duration (minutes)	Surface Area (sq ft)	Pounds ai Handled	Dermal Exposure (mg)	Unit Exposures Dermal (mg/lb ai)
1	WS-04	W50	51	1077.4	0.000419	2.1591	5154.55
	WS-06	W24	70	640.0	0.000375	0.9432	2516.64
	WS-07	W27	93	1406.5	0.000928	2.7738	2988.57
	WS-09	W10	142	3243.7	0.001153	1.2061	1045.99
	WS-12	W19	174	3628.7	0.001764	1.7475	990.82
	WS-03	W7	187	3186.3	0.002055	2.9414	1431.54
		Mean	**120**	**2197.1**	**0.001116**	**1.9619**	**2354.69**
		Std	**56**	**1298.2**	**0.000689**	**0.8140**	**1593.25**
2	WS-16	W6	60	1269.0	0.000672	0.8237	1224.94
	WS-23	W25	89	1444.0	0.000822	0.7361	895.19
	WS-18	W18	121	1130.0	0.001435	1.1271	785.31
	WS-22	W44	150	2501.0	0.002013	4.5297	2250.41
	WS-19	W12	180	3076.0	0.004742	6.1951	1306.39
	WS-15	W56	209	3617.0	0.001973	1.3512	684.79
		Mean	**135**	**2172.8**	**0.001943**	**2.4605**	**1191.17**
		Std	**56**	**1043.5**	**0.001481**	**2.3191**	**573.61**
3	WS-36	W55	59	387.0	0.000399	0.8660	2170.13
	WS-25	W35	60	1256.0	0.000747	1.8248	2441.57
	WS-35	W4	104	1072.0	0.001177	2.0637	1752.94
	WS-33	W1	137	2740.0	0.001307	1.6288	1245.86
	WS-29	W40	153	421.0	0.001276	1.4952	1171.37
	WS-26	W28	185	2047.0	0.001268	1.5134	1193.82
		Mean	**116**	**1320.5**	**0.001029**	**1.5653**	**1662.61**
		Std	**51**	**926.2**	**0.000373**	**0.4041**	**549.05**
Overall		Mean	124	1896.8	0.001363	1.9959	1736.16
		Std	52	1115.4	0.001003	1.4024	1083.42
		Median	129	1425.3	0.001222	1.5711	1276.12
		Geo Mean	112	1547.1	0.001112	1.6762	1507.34
		95th%tile	190	3618.8	0.002458	4.7795	3313.47

2.4 Evaluation of Scenario Benchmark Objective

Benchmark Objective -- The data from the two wipe studies have been analyzed to see if the two wipe scenarios meet the AEATF II objective of a relative 3-fold accuracy (i.e., K=3). Using the SAS code originally developed by the Agricultural Handler Exposure Task Force (AHETF) and independently confirmed by the Health Effects Division (HED) (and now modified by AD), EPA has determined and presents the analysis that the wipe study results meet the 3-fold relative accuracy objective. Appendices A and B provide the detail benchmark analysis which is summarized as follows:

Benchmark Objective: fold Relative Accuracy (fRA)

The benchmark objective for AEATF II scenarios is for select statistics – the geometric mean (GM), the arithmetic mean (AM), and the 95th percentile (P95) – to be accurate within 3-fold with 95% confidence (i.e., "fold relative accuracy"). EPA has analyzed the data using various statistical techniques to evaluate this benchmark. First, to characterize the unit exposures (also referred to as "normalized exposure"), lognormal probability plots of dermal and inhalation UEs (adjusted for residue method collection efficiencies) are provided in Figures 2 to 5 (RTU Wipes) and Figures 6 to 9 (Trigger Spray & Wipe) for the 3 clothing configurations as well as inhalation exposure. These plots support the assumed lognormal distributions for the normalized exposure. Note: The figure titles are provided both above and below the graphs because they were cut and pasted as file images.

Quantile plot normalized long dermal exposure data with a lognormal distribution
Normalized by Pounds Active Ingredient Handled

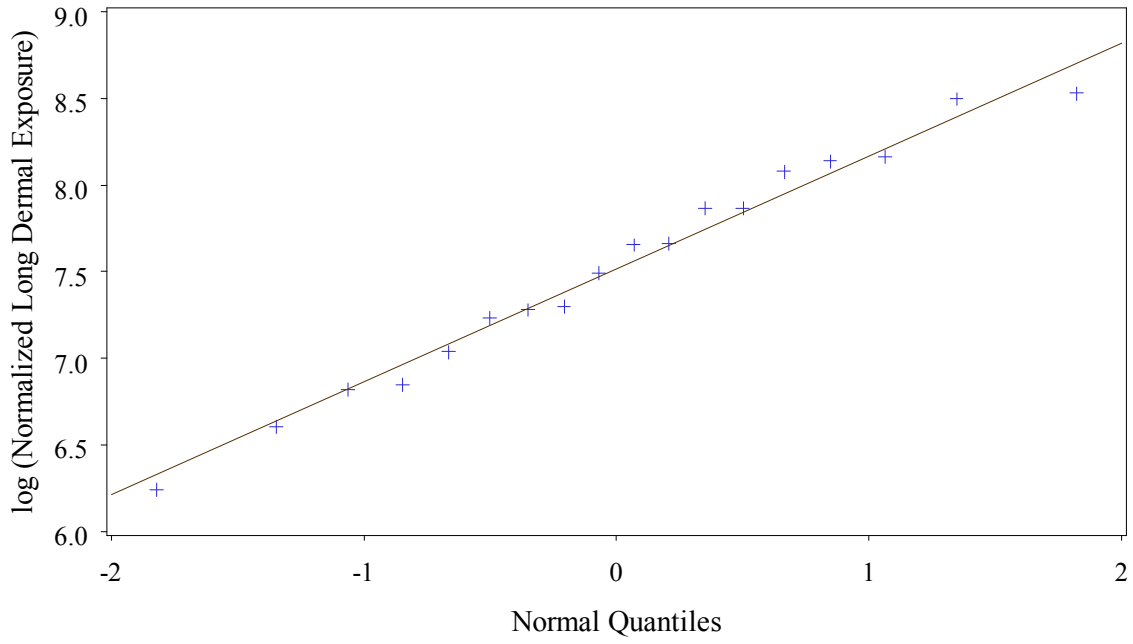

Figure 2. RTU Wipes: Quantile plot of normalized long dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

