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OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

May 20, 2004

Memorandum

SUBJECT: Review of "Evaluation of the Potential Exposure of Workers to Propanil During Mixing/Loading and Aerial Application to Rice Fields Using Simultaneous Dermal Dosimetry and Biological Monitoring Techniques"

FROM: Shanna Recore, Industrial Hygienist Shanna Recore 5/20/04
Bill Smith, Environmental Protection Specialist Bill Smith 5/20/04
Reregistration Branch II
Health Effects Division (7509C)

THRU: Al Nielsen, Branch Senior Scientist Al Nielsen 5/25/04
Reregistration Branch II
Health Effects Division (7509C)

TO: Carmen Rodia, Chemical Review Manager
Reregistration Branch
Special Review and Reregistration Division (7508C)

DP Barcode: 293906

PC Code: 028201

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Attached is a review of the propanil data from mixing/loading and aerial application to rice fields using simultaneous dermal dosimetry and biological monitoring techniques submitted by The Propanil Task Force II. This review was completed by Versar, Inc. on May 18, 2004, under supervision of HED. It has undergone secondary review in HED and has been revised to reflect Agency policies. The data collected meets some of the criteria specified by the U.S. Environmental Protection Agency's (US-EPA) OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Guidelines, 875.1200 (dermal) and 875.1400 (inhalation).

06/04

Reviewers: Kelly McAloon/Sally McDonald **Date:** May 18, 2004

STUDY TYPE: Mixer/Loader and Pilot Passive Dosimetry Study Using Passive Dosimetry plus Personal Air Sampling and Biomonitoring Study Using Urinalysis

TEST MATERIAL: Propanil is a herbicide used to control weedy grasses in rice. Five product formulations were used in this study: Stam M4 Herbicide, Arrosolo® 3-3E, Blue Drum® Propanil, Duet® CA, and Super Wham®. Each formulation was an emulsifiable concentrate.

SYNONYMS: propanil, 3,4-dichloropropionanilide

CITATION:

Authors/Study Director:	Richard C. Honeycutt, PhD.
Title:	*Evaluation of the Potential Exposure of Workers to Propanil During Mixing/Loading and Aerial Application to Rice Fields Using Simultaneous Dermal Dosimetry and Biological Monitoring Techniques*
Report Date:	September 13, 2003
Testing Facility:	H.E.R.A.C., Inc. 220-1 Swing Road Greensboro, North Carolina 27409
Analytical Facility:	EN-CAS Analytical Laboratories 2359 Farrington Point Drive Winston Salem, NC 27107
Identifying Codes:	H.E.R.A.C., Inc. Study Number: 03-01HE

SPONSOR:

Propanil Task Force II
c/o Edward M. Ruckert, Chairman
McDermott, Will & Emery
600 13th Street N.W.
Washington, DC 20003-3096

EXECUTIVE SUMMARY:

The purpose of this study was to quantify inhalation and dermal exposure of handlers during mixing/loading and aerial application of propanil to rice fields. The following formulations were included in the study: Stam M4 Herbicide (containing 44.8% active ingredient (a.i.)), Arrosolo® 3-3E (containing 33.1% a.i.), Blue Drum® Propanil (containing 43.5% a.i.), Duet® CA (containing 41.2% a.i.), and Super Wham® (containing 41.2% a.i.). The sites for this study were Texas, Louisiana, and Arkansas, with multiple sites in each state. Thirty individuals participated in the study at eleven test sites (15 mixer/loaders, 14 pilots, and 1 combined mixer/loader/pilot). The average amount of active ingredient handled was 556 pounds for mixers/loaders and 416 pounds for pilots. The average duration of each replicate was 2.2 hours for mixers/loaders and 1.7 hours for pilots.

The study author indicates that the study design employs a "commonly used technique of simultaneous dosimetry and biological monitoring." The technique involves the use of an outer dosimeter (long-sleeve shirt and long pants) worn over an inner dosimeter (tee shirt and briefs). The author states that this dosimetry design "allows for penetration of the propanil residues through the clothing as would occur under normal field agricultural practices, and does not block the penetration of propanil through the skin as would occur if a long underwear whole body dosimeter were worn under the long-sleeve shirt and long pants." The study author does not indicate what effect a chemical-resistant apron or Tyvek coveralls worn by mixers/loaders over the "outer" dosimeter would have on either the passive dosimetry or biological monitoring.

In the study, dermal exposure was estimated through passive dosimetry using hand washes and hat patches and by the use of an "outer" dosimeter for the torso, arms, and legs and an "inner" dosimeter for the torso. The study author compared the residues on the inner dosimeter to the torso residues on the outer dosimeter and derived a "protection factor" attributable to the outer dosimeter. Dermal exposure to the torso, arms, and legs was then estimated by applying the protection factor to the outer dosimeter residues. Total dermal exposure was calculated by adding the adjusted torso, arms, and legs exposure to the hand exposure values and head/face/neck exposure values. Inhalation exposure was measured using personal air samplers. The study author provided exposure values expressed in micrograms per kilogram of handler body weight per day (μg/kg body weight/day) and micrograms per kilogram active ingredient handled per day (μg/kg a.i./day). Total exposure was calculated by the study author by summing the internal inhalation dose (assuming 100% lung absorption of the inhalation exposure) and the internal dermal dose (assuming 20% dermal absorption of the dermal exposure).