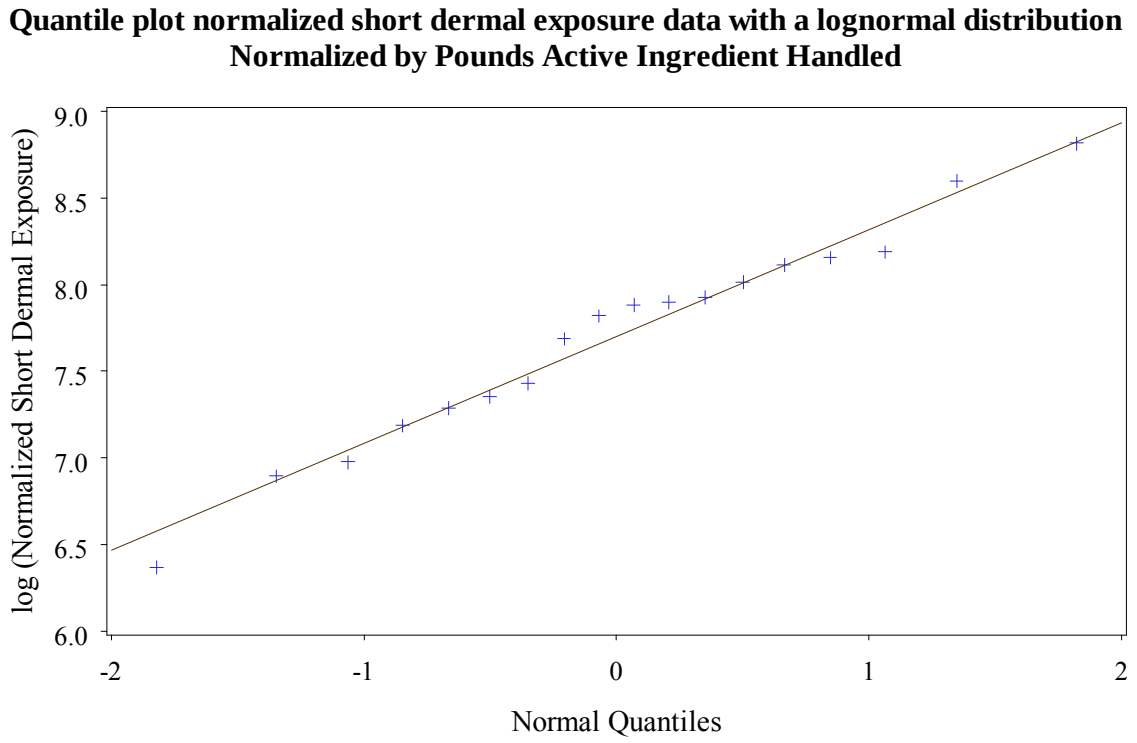

Figure 3. RTU Wipes: Quantile plot of normalized short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

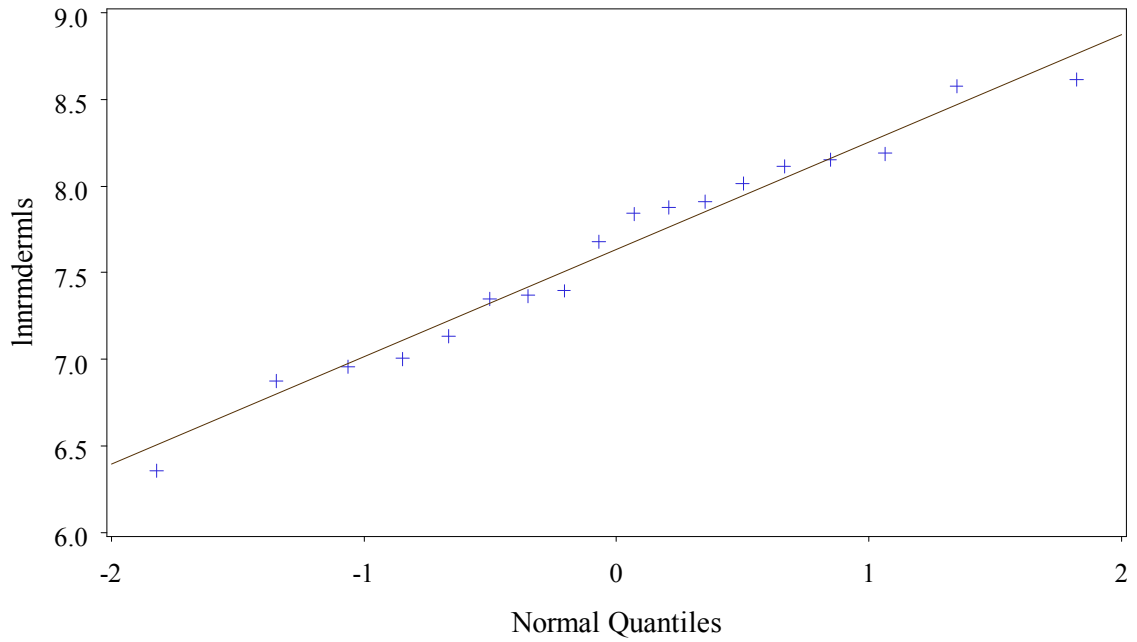

Figure 4. RTU Wipes: Quantile plot of normalized long short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

Quantile plot normalized inhalation exposure data with a lognormal distribution
Normalized by Pounds Active Ingredient Handled

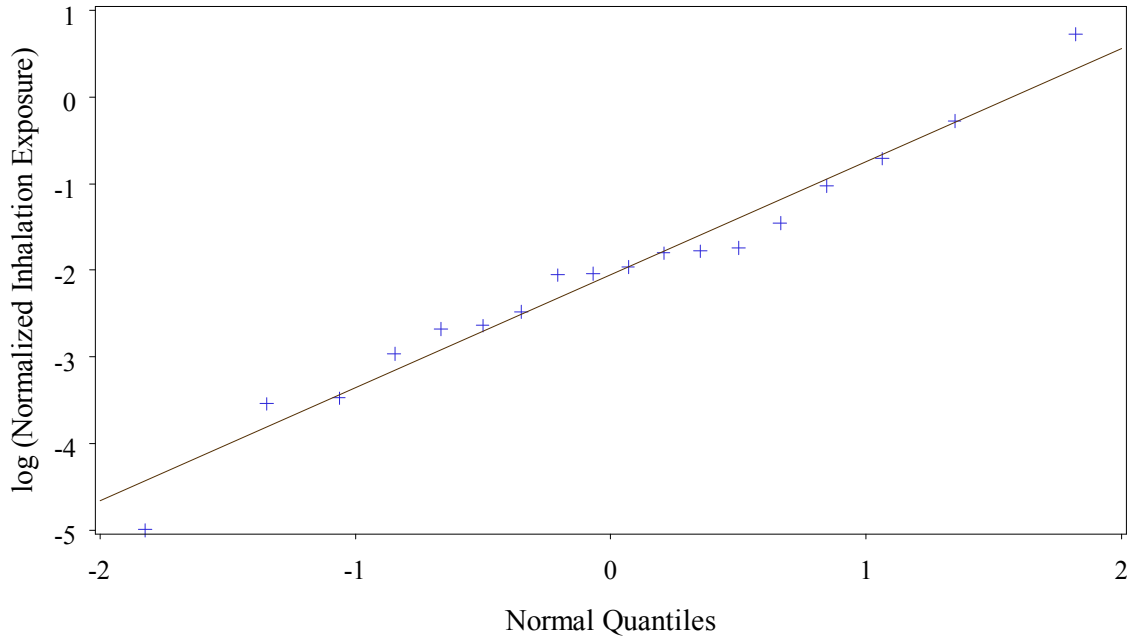

Figure 5. RTU Wipes: Quantile plot of normalized inhalation exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

Quantile plot normalized long dermal exposure data with a lognormal distribution
Normalized by Pounds Active Ingredient Handled