In the study, total exposure was also calculated using biomonitoring through analysis of the handlers' urine for 3,4-dichloroaniline (3,4-DCA), which the study author cites as the major metabolite of propanil. The study author reported exposures of 54.7 ± 120 μg/kg ai/day for mixer/loaders and 35.5 μg/kg ai/day for pilots. For both mixer/loaders and pilots, the exposure values obtained from biomonitoring are much higher than those obtained from whole body dosimetry. The study author did not provide an explanation for this discrepancy.

Versar calculated a mean potential inhalation unit exposure, in micrograms per pounds active ingredient handled (μg/lb ai handled), as per EPA's request. The mean inhalation unit exposure for mixers/loaders is 1.37E-02 μg/lb ai handled, for pilots is 2.04E-03 μg/lb ai handled, and for the mixer/loader/pilot is 6.94E-04 μg/lb ai handled. Versar also calculated a mean potential dermal unit exposure of 1.27E-03 mg/lb ai handled for pilots. Versar has not calculated a mean potential dermal unit exposure for mixers/loaders or for the mixer/loader/applicator, since appropriate dermal exposure values for the torso, arms, and legs could not be determined for these handlers in this study.

The study met some of the Series 875.1200 and 875.1400 Guidelines. However, there were major issues of concern, including:

(1) Mixers/loaders in the study wore either a chemical-resistant apron or a Tyvek coverall over the "outer" dosimeter and also wore chemical-resistant footwear. In calculating potential dermal exposures to mixers/loaders, the study author does not factor in this additional personal protective equipment, which exceeds the requirements of the product labeling;
(2) The study states that most mixers/loaders used a siphoning device to transfer the propanil from the drum into the mix tank and then used a dry-lock system (an engineering control) to pump the dilute mixture into the airplane spray tank. This would result in artificially low mixer/loader exposures due to the use of the engineering control in part of the mix/load process.
(3) The average duration of each replicate was 2.2 hours for mixers/loaders and 1.7 hours for pilots, rather than the usual 4-5 hour replicate expected in handler exposure studies;
(4) The average application rate used in the study was approximately 3 pounds active ingredient per acre, rather than the label maximum of 6 pounds active ingredient per acre on the STAM-M4 label;
(5) Trapping efficiency tests for the air monitoring media chosen were not documented;
(6) There was no mention of breakthrough tests being run on the air filters;
(7) No information was provided on how the air filters/tubes were stored after sample collection;

(8) There was no mention of preliminary hand rinse studies; and
(9) It was not mentioned if a sample history sheet had been prepared by the laboratory upon receipt of samples.

COMPLIANCE: A signed and dated Data Confidentiality statement was provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The study sponsor and author stated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR Part 160), with certain exceptions. The deviations identified were that: (1) the test substance was not characterized prior to the initiation of the study since a commercial product was used in the study; (2) creatinine analyses in urine samples were not performed under GLPs; (3) the wind meter used to determine wind speed at the test sites was not calibrated; (4) the airplane used to apply the test substance was not calibrated prior to use on 4/3/03, but was calibrated prior to its use on 4/14/03 and all other airplanes used were calibrated prior to use; (5) the generation of the data and the writing of the report on the modeling of urine excretion of 3,4-DCA from the handlers was not performed under GLPs; and (6) the tags on the urine collection containers were not filled out by the test subject under GLPs.

GUIDELINE OR PROTOCOL FOLLOWED: A study protocol was provided. OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1200 (dermal exposure-indoor handler), and 875.1400 (inhalation exposure-indoor handler) were followed for the compliance review of this study.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	Stam M4 Herbicide: 44.8% active ingredient (a.i.) Arrosolo® 3-3E: 33.1% a.i. Blue Drum® Propanil: 43.5% a.i. Duet® CA: 41.2% a.i. Super Wham®: 41.2% a.i.
Lot/Batch # technical:	Not provided.
Lot/Batch # formulation:	The Study Report provided lot numbers of the test substances used at each specific test site. (See Table 1A of Study Report.)
Purity in technical:	Not provided.
Reference Substances:	Stam M4: Lot/Batch No.: TSN104109 (45.6% a.i.) Propanil: Lot/Batch No.: STRL-99-AG-005 (99.61% a.i.) 3,4-dichloroaniline: Lot/Batch No.: 287-74A (99.5% a.i.) The certificate of analysis of the reference substance is provided in Appendix B of the study.
Other Relevant Information:	CAS No: 709-98-8

2. Relevance of Test Material to Proposed Formulation(s):

The test materials used in this study were the same formulations available for commercial use.

3. **Packaging:**

The packaging of the test product was not reported in the study.

B. STUDY DESIGN

There were thirteen amendments and forty deviations to the study protocol. The amendments included:

(1) clarifying the analytical work associated with the study,
(2) clarifying the definition of sites and sub-sites,
(3) defining loading time as the time "from when the first load is started until the last load is finished" and application time as the time "from when the plane leaves the loading site until it returns for the next load.
(4) changing the level of the field spike from 0.05 to 5.0,
(5) changing the application rate per acre from "6 lb ai/acre" to "a typical lb ai/acre";
(6) allowing the use of several different propanil liquid end-use products in the study, rather than using only STAM -M4;
(7) changing the timing of urine specimen collection "to provide more flexibility in sampling since propanil application schedules are not known well ahead of time;"
(8) changing the replicate monitoring time for mixing/loading and applying from 5 hours to 3 hours,
(9) changing the level of fortification from 1 μg to 20 μg,
(10) clarifying the calibration method of the plane,
(11) clarifying the tank sample number designation,
(12) clarifying the pre-urine sample number designation, and
(13) changing the personal protective equipment worn by mixers/loaders "to allow for the use of Tyvek in the field phase of the study."