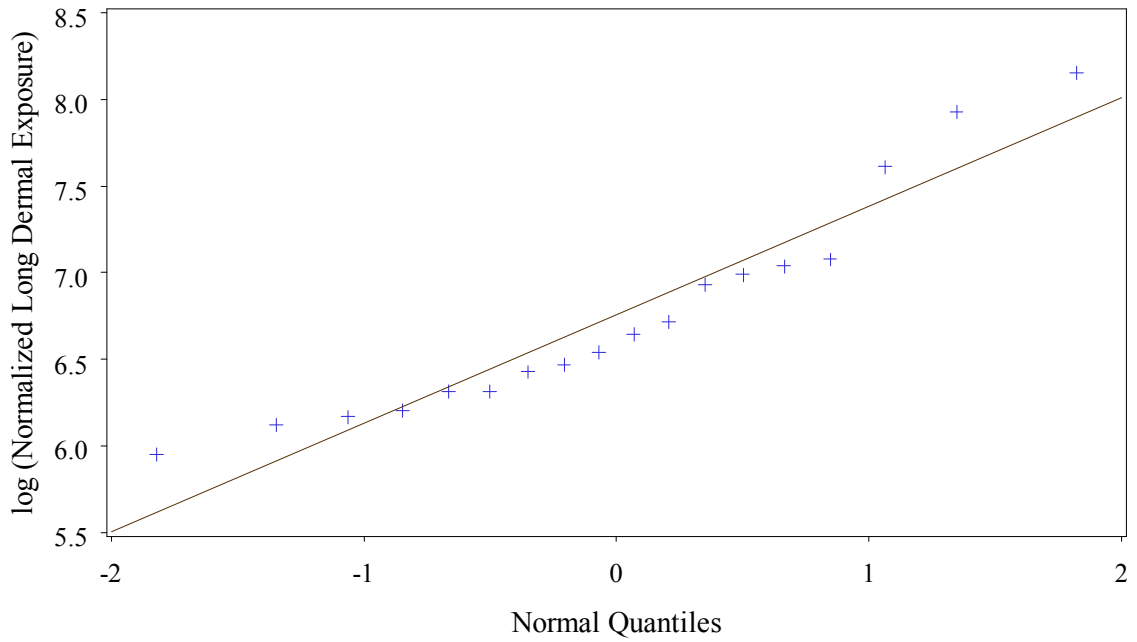

Figure 6. Trigger Spray & Wipe: Quantile plot of normalized long dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

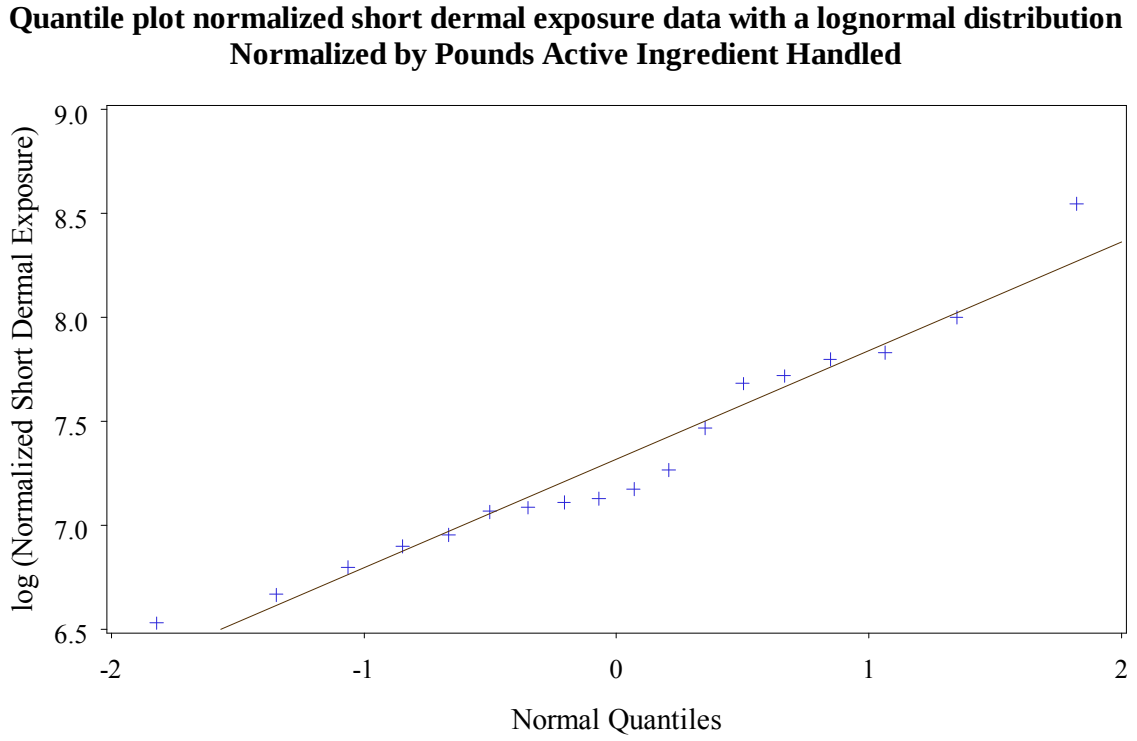

Figure 7. Trigger Spray & Wipe: Quantile plot of normalized short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

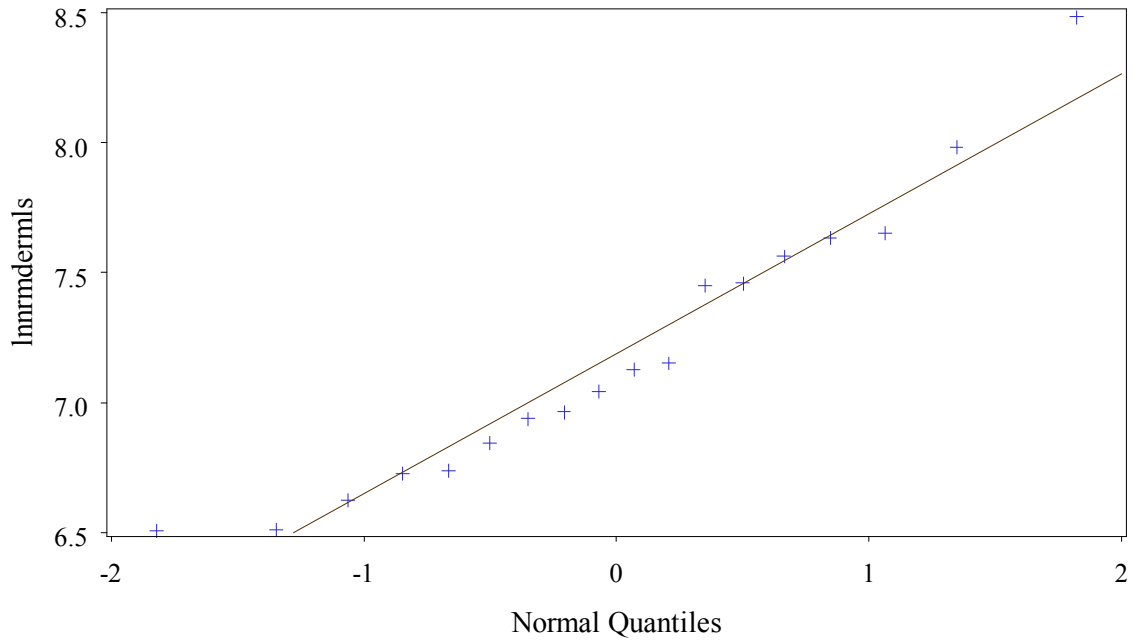

Figure 8. Trigger Spray & Wipe: Quantile plot of normalized long short dermal exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

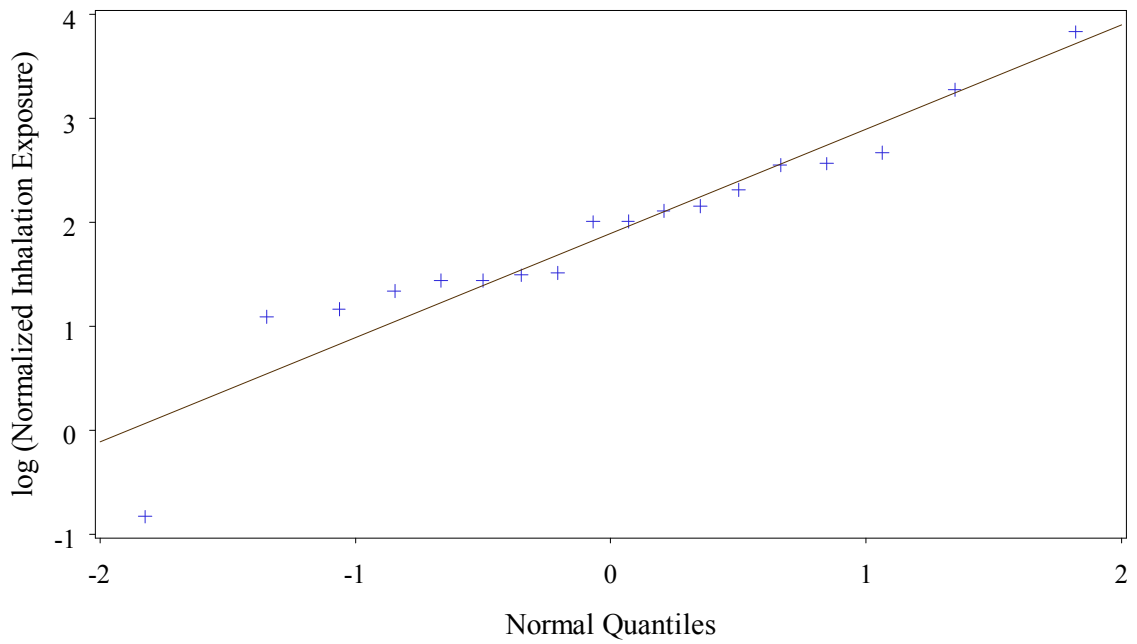

Figure 9. Trigger Spray & Wipe: Quantile plot of normalized inhalation exposure data with a lognormal distribution normalized by pounds of Active Ingredient handled.

Next, EPA calculated estimates of the GM, AM and P95 based on three different calculation methods:

- Empirical estimates;
- Assuming a lognormal distribution and a simple random sample (SRS); and,
- Hierarchical variance component modeling to account for potential ME correlations.

The 95% confidence limits for each of these estimates were obtained by generating 10,000 parametric bootstrap samples. Then, the fRA for each was determined as the maximum of the two ratios of the statistical point estimates with their respective upper and lower 95% confidence limits. Table 8 below presents the results for the ready-to-use wipes scenario, for the long pants, short-sleeved shirt and the inhalation exposures. Table 9 below presents the results for the trigger spray and wipe scenario, for the long pants, short-sleeved shirt and the inhalation exposures. The results of the benchmark analysis for the other clothing configurations are reported in Appendices A and B, Table 3 (long pants, long-sleeved shirt) and Appendices A and B, Table 4 (short pants, short-sleeved shirt).

Table 8. RTU Wipes: Results of Primary Benchmark Analysis for Long Pants, Short-sleeved Shirt and Inhalation.						
	Dermal Exposure			**Inhalation Exposure**		
Statistic	**Unit Exposure Estimate (mg/lb ai)**	**95% CI**	**fRA**	**Unit Exposure Estimate (mg/m^3/lb ai)**	**95% CI**	**fRA**
GM_S	2068.5	1170.4 – 3630.9	1.8	0.13	0.07 – 0.26	2.0
GSD_S	1.9	1.5 – 2.6	1.4	3.70	2.41 – 5.69	1.5
GM_M	2068.5	1170.4 – 3630.9	1.8	0.13	0.07 – 0.26	2.0
GSD_M	1.9	1.5 – 2.9	1.5	3.73	2.43 – 5.92	1.6
ICC	0.5	0.0 – 0.8		0.05	0.0 – 0.47	
GM_S = geometric mean assuming SRS = "exp(average of 18 ln(UE)) values" GSD_S = geometric standard deviation assuming SRS = "exp(standard deviation of 18 ln(UE)) values" GM_M = variance component model-based geometric mean GSD_M = variance component model-based geometric standard deviation ICC = intra-cluster correlation						
AM_S	2449.3	1356.7 – 4526.5	1.8	0.29	0.12 – 0.71	2.5
AM_U	2505.4	1375.5 – 4613.8	1.8	0.30	0.13 – 0.77	2.5
AM_M	2583.6	1397.7 – 4916.1	1.9	0.31	0.13 – 0.81	2.6
AM_S = average of 18 unit exposures AM_U = arithmetic mean based on $GM_S = GM_S * \exp\{0.5*(\ln(GSD_S)^2\}$ AM_M = variance component model-based arithmetic mean = $GM_M * \exp\{0.5*(\ln(GSD_M)^2\}$						
$P95_S$	5526.7	2753.6 – 14895.8	2.7	2.07	0.40 – 6.70	5.2
$P95_U$	5726.4	2726.2 – 11872.3	2.1	1.11	0.40 – 2.94	2.8
$P95_M$	6194.8	2783.4 – 14093.2	2.3	1.13	0.41 – 3.09	2.8
$P95_S = 95^{th}$ percentile (i.e., estimated as the maximum unit exposure from the 18 unit exposures) $P95_U = 95^{th}$ percentile based on $GM_S = GM_S * GSD_S^{1.645}$ $P95_M$ = variance component model-based 95^{th} percentile = $GM_M * GSD_M^{1.645}$						

Table 9. Trigger Spray & Wipe: Results of Primary Benchmark Analysis for Long Pants, Short-sleeved Shirt and Inhalation.						
	Dermal Exposure			Inhalation Exposure		
Statistic	**Unit Exposure Estimate (mg/lb ai)**	**95% CI**	**fRA**	**Unit Exposure Estimate (mg/m^3/lb ai)**	**95% CI**	**fRA**
GM_S	1325.1	1016.8 – 1735.7	1.3	6.7	3.1 – 14.4	2.2
GSD_S	1.7	1.4 – 2.1	1.2	2.7	1.9 – 4.1	1.5
GM_M	1325.1	1016.8 – 1735.7	1.3	6.7	3.1 – 14.4	2.2
GSD_M	1.7	1.4 – 2.1	1.2	2.9	1.9 – 4.7	1.6
ICC	0.0	0.0 – 0.4		0.3	0.0 – 0.7	
GM_S = geometric mean assuming SRS = "exp(average of 18 ln(UE)) values" GSD_S = geometric standard deviation assuming SRS = "exp(standard deviation of 18 ln(UE)) values" GM_M = variance component model-based geometric mean GSD_M = variance component model-based geometric standard deviation ICC = intra-cluster correlation						
AM_S	1544.7	1150.0 – 2021.2	1.3	10.2	4.5 – 25.2	2.5
AM_U	1531.9	1160.2 – 2038.8	1.3	11.0	4.7 – 26.6	2.4
AM_M	1533.3	1162.6 – 2050.8	1.3	11.6	4.8 – 29.9	2.6
AM_S = average of 18 unit exposures AM_U = arithmetic mean based on $GM_S = GM_S * \exp\{0.5*(\ln(GSD_S)^2\}$ AM_M = variance component model-based arithmetic mean = $GM_M * \exp\{0.5*(\ln(GSD_M)^2\}$						
$P95_S$	4841.8	2138.5 – 6653.3	2.3	46.3	12.8 – 153.4	3.6
$P95_U$	3213.0	2138.3 – 4753.6	1.5	34.8	12.6 – 92.8	2.8
$P95_M$	3222.2	2148.2 – 4835.4	1.5	37.5	13.0 – 109.6	2.9
$P95_S = 95^{th}$ percentile (i.e., estimated as the maximum unit exposure from the 18 unit exposures) $P95_U = 95^{th}$ percentile based on $GM_S = GM_S * GSD_S^{1.645}$ $P95_M$ = variance component model-based 95^{th} percentile = $GM_M * GSD_M^{1.645}$						

Tables 3, 4, 5 and 6 of Appendices A and B also present confidence intervals computed using a non-parametric bootstrap approach instead of the bootstrap parametric approach, as suggested by HSRB reviewers of the mop study. The parametric bootstrap approach assumes that the exposure data were generated from the fitted lognormal mixed model. The non-parametric bootstrap approach assumes that the data were generated using a simple random sample from each cluster. For the RTU wipe scenario, the parametric and non-parametric bootstrap confidence intervals were generally similar for inhalation exposure, but the non-parametric bootstrap intervals tended to be narrower than the parametric bootstrap intervals for dermal exposure. For the Trigger Spray & Wipe scenario, the parametric and non-parametric bootstrap confidence intervals were generally similar for dermal exposure, but the non-parametric bootstrap intervals tended to be narrower than the parametric bootstrap intervals for inhalation exposure.