The deviations included:

(1) the air tube validation was carried out with analytical grade propanil instead of with the propanil formulation,
(2) fortification solutions were prepared in smaller volumes,
(3) two additional fortification levels were prepared and 3 mL were send to the field,
(4) each fortification bottle was not wrapped in bubble wrap,
(5) the high level samples of urine were fortified at 50X LOQ rather than 500X LOQ,
(6) one of the LOQ fortification recoveries in the method validation was 68%,
(7) one of the fresh LOQ fortification recoveries in the 14 day stability set for air tubes was 125%,
(8) one of the fresh LOQ fortification recoveries in the 6 week stability set for air tubes was 123%,
(9) for outer dosimeters the low fortification was 10X LOQ,
(10) for one set of samples the calibration curve was constructed from only 4 concentrations,
(11) one LOQ fortification recovery in a set of urine samples was 65%,
(12) one LOQ fortification recovery in a set of air tube samples was 215%,
(13) for one set of samples the calibration curve was constructed from only 4 concentrations when one sample needed a dilution,
(14) the hat patch samples were only quantitated to 0.5 ng/cm^2,
(15) one LOQ fortification recovery in a set of outer dosimeter samples was 171%,
(16) 6 dosimeter recovery sets gave one recovery in the 60% range,
(17) for several chromatographic runs, the calibration curve was only constructed from 4 concentrations,
(18) control urine was spiked and kept on blue ice for 25 hours instead of 24 hours,
(19) only one mixer/loader was tested on 4/1/03 and was designated VP1 and was not dressed in dosimeters,
(20) handlers were paid $150.00 for participation,
(21) weather data was not taken hourly during mixing/loading and application,
(22) dosimeters were not hung up to cut,
(23) one of the planes was not calibrated prior to the application date of 4/3/03 at site 1,1A, and 1B,

(24) there were not exactly five locations in each of the three states,
(25) hand washes were taken before initiation of exposure on day 0 and at the end of the replicate (since replicate times were not long enough so that they included a lunch break for the test subjects,
(26) all test subjects did not avoid contact with any product containing propanil for 3 days prior to the day 0 application or did not avoid contact with any product containing propanil for 3 days after day 0,
(27) thirteen test subjects handled propanil within 3 days prior to the test day,
(28) four test subjects handled propanil within 4-7 days prior to the test day,
(29) the test substance expiration date was not recorded in the field raw data of the study,
(30) the daily max/min temperatures were not recorded at the test sites,
(31) the carrier rate was 8-10 gallons and not 10-15,
(32) the pants, t-shirt, and briefs were taken off by the test subject and each laid on a separate clean piece of aluminum foil and then collected,
(33) during the process of preparing field fortifications, all three field fortification type solutions were used to fortify the field spikes,
(34) field fortifications were not performed at location sites 1,2,and 3, but at five locations selected throughout the study,
(35) field fortifications and field controls were not always upwind from the loading and/or treated rice fields,
(36) only one patch and not a pair of patches were fortified,
(37) outer dosimeters were fortified at 20 and 100 μg/sample,
(38) there was no sample collection date on the chain of custody,
(39) spike solution "02" was used on 4/29/03 and 5/1/03 instead of "01" and spike solution "03" was used on 5/22/03 and 6/3/03 instead of "01", and
(40) the maximum and minimum temperatures were not reported where the test substance was stored just prior to the replicate.

Most of these deviations were reported by the study author to have none or minimal effects on the study, however, the deviations related to contact with the product did cause some interference with the urine residues observed in the baseline.

1. Number and type of handlers and sites:

Thirty individuals participated in the study at eleven test sites (15 mixer/loaders, 14 pilots, and 1 combined mixer/loader/pilot). In the Study Report, odd numbered replicates (e.g., V1, V3) represented mixer/loaders and even number replicates represented applicator pilots, except that V12 represented the mixer/loader/pilot. The study was performed with typical, experienced (0.2 to 42 years of experience) handlers who mix, load and aerially apply propanil to rice fields. The age of the handlers ranged from 19 to 60 years; weight ranged from 138 to 285 pounds; and height ranged from 60 to 75 inches tall. Each participant signed an informed consent form prior to the initiation of the study after being provided with the proper information regarding the study, products being used, and proper precautions.

The sites for this study were located in Texas, Louisiana, and Arkansas and there were multiple sites in each state. For each site, the site number provided in the Study Report identified the aerial applicator facility, the loading site and the rice fields that were treated if these were in different locations. For example, "site 1, 1A, 1B" indicates that the aerial facility, loading site and treated rice fields were all in different locations. Table 1A of the Study Report provides information on the site numbers associated with each location.

2. Meteorology:

Temperature, relative humidity, and wind speed and direction were monitored at each loading location on the application date. Table 1 provides a summary of the measurements taken during the study.