The benchmark of 3-fold accuracy for dermal and inhalation unit exposures has been met for the wipe scenarios for all 3 clothing scenarios and inhalation exposures for all 3 statistical models, except (as highlighted in yellow in the tables) for the empirical 95^{th} percentile for the inhalation exposure where the fold relative accuracy is 5.2 for the RTU Wipes scenario (Table 8 above) and is 3.6 for the Trigger Spray & Wipe scenario (Table 9 above).

Presumption of Proportionality -- EPA evaluated the presumption of proportionality between exposure and amount of active ingredient handled (AaiH). EPA tested proportionality using a statistical benchmark to be able to distinguish, with 80% statistical power, complete proportionality from complete independence between exposure and amount of active ingredient handled.

To evaluate the relationship for this scenario EPA performed regression analysis of ln(exposure) and ln(AaiH) to determine if the slope is not significantly different than 1 – providing support for a proportional relationship – or if the slope is not significantly different than 0 – providing support for an independent relationship. If slope is positive, not zero and not 1 then the exposure tends to increase with the AiaH but not proportionally, so that, for example, doubling the AiaH will not tend to double the exposure. If the slope confidence interval excludes both 1 and 0 then the statistical evidence rejects both proportionality and independence and shows that the exposure tends to increase with the AiaH but not proportionally. Note: the slope measures the change in log mg dermal exposure for each unit change in log lb ai.

A simple linear regression, a mixed-effect regression, and a more complex "repeated measures" model (see Appendix A page 36 or Appendix B page 34 for more details) were used to analyze the data to take into account the clustered nature of the data and were used to evaluate the relationship between exposure and AaiH. Appendices A and B also provide an analysis of the proportionality for each of the three clothing configurations for each scenario. For the RTU Wipes scenario, all three clothing configurations did not show proportionality and did not show independence. However, for this same scenario, the alternative approach in the Appendix to Appendix A shows proportionality to the wiping duration, For the Trigger Spray and Wipe scenario, the results of the proportionality analysis for the three clothing configurations are inconsistent; either all or none of the clothing configurations should show proportionality to AaiH. To investigate the proportionality issues further, an alternative model ("repeated measures") was developed to fit the data from all of the clothing configurations. The reader is referred to the SAS code for specific details on this repeated measures model.

The resulting regression slope and confidence intervals for the two wipe scenarios are summarized in Tables 10 and 11 and in Figures 10 to 13 (for the long pants, short-sleeved shirt dermal exposure and for inhalation exposure) below. To calculate the confidence intervals, the Kenwood-Rogers method was used to estimate the denominator degrees of freedom for the repeated measures models and for the mixed-effect regression with a non-zero estimated ICC. However, following comments from HSRB reviewers of the mop study analyses, we used the containment method to estimate the denominator degrees of freedom for the mixed-effect regression with a zero estimated ICC, since in those cases the Kenwood-Rogers method ignores the uncertainty of the estimated ICC and produces a confidence interval that is too narrow.

Note that a confidence interval width of 1.4 (or less) indicates at least 80% statistical power, which was achieved for dermal exposures and almost achieved (width = 1.47 for RTU Wipes) for inhalation exposures. Although the slopes are positive, the results for the dermal models indicate that exposure is not directly proportional (1:1) to AaiH (i.e., the confidence interval does not include 1) and also indicate that exposure is not independent of AiaH (i.e., the confidence interval does not contain 0, except for the trigger spray and wipe scenario long pants and long-sleeves dermal exposure). The results for the inhalation models indicate that exposure is not directly proportional (1:1) to AaiH (i.e., the confidence interval does not include 1) and suggest that exposure is independent of AiaH (i.e., confidence interval contains 0). For more

details including results for other normalizing variables, the reader is referred to Appendices A and B, Tables 8, 8b, 8c, 8d, and 8e.

Table 10. RTU Wipes: Results of Analysis of Proportionality for Dermal and Inhalation Exposure.

Exposure Route	Clothing	Model	Slope	Confidence Interval	Confidence Interval Width
Dermal (mg)	Long pants and long sleeves	Mixed	0.56	0.28 – 0.85	0.57
	Short pants and short sleeves	Mixed	0.48	0.15 – 0.81	0.66
	Long pants and short sleeves	Mixed	0.50	0.21 – 0.80	0.59
	Any	Repeated Measures	0.54	0.12 – 0.87	0.66
Inhalation (mg/m^3)		Mixed	-0.15	-0.89 – 0.58	1.47

Table 11. Trigger Spray & Wipe: Results of Analysis of Proportionality for Dermal and Inhalation Exposure.

Exposure Route	Clothing	Model	Slope	Confidence Interval	Confidence Interval Width
Dermal (mg)	Long pants and long sleeves	Mixed	0.37	-0.02 – 0.76	0.78
	Short pants and short sleeves	Mixed	0.57	0.21 – 0.93	0.73
	Long pants and short sleeves	Mixed	0.58	0.20 – 0.97	0.77
	Any	Repeated Measures	0.49	0.03 – 0.96	0.93
Inhalation (mg/m^3)		Mixed	0.25	-0.46 – 0.96	1.42

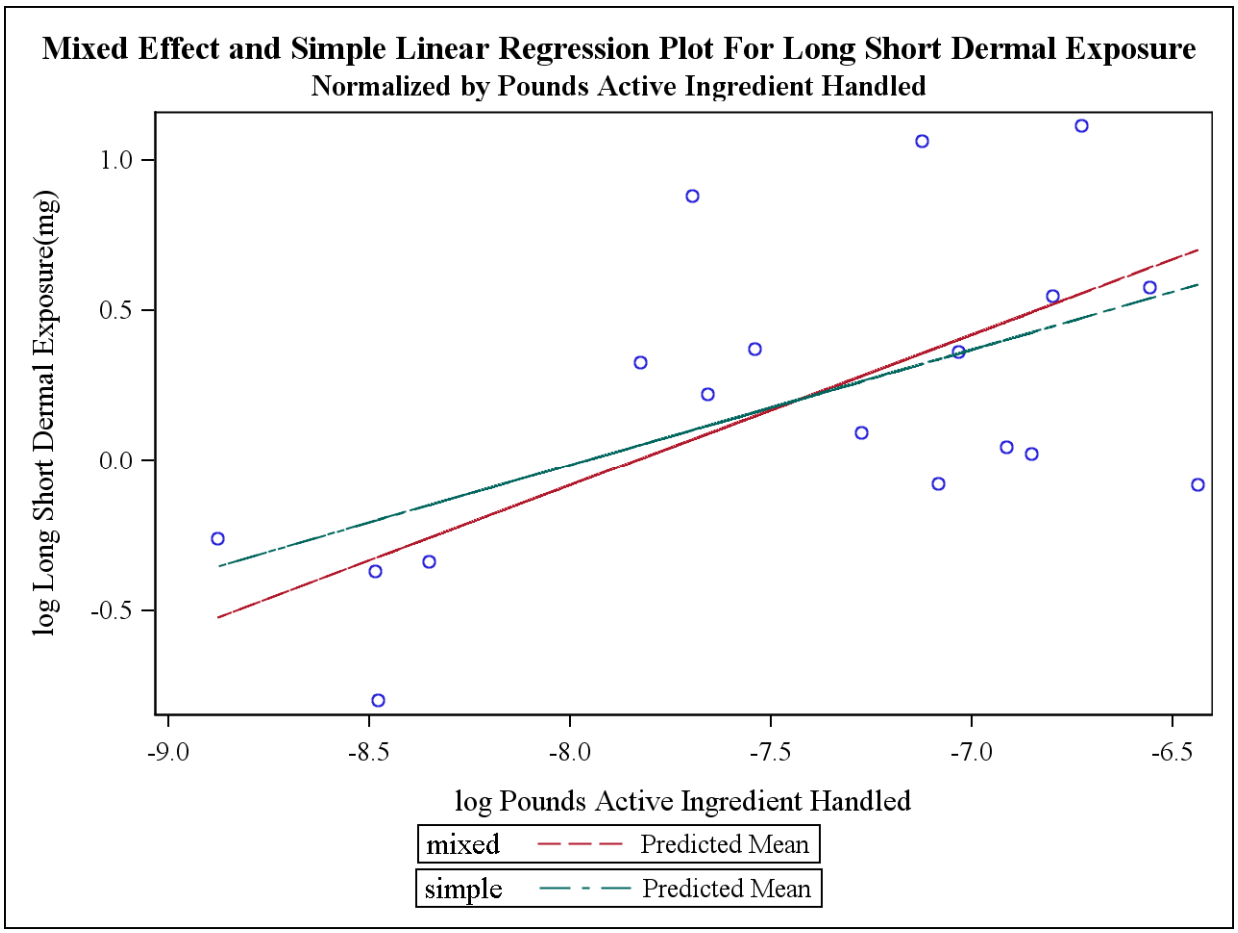

Figure 10. RTU Wipes: Mixed and simple linear regression plots for long short dermal exposure

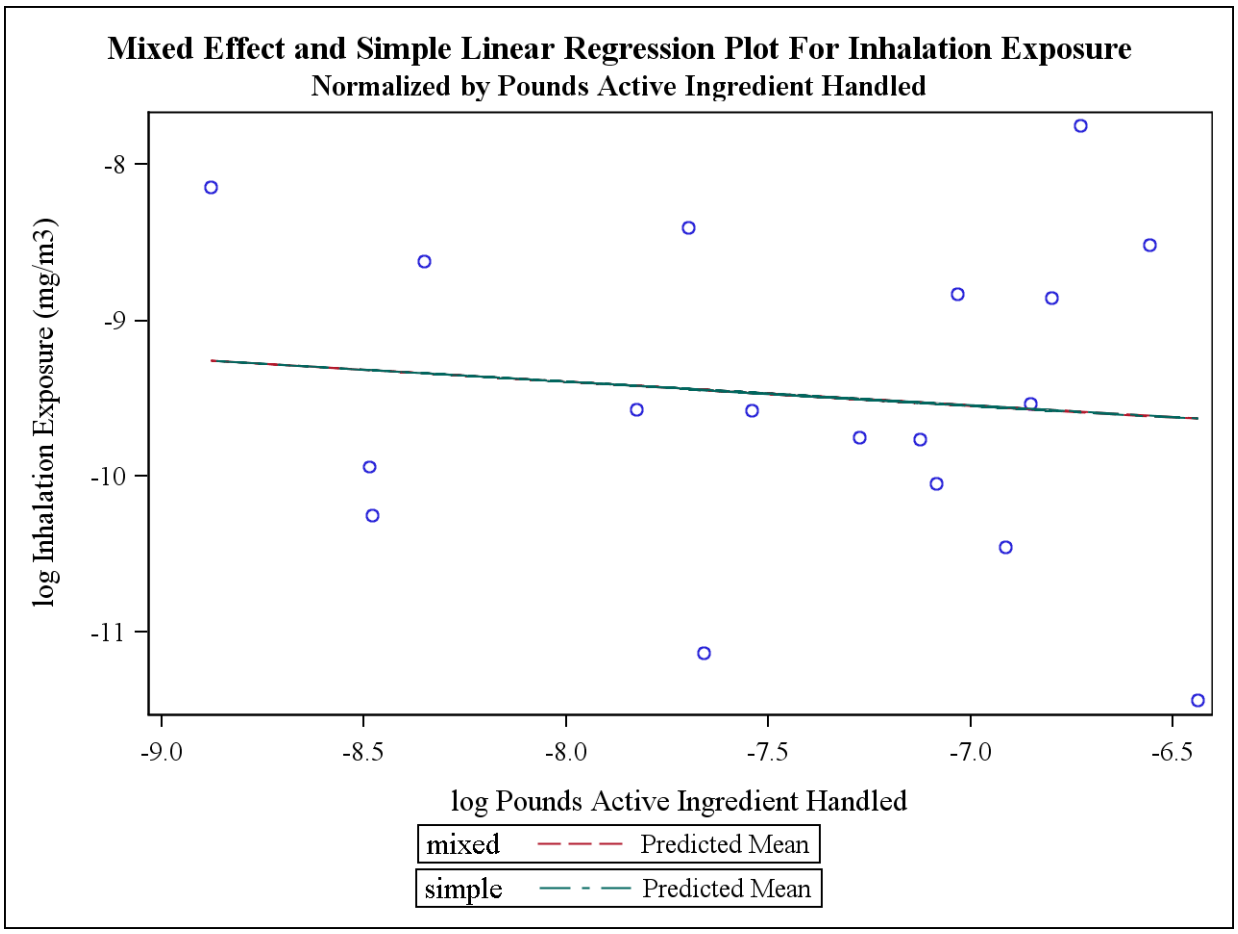

Figure 11. RTU Wipes: Mixed and simple linear regression plots for inhalation exposure.