Table 1. Meteorological Measurements

Sites	Min Temp (F)	Max Temp (F)	Min Relative Humidity (%)	Max Relative Humidity (%)	Min Wind Speed (mph)	Max Wind Speed (mph)	Wind direction at loading site
1, 1A*	69	69	90	90	3 to 5	3 to 5	Fr N
1, 1C*	72	78	75	88	2	10	Fr E
2	67	78	56	76	1	6	W-S-SW
3	72	73	88	89	1.5	4	Fr W
4	64	68	83	93	0	1.2	FrNE
5	81	83	68	72	1.4	5.6	Fr SE-SW
6, 6A*	74	76	90	95	7	16	Fr S-SW
6, 6D*	76	76	84	84	8	11	Fr SW
7	74	76	90	100	1	4	Fr SE
8	74	81	72	90	1	2	Fr SE
9	64	64	75	85	3	7	Fr N-NW
10	62	71	65	88	4	9	Fr NE
11	73	74	96	98	2	3	Fr SE

*Both sites 1 and 6 had different loading sites for the same aerial facility; and therefore different meteorological measurements.

3. Replicates:

This study consisted of a total of 30 replicates using one of four propanil formulations. The replicates included 15 mixer/loaders, 14 pilots, and 1 combined mixer/loader/pilot. Tables 2a-2c present summaries of the mixer/loader, pilot, and mixer/loader/pilot replicates.

Table 2a. Summary of Mixer/Loader Replicates

Mixer/ Loader Replicate	Location	Product Formulation Used	Loads per Day	Pounds AI Handled per Day	Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE Worn
V1	Garwood, TX	STAM M-4	16	1328	3.43	6.2	6.7	apron, boots
V3	Edna, TX	Arrosolo 3-3E	12	1080	2.33	4	4.3	apron, boots
V5	Edna, TX	Arrosolo 3-3E	8	870	2.82	6.5	6.8	apron, boots
V7	Almyra, AR	STAM M-4	5	644	2.38	2.5	2.8	apron, boots
V9	Garwood, TX	STAM M-4	16	1328	3.43	6.4	7.2	apron, boots
V13	Lessie, TX	Blue Drum	6	510	1.75	2.3	2.8	apron, boots
V15	Lessie, TX	Blue Drum	6	510	1.75	2.3	2.7	apron, boots
V17	Weiner, AR	Blue Drum	9	776	5.3	6.1	6.4	tyvek, boots
V19 (repl #1)	Lake Arthur, LA	Arrosolo 3-3E	2	138	0.32	1.9	2.3	apron, boots
V19 (repl #2)	Lake Arthur, LA	Duet	1	156	0.05			
V19 (TOTAL)	NA	NA	3	294	0.37			

Mixer/ Loader Replicate	Location	Product Formulation Used	Loads per Day	Pounds AI Handled per Day	Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE Worn
V21	Cheneyville, LA	Arrosolo 3-3E	6	579	2.8	3.5	4.1	apron, boots
V23	Almyra, AR	STAM M-4	2	196	0.53	1.4	1.8	apron, boots
V25 (repl #1)	Mer Rouge, LA	STAM M-4	4	600	1.63	3	no data	tyvek, boots
V25 (repl #2)	Mer Rouge, LA	STAM M-4	2	204	0.78			
V25 (TOTAL)	NA	NA	6	804	2.41			
V27	Lake Village, AR	Super Wham	3	576	1.32	2.9	5	apron, boots
V29	Eudora, AR	STAM M-4	5	790	1.62	2.2	2.4	tyvek, boots
V31 (repl #1)	Weiner, AR	STAM M-4	1	76	0.35	5.6	6	tyvek, boots
V31 (repl #2)	Weiner, AR	Blue Drum	2	192	0.82			
V31 (repl #3)	Weiner, AR	STAM M-4	1	96	0.17			
V31 (TOTAL)	NA	NA	4	364	1.34			
Mean			**7.1**	**710**	**2.2**	**3.8**	**4.4**	**N/A**

Table 2b. Summary of Pilot Replicates

Pilot Replicate	Location	Product Formulation Used	Loads	Pounds AI per Acre	Acres Treated per Replicate (acres/day)	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE
V2	Garwood, TX	STAM M-4	9	3	246	1.73	6.6	7.1	single layer, shoes, socks + gloves when entering or exiting
V4	Edna, TX	Arrosolo 3-3E	6	2.25	240	1.48	4.2	4.7	
V6	Edna, TX	Arrosolo 3-3E	8	3	334	1.72	6.2	6.5	
V8	Garwood, TX	STAM M-4	7	3	197	1.75	6.6	6.8	
V10	Lessie, TX	Blue Drum	6	2	254	1.70	2.5	2.9	
V14 (repl #1)	Almyra, AR	STAM M-4	4	4	137	1.3	3.2	3.9	
V14 (repl #2)	Almyra, AR	STAM M-4	1	3	32	0.15			
V14 (TOTAL)	NA	NA	5	N/A	169	1.45			
V16 (repl #1)	Lake Arthur, LA	Arrosolo 3-3E	2	1.9	72	0.38	2.8	3.1	
V16 (repl #2)	Lake Arthur, LA	Duet	1	3.1	51	0.3			
V16 (TOTAL)	NA	NA	3	N/A	87	0.68			
V20 (repl #1)	Cheneyville, LA	Arrosolo 3-3E	2	3	73	0.53	NONE	4	
V20 (repl #2)	Cheneyville, LA	Arrosolo 3-3E	4	2.25	160	1.5			

Pilot Replicate	Location	Product Formulation Used	Loads	Pounds AI per Acre	Acres Treated per Replicate (acres/day)	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE
V20 (TOTAL)	NA	NA	6	N/A	233	2.03			
V22	Almyra, AR	STAM M-4	2	4	49	0.87	1.4	2.2	
V24 (repl #1)	Mer Rouge, LA	STAM M-4	4	3	200	1.17	3	3.2	
V24 (repl #2)	Mer Rouge, LA	STAM M-4	2	2	102	0.98		3.1	
V24 (TOTAL)	NA	NA	6	N/A	302	2.15		6.3	
V26	Lake Village, AR	Super Wham	3	4.5	129	1.28	2.3	5	
V28 (repl #1)	Weiner, AR	Blue Drum	6	1.9	240	2.62	6	6.3	wore "flight" gloves
V28 (repl #2)	Weiner, AR	Blue Drum	3	2	156	1.2			
V28 (TOTAL)	NA	NA	9	N/A	396	3.82			
V30	Eudora, AR	STAM M-4	5	4	197.5	1.32	2	2.2	same as V2
V32 (repl #1)	Weiner, AR	STAM M-4	1	2	37.5	0.23	5	5.3	wore "flight" gloves
V32 (repl #2)	Weiner, AR	Blue Drum	3	2.1	138	1.22			
V32 (TOTAL)	NA	NA	4	N/A	175.5	1.45			
Mean			**5.6**	**2.8**	**218**	**1.7**	**4**	**4.5**	**N/A**

Table 2c. Summary of Mixer/Loader/Pilot Replicate

Mixer/Loader/ Pilot Replicate	Location	Product Formulation Used	Loads	Pounds AI per Acre	Acres Treated per Load	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE
V12 (mixing)	Bunkie, LA	STAM M-4	4	4	118	0.4	2.5	3.5	M/L: apron, boots Pilot: no boots, no apron
V12 (applying)						1.4			
V12 (total)						1.8			

4. Personal Protective Equipment:

A summary of personal protective equipment worn by the mixer/loaders and pilots is presented in Tables 2a, 2b, and 2c. Mixer/loaders and pilots wore 100% cotton long sleeve shirts, 100% cotton long pants, 100% cotton t-shirt, 100% cotton briefs, and socks. Mixer/loaders also wore full rubber boots, a baseball-style cap, goggles, chemical-resistant gloves, and either a chemical-resistant apron or Tyvek coveralls. Pilots also wore tennis shoes, a helmet with a visor (instead of baseball- style cap and goggles), and were given a pair of chemical-resistant gloves to wear when outside of the airplane. Two of the pilots wore "flight gloves" throughout the application process. The mixer/loader/pilot removed the chemical-resistant apron, rubber boots, and baseball-style cap and put on tennis shoes and a helmet with a visor when piloting the airplane. The personal protective equipment worn by mixers/loaders exceeded the requirements on the product labeling by adding chemical-resistant footwear and a chemical-resistant apron or Tyvek coveralls. No explanation is offered for the deviation from the product labeling and the study protocol.

5. Mixing/application method:

Most of the mixer/loaders used a semi-open system (siphon device) to remove the propanil product from 30 to 35 gallon drums into a mix tank, where it was mixed with water and additives. The mixture was then pumped through a dry lock system into an airplane with additional water. The airplane spray tank was filled to capacity with water and a bypass system was used to agitate the mixture. Therefore, the mixing/loading system was a combination of open loading (siphon) and closed loading (dry lock). No open pour methods were used in the study.

All airplanes had enclosed cockpits. They were manufactured by Air Tractor or Ayres Thrush (except for site 2–Grumman planes) and had 500-800 gallon capacity spray tanks. Flaggers were not used in this study since each plane was equipped with a SAT-LOC® or equivalent computer/GIS system to guide the application of the propanil.

6. Application Rate:

Each of the formulations used in this study contained 3-4 pounds active ingredient per gallon and were applied using 10 gallons of carrier per acre. According to the different product labels, the maximum application rate varies among 3, 4, and 6 pounds active ingredient per acre. STAM-4, the formulation identified in the protocol as the formulation to be used, has the 6 pounds active ingredient per acre application rate. Table 3 provides the lbs a.i./gallon, the acres treated, the lbs a.i./acre and the carrier volume per acre.

Table 3. Application rates

Site Number	Handler Replicate	Product	Lbs a.i./gallon	Acres treated	Lbs a.i./acre	Carrier (gal/acre)
1, 1A, 1B	V4	Arrosolo 3-3E	3	240	2.25	10
1, 1C, 1D	V6	Arrosolo 3-3E	3	334	2.6	10
2, 2A, 2B, 2C	V2	STAM M-4	4	246	3	9.65
2, 2A, 2B, 2C	V8	STAM M-4	4	197	3	8.49
3, 3A, 3B	V10	Blue Drum	4	254	2	10
4, 4A	V16	Arrosolo 3-3E	3	72	1.9	10
4, 4B	V16	Duet	4	51	3.1	10
5, 5A	V12	STAM M-4	4	118	4	8
6, 6A, 6B	V14	STAM M-4	4	137	4	8

Site Number	Handler Replicate	Product	Lbs a.i./gallon	Acres treated	Lbs a.i./acre	Carrier (gal/acre)
6, 6C	V14	STAM M-4	4	32	3	8
6, 6D, 6E	V22	STAM M-4	4	49	4	10
7, 7A	V20	Arrosolo 3-3E	3	73	3	10
7, 7B	V20	Arrosolo 3-3E	3	160	2.25	10
8, 8A	V26	Super Wham	4	129	4.5	10
9, 9A	V24	STAM M-4	4	200	3	10
9, 9B	V24	STAM M-4	4	102	2	10
10, 10A, 10B	V28	Blue Drum	4	240	1.9	10
10, 10C	V28	Blue Drum	4	156	2	9.6
10, 10D	V32	STAM M-4	4	37.5	2	10
10, 10E	V32	Blue Drum	4	138	2.1	10
11, 11A, 11B	V30	STAM M-4	4	197.5	4	10

7. Exposure monitoring methodology:

Dermal dosimeters: Inner and outer body dosimeters were used. Before the initiation of the work period, the handlers would use a private dressing room to change out of their street clothes into the study dosimeters. The handlers would put on a pair of surgical gloves, remove their street clothes and then change gloves and put on the inner and outer dosimeters, and, presumably, any other personal protective equipment, such as an apron, Tyvek coveralls, chemical-resistant footwear, and chemical-resistant gloves. At the end of the work period, the handlers reentered the dressing room, and removed the footwear, socks, outer dosimeters, and inner dosimeters, and, presumably any other personal protective equipment, such as an apron, Tyvek coveralls, chemical-resistant footwear, and chemical-resistant gloves – changing gloves between each removal. The dosimeters were placed on fresh aluminum foil. The inner dosimeters were wrapped in the aluminum foil and placed in a pre-labeled zip lock bag. The outer dosimeters were cut into three pieces (arm, leg, and torso sections). Each section's samples were separately wrapped in aluminum foil, placed in a pre-labeled plastic zip lock bag and frozen until analysis.

Hand: Exposure to the handlers' hands was determined by the hand-rinse method. Hand wash samples were taken at the beginning and end of the work period. The handlers held their hands over a glass bowl and 250 mL of 0.01% Aerosol® OT solution was poured over their hands while they rubbed their hands together for approximately 30 seconds. This was repeated with another 250 mL of hand wash solution and both solutions were pooled into one sample jar, placed into a zip lock bag, wrapped with bubble wrap and frozen until analysis.

Head Patches: A 4"x4" cotton head patch was used to estimate head/face/neck exposure. The patches were attached to the back and front of the baseball-style cap worn by mixers/loaders and to the right front and center back of the helmet worn by pilots. The patch, made of the same material as the pants, was stapled to an aluminum-foil-covered backing that was

held to the cap or helmet using Velcro®. After the exposure period, the two head patches were combined into one sample, wrapped in aluminum foil, and placed in a prelabeled zip lock bag, and frozen until analysis.

Inhalation: Inhalation was monitored using MSA air-sampling pumps attached to the handlers' belts and a Gelman filter/XAD-4 air tube was pinned to the handlers' shoulders with the filter orifice pointing downward. The pumps were calibrated to an airflow of 2 liters/minute and turned on as the exposure period began. After the work period, the air pumps were turned off and were removed.

Biological Monitoring: Approximately 12 hour urine samples were collected one day prior to application of propanil (Day -1), on the day of application (Day 0), and for 2 days past the test (Day 1 and Day 2). An individual small cooler containing frozen blue ice and two polyethylene urine collection vessels were provided to the handler for the Day-1 and Day 0 samples. Another cooler was provided for the Day 1 and Day 2 samples. Some of the handlers had not been exposed to propanil for at least 4 days prior to the application test period, however, many had been exposed for several days leading up to the test day. The study author indicates that this occurred because the study was integrated into the normal commercial use of propanil products. After collection, the samples were transported to the H.E.R.A.C., Inc field laboratory where they were weighed and stored frozen until analysis.

8. Analytical Methodology:

Extraction method(s):

OVS (Air) Tubes - The contents of the air tube were emptied into a centrifuge tube and extracted with EtOAc by sonicating for ten minutes. The ethyl acetate was decanted into a clean tube and evaporated under nitrogen to just below 1 mL.

Gelman (Air) Filters - Filters were extracted with EtOAc by sonicating for ten minutes. The sample solvent was taken to dryness under nitrogen. The sample was then reconstituted in MeOH and HPLC grade water and cleaned up by loading onto a C-18 SPE cartridge and eluting with EtOAc. The sample was dried through sodium sulfate and brought to 1 mL final volume.

Dosimeters - The inner dosimeters were extracted with 25:75 methanol:water by shaking for 1 hour. An aliquot of the extraction solvent was partitioned with dicloromethane (DCM) and then the DCM was taken to dryness by rotary evaporation. The sample was reconstituted in HPLC grade water and cleaned up by loading onto a C-18 SPE cartridge and eluting with ethyl acetate. The eluate was dried through sodium sulfate and brought to a final volume. The outer dosimeters were extracted with 40:60 acetone:hexanes by shaking for one hour. An aliquot of the extraction solvent was taken to dryness by rotary evaporation. The sample was reconstituted in HPLC grade water, filtered, and cleaned up by loading onto a C-18 SPE cartridge and eluting with 75:25 MeOH:water. No explanation is given in the study why the extraction method for the inner dosimeters differed from the extraction methods for the outer dosimeters and the head patches. All dosimeters were 100 percent cotton.

Head Patches - The head patches were extracted with 40:60 acetone:hexanes by shaking for thirty minutes. An aliquot of the extraction solvent was taken to dryness by rotary evaporation. The sample was reconstituted in HPLC grade water, filtered, and cleaned up by loading onto a C-18 SPE cartridge and eluting with MeOH. After the sample was dried, it was reconstituted in 75:25 MeOH:water.

Hand Washes - An aliquot of the hand wash sample was diluted with HPLC grade water and phosphate buffer (pH 6.5). The aliquot was cleaned up by loading onto a C-18 SPE cartridge and eluting with EtOAc. The sample was dried through sodium sulfate and brought to a final volume of 10 mL.

Urine Samples - For hydrolyzed urine residues, a portion of each sample was centrifuged before an aliquot was taken. This aliquot was hydrolyzed with hydrochloric acid for one hour, had the pH adjusted to 12 or 13, and extracted with ethyl ether by shaking. An aliquot of the ethyl ether was taken to 100 µL on an N-Evap. The aliquot was reconstituted in 1mL MeOH, diluted with 50 mL of 0.2M phosphate buffer, pH 6.5, loaded onto a C-18 SPE cartridge and eluted with 75:25 MeOH:0.02M ammonium acetate. For non-hydrolyzed urine residues, the same procedure was followed except the sample was not hydrolyzed.

Detection method(s): See Table 4.

Table 4. Summary of GC Chromatographic Conditions

Media	Inner Dosimeters	Outer Dosimeters	Hand Washes	Hat Patches	OVS Tubes	Gelman Filters	Urine Samples
Instrument	Hewlett Packard Model 5970 GC/MSD	Shimadzu SIL-10AXL	Hewlett Packard Model 5970 GC/MSD	Shimadzu SIL-10AXL	Hewlett Packard Model 5970 GC/MSD	Hewlett Packard Model 5970 GC/MSD	Shimadzu SIL-10AXL #2
Column	Fused silica DB-17 capillary column, 10m x 0.18mm, 0.18 µm film thickness	4.6 mm Spherisorb Phenyl, 5 µm ps	Fused silica DB-17 capillary column, 10m x 0.18mm, 0.18 µm film thickness	4.6 mm Spherisorb Phenyl, 5 µm ps	Fused silica DB-17 capillary column, 10m x 0.18mm, 0.18 µm film thickness	Fused silica DB-17 capillary column, 10m x 0.18mm, 0.18 µm film thickness	A = 4.6 x 150 mm Zorbax SB-CN #174, 5 µm, ps 80A B = 4.6 x 150 mm Zorbax ODS #176, 5 µm, ps 70A
Temperatures	Detector: 275°C Injector: 250°C	Oven: 35°C	Detector: 275°C Injector: 250°C	Oven: 35°C	Detector: 275°C Injector: 250°C	Detector: 275°C Injector: 250°C	Oven: 35°C
Injection Volume	1 µL	15 µL	1 µL	15 µL	1 µL	1 µL	30 µL
Retention Time	9 minutes	9 minutes	7.99 minutes	9 minutes	7.99 minutes	7.99 minutes	11.6 minutes

Method validation: Method validation samples were analyzed prior to the study. LOQs for each sample matrix were also determined prior to initiation of the study. Table 5 provides the results of the method validation recoveries and the LOQs.

Table 5. Method Validation Recoveries and LOQ

Matrix	LOQ	Range of Recoveries (%)	Average Recovery (%)	Standard Deviation (%)	n
Inner dosimeter	0.1 ng/cm^2	79-111	93	12	6
Outer dosimeter	0.1 ng/cm^2	71-101	89	12	6
Hand washes	0.010 μg/mL	94-115	107	7.9	6
Hat Patches	0.10 μg/sample	69-113	92	16	7
Air tubes	0.010 μg/sample	78-117	91	15	5
Gelman Filters	0.010 μg/sample	68-101	83	13	6
Urine	0.01 μg/mL	87-96	90	3.4	6

Recovery experiments (both procedural and field fortification) were performed for all sampling media prior to the commencement of field work. In an effort to establish storage stability, additional samples were stored in a freezer and analyzed at a later date.

Instrument performance and calibration: Information on instrument performance and calibration was not provided in the Study Report.

Quantification: Sample concentrations were calculated using linear regression equations. Examples of calculations were provided in the Study Report. Concentrations of propanil in the samples were determined directly from the standard curve.

9. Quality Control:

Lab Recovery: Concurrent laboratory fortifications were analyzed with each set of samples to evaluate the validity of the analytical data. Table 6 summarizes the results for the concurrent laboratory fortification sample recoveries. For each matrix, the mean recovery fell within the acceptable range of 70% to 120% and the standard deviation was less than 20%.

Table 6. Concurrent Laboratory Fortification Sample Recovery Summary

Matrix	Recovery Range (%)	n	Average Recovery (%)	Standard Deviation (%)
Inner Dosimeters	62-111	24	86	14
Outer Dosimeters	63-111	31	85	14
Hand Washes	70-115	26	92	15
Hat Patches	73-117	16	100	12
Air Tubes	79-120	13	100	14
Gelman Filters	75-122	27	97	16
Urine Samples	86-114	7	99	9.9

Field Blanks: Field blanks were collected for each media. For the air filters and air tubes, there were some trace residues of propanil just above the background in certain sets of field controls. It was suggested in the Study Report that some traces of propanil may have been picked up, since samples were

collected at the aerial facility. There were no traces of propanil in any of the hand wash field controls. For the patch samples, residues of propanil ranged from 0.0167 to 0.5312 μg/sample. Outer dosimeter control samples had residues ranging from 0 to 1.5882 μg/sample and inner dosimeter samples had residues ranging from 0 to 1.8549. The study author suggested that these levels may have been a results of cross contamination in the field or laboratory.

Field Recovery: Handwash Samples: Hand wash fortification samples were prepared on five occasions during the study. Triplicate 500 mL hand wash solutions were fortified with 5 μg or 5000 μg of propanil. The fortification samples were immediately placed in frozen storage.

Air Filters: Inhalation fortification samples were prepared on five occasions during the study. Triplicate samples were fortified with 0.5 μg propanil. Another set of triplicate samples were fortified with 25 μg propanil. After addition of the propanil, the filter or air tube was left to dry for at least 15 minutes before the air pump was turned on. The pumps were then run for approximately the time it took to complete the application replicate for that day. After the specific time period, the air tubes and filters were removed from the pumps, wrapped in a paper towel, taped, placed in pre-labeled plastic zip lock bags and immediately placed in frozen storage.

Hat Patches: Hat patch fortification samples were prepared on five separate occasions during the study. Triplicate control sets of patches were fortified with 1 μg propanil and another set of patches with 1000 μg propanil. The patch was folded four times and placed on aluminum foil. The patches were weathered in the same manner as that for the air tubes/filters, collected, wrapped in aluminum foil, placed in pre-labeled plastic bags and stored frozen.

Outer dosimeters: Outer dosimeter fortification samples were prepared on five occasions throughout the course of the study. Triplicate control dosimeter sections were folded in at least six layers and pinned to a table covered with aluminum foil. Each sample was fortified with 20 μg propanil or 1000 μg propanil. The dosimeters were weathered in the same manner as that for the air tubes/filters, then wrapped separately in aluminum foil, placed in pre-labeled plastic zip lock bags and stored frozen.

Inner dosimeters: Inner dosimeter fortification samples were prepared on five occasions throughout the course of the study. Triplicate control dosimeter sections were folded in at least six layers and pinned to a table covered with aluminum foil. Each sample was fortified with 1 μg propanil or 1000 μg propanil. The inner dosimeter was folded so that at least one layer of the cloth was left over the fortified area and then was weathered in the same manner as that for the air tubes/filters. The inner dosimeters were then folded with the treated area inside, wrapped in aluminum foil, placed in plastic bags, and stored frozen.

Urine samples: Control urine samples collected prior to test initiation were used as fortification samples. 400 mL of sample were taken and split into eight 50 mL aliquots and placed in pre-labeled 4-ounce amber bottles with Teflon lids (2 samples kept as control, 3 fortified). The fortification samples were fortified with 0.5 μg 3,4-DCA or 5 μg 3,4-DCA. The samples were placed in plastic bags, wrapped in bubble wrap, and placed in a cooler of dry ice or stored frozen.

Table 7. Field Fortification Recoveries for Propanil

Media	Set #	Fortification level	% Recovered/day	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation
Air filters	1	0.5 μg/sample	69	56	70	16
	2		41			
	3		58			

Media	Set #	Fortification level	% Recovered/day	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation
	4		56			
	5		56			
	1		77			
	2		85			
	3	25 μg/sample	86	84		
	4		86			
	5		86			
	1		94			
	2		66			
	3	0.5 μg/sample	77	80		
	4		66			
Air Tubes	5		97		88	16
	1		76			
	2		104			
	3	25 μg/sample	109	96		
	4		92			
	5		99			
	1		74			
	2		77			
	3	0.01 μg/mL	63	82		
	4		96			
Hand washes	5		102		82	12
	1		91			
	2		67			
	3	25 μg/mL	82	81		
	4		82			
	5		83			
	1		87			
	2		79			
	3	1 μg/sample	66	73		
	4		71			
Patches	5		65		81	13
	1		100			
	2	1000 μg/sample	79	90		
	3		95			

Media	Set #	Fortification level	% Recovered/day	Average Recovery (%)	Overall Average Recovery (%)	Standard Deviation
	4		101			
	5		73			
Outer dosimeters	1	20 μg/sample	69	71	71	10
	2		72			
	3		68			
	4		85			
	5		59			
	1	1000 μg/sample	80	71		
	2		60			
	3		64			
	4		87			
	5		61			
Inner dosimeters	1	1.0 μg/sample	a	110	96	14
	2		109			
	3		96			
	4		a			
	5		125			
	1	1000 μg/sample	76	92		
	2		91			
	3		101			
	4		99			
	5		94			
Urine	1	0.01 μg/mL	109	105	95	16
	2		b			
	3		b			
	4		b			
	5		100			
	1	0.10 μg/mL