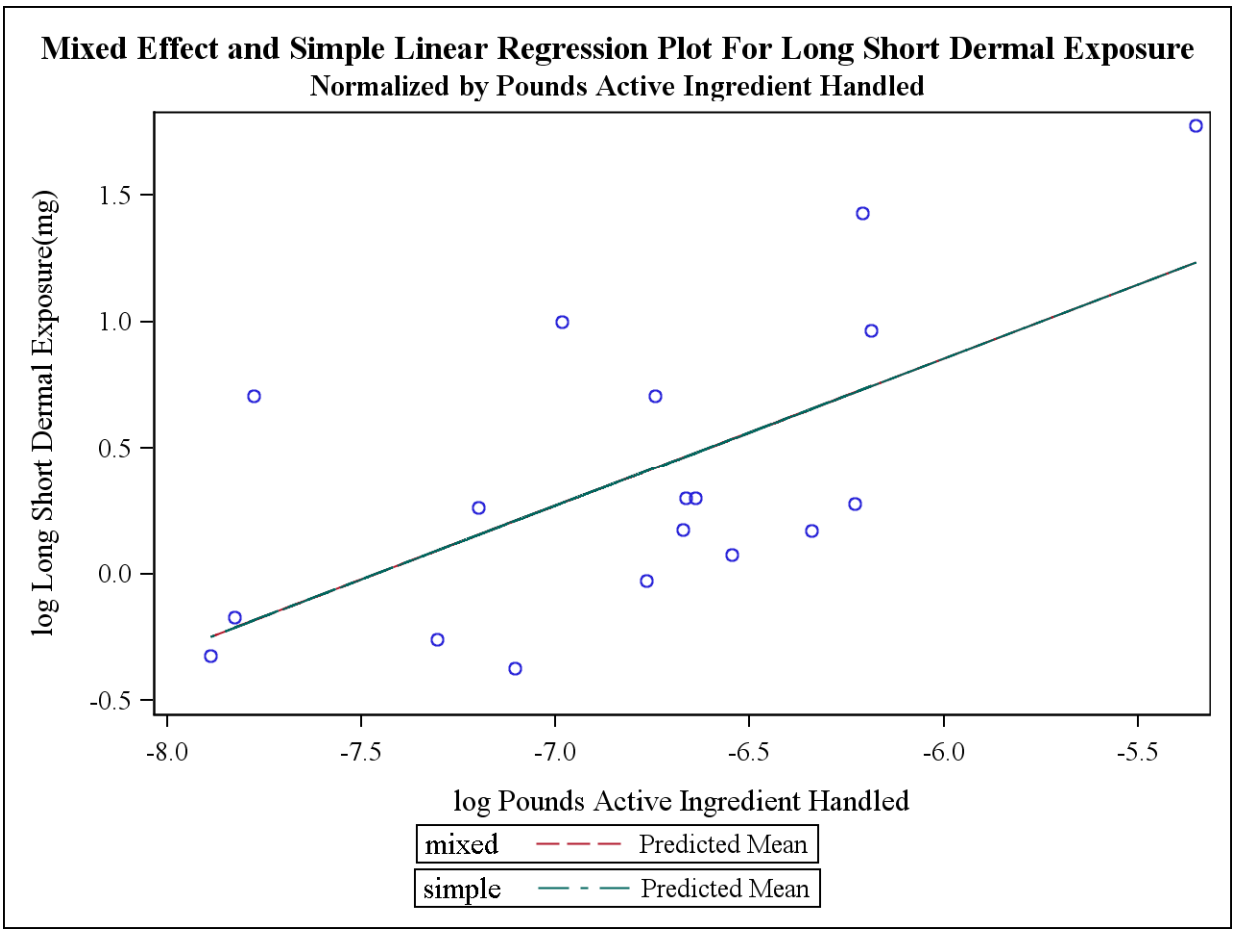

Figure 12. Trigger Spray & Wipe: Mixed and simple linear regression plots for long short dermal exposure.

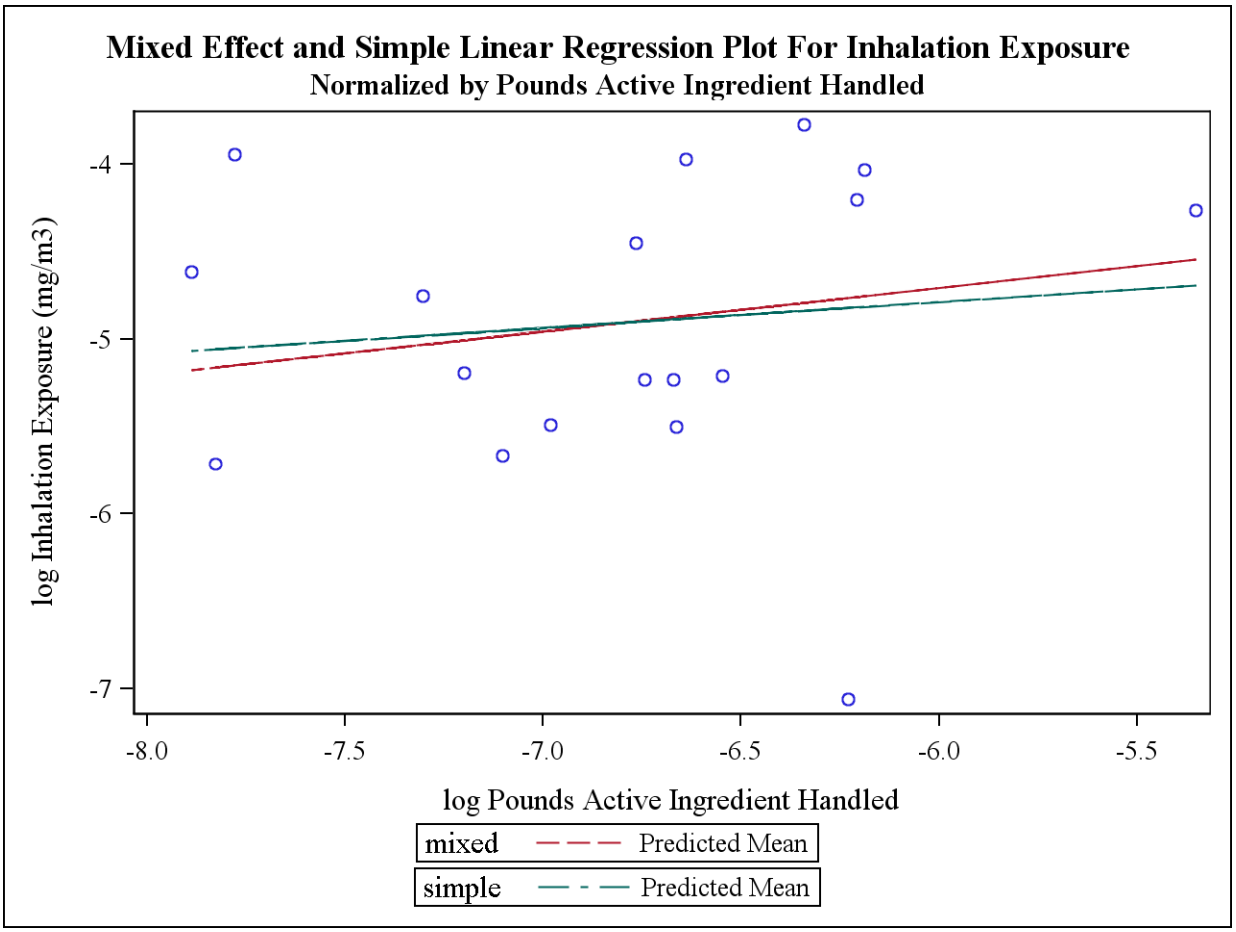

Figure 13. Trigger Spray & Wipe: Mixed and simple linear regression plots for inhalation exposure.

Threshold of AaiH for Over- or Under-Predicting Exposure -- Although the confidence intervals for the regression slopes are below one, it is shown in Appendices A and B that if the mixed model formulation is correct and the estimated regression slope is less than one, then the exposure will be over-predicted if the proportionality model is extrapolated to high levels of the amount of active ingredient and the exposure will be under-predicted at low levels of the amount of active ingredient. Tables 12 and 13 give the minimum amount of active ingredient handled for which the proportionality model will over-estimate the expected exposure.

Table 12. RTU Wipes: Minimum Pounds of Active Ingredient for Which Normalized Exposure Model Over-Predicts Dermal and Inhalation Exposure.				
Exposure Route	**Clothing**	**Model**	**Slope**	**Threshold Level (lb AiaH)**
Dermal (mg)	Long pants and long sleeves	Mixed	0.56	0.00033
	Short pants and short sleeves	Mixed	0.48	0.00039
	Long pants and short sleeves	Mixed	0.50	0.00038
Inhalation (mg/m^3)		Mixed	-0.15	0.00028

Table 13. Trigger Spray & Wipe: Minimum Pounds of Active Ingredient for Which Normalized Exposure Model Over-Predicts Dermal and Inhalation Exposure.				
Exposure Route	**Clothing**	**Model**	**Slope**	**Threshold Level (lb AiaH)**
Dermal (mg)	Long pants and long sleeves	Mixed	0.37	0.00081
	Short pants and short sleeves	Mixed	0.57	0.00080
	Long pants and short sleeves	Mixed	0.58	0.00078
Inhalation (mg/m^3)		Mixed	0.25	0.00053

In response to suggestions from HSRB reviewers of the mop study analyses, we also considered quadratic models for the relationship between the logarithm of exposure and the logarithm of the amount of active ingredient. Appendices A and B present the equations for the quadratic models and discuss their applicability for predicting exposures attributable to use of antimicrobial pesticides. For both scenarios, and in all cases, the quadratic coefficient was not statistically significantly different from zero, so we concluded that the quadratic models are not supported and that the simple linear models discussed here are preferred.

3.0 Discussion of Data Generalizations and Limitations

The regulatory need for a generic data base of pesticide handlers for antimicrobial pesticide products has been discussed previously (Christian 2007). This wipe study represents two exposure scenarios in the overall design of an AEATF II generic handler data base. This wipe study was designed to represent the high end of potential exposure for RTU wipes and trigger

spray and wipe activities. The study design also incorporated random diversity selection where feasible. Such a study design requires a discussion of how the data can be generalized and the limitations of the results. The following items are provided to characterize the results of this sampling effort:

(1) The study purposively selected Fresno, CA, as the study location. This selection criterion, rather than a random selection of sites across the country, limits to some degree the statistical generalizations of the data. Thus we cannot determine whether these results provide unbiased estimates of exposure distributions from wiping activities in locations other than Fresno, CA, and it is not possible to use these data to estimate the potential bias or the geographic variability. To generalize these results to the whole country requires an assumption that the exposure distribution for these scenarios is independent of the geographic location. The statistical limitations of the purposive site selection are deemed acceptable by the JRC. It is reasonable to assume that the mechanics of wiping surfaces inside buildings in Fresno are not substantially different than wiping surfaces inside other buildings throughout the country. Given a limited set of resources for the overall AEATF II monitoring program, the assumption that indoor wiping of surfaces does not vary geographically was sufficiently reasonable to forgo the random site selection in favor of spending the limited resources to monitor additional distinctly different scenarios (e.g., wiping, aerosol cans, painting, metal working fluids, pressure treatment of wood, etc).
(2) The data generated in this study are acceptable to use as surrogate for assessing other chemicals considered to have low volatility (i.e., vapor pressures less than ~1E-4 mmHg @ 20C). This "rule-of–thumb" for the vapor pressure threshold is reviewed by EPA on a case-by-case basis, particularly for those antimicrobial pesticides with vapor pressures that are near to this threshold. For example, for those chemicals with vapor pressures of ~1E-4 mmHg, EPA reviews the pesticide application method for the potential for aerosol generation and the available inhalation toxicity data to see if the toxicity studies were performed as a gas or with an aerosol.
(3) The data generated in this study are acceptable to use as surrogate to assess pesticide labeled uses of wiping surfaces. This includes the pesticide products that are packaged as RTU wipes or the products that indicate they can be applied by spray and wipe.
(4) The dermal wipe exposure data generated in this study are acceptable to use for clothing configurations of long pants, long-sleeved shirts, and no gloves; long pants, short-sleeved shirts, and no gloves; as well as short pants, short sleeved-shirts, and no gloves.
(5) The small sample size by itself does not cause statistical limitations other than the high level of uncertainty shown by wide confidence intervals for some of the summary statistics. More important is the fact that the original sets of subject participants, locations, and dates from which the subjects, clusters, and sampling dates were chosen were limited and hence might not be representative of all Fresno wipers (e.g., wipers that did not volunteer), buildings (e.g. only empty buildings were eligible for this study), and time periods (e.g., winter versus summer, night versus day, etc.). In other words, the most significant limitation is that these data were not derived from a stratified random sample of MEs even though the statistical analyses made that assumption. At a minimum this increases the uncertainty of the estimates (so the calculated confidence intervals are too narrow) and there may also be some bias (e.g., study participants not in the volunteer pool might be more or less prone to exposure than the selected group).
(6) The wipe study report noted: "*There were always three to four study personnel following the subject during a given monitoring event",* with one being the *"observer".* The HSRB review of the protocol discussed the Hawthorne Effect and cautioned the researchers on observing the workers as they worked. The Hawthorne Effect is

(http://psychology.about.com/od/hindex/g/def_hawthorn.htm) … "*A term referring to the tendency of some people to work harder and perform better when they are participants in an experiment. Individuals may change their behavior due to the attention they are receiving from researchers rather than because of any manipulation of independent variables. This effect was first discovered and named by researchers at Harvard University who were studying the relationship between productivity and work environment. Researchers conducted these experiments at the Hawthorne Works plant of Western Electric. The study was originally commissioned to determine if increasing or decreasing the amount of light workers received increased or decreased worker productivity. The researchers found that productivity increased due to attention from the research team and not because of changes to the experimental variable. Later research into the Hawthorne effect has suggested that the original results may have been overstated. In 2009, researchers at the University of Chicago reanalyzed the original data and found that other factors also played a role in productivity and that the effect originally described was weak at best.*" It is unknown what, if any, effect the observers had on the workers's potential exposure. The AEATF II is again cautioned for future research on the need for less obtrusive observations during the monitoring event balanced with the need to collect information on the event itself.

(7) EPA will continue using exposures normalized by AaiH as a default condition. The results of the two wipe study scenarios show that dermal exposure tends to increase with AaiH but that the proportionality is not a one-to-one ratio. The choice of normalizing variable of AaiH is based upon considerations of suitability for product labeling and consistency between scenarios. The lack of a direct proportionality of exposure to AaiH when extrapolating to the high end of AaiH – the EPA regulates on the high end of AaiH – tends to overestimate the exposure, resulting in conservative risk assessments and human health protective regulatory decisions. Tables 12 and 13 above provide for the minimum amount of AaiH for the normalized exposures to be over-predicting exposures (i.e., protective of human health). Data will continue to be collected by the AEATF II to add to the knowledge base of normalized exposures.

4.0 Conclusions

EPA has reviewed the AEATF II wipe study and concludes that the AEATF II made the appropriate changes to the protocol proposed by the EPA and HSRB and has executed the study successfully. The protocol deviations that occurred and were reported on have not adversely impacted the reliability of these data. The EPA recommends that the inhalation and dermal UE generated in this wipe study be used provided the data are used within the boundaries set forth in this review.

The following is a summary of our conclusions.

- The AEATF II data for inhalation and dermal exposures represent reliable data for assessing wiping of surfaces using either RTU wipes or a trigger sprayer and subsequent wipe with a rag using antimicrobial products. Alternative data sources or special circumstances will be considered on a case by case basis.
- Estimates of the GM, AM, and P95 were shown to be accurate within 3-fold with 95% confidence for all of the analyses, except for the empirical 95th percentile for the inhalation exposure where the fold relative accuracy is 5.2 for the RTU Wipes scenario and is 3.6 for the Trigger Spray & Wipe scenario (see Tables 8 and 9).
- The data provided 80% statistical power to distinguish complete proportionality or independence between exposure and AaiH for both dermal and inhalation routes of

exposure. A direct proportionality (1:1 relationship) between inhalation or dermal exposure and AaiH was not established but the trend of dermal exposure increases as AaiH increases. Additionally, Tables 12 and 13 provide thresholds that are minimum AaiH values where exposure will be over-estimated when extrapolating the normalized exposure (mg/lb ai) to other chemical assessments (i.e., using these unit exposures as surrogates to assess other chemicals that handle more than the threshold).

5.0 References

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Appendix A

Statistical Review of the AEATF II Wipe Study for Ready-to-use Wipes

(Attached in a separate electronic .pdf file)

Appendix B

Statistical Review of the AEATF II Wipe Study for Trigger Spray & Wipe

(Attached in a separate electronic .pdf file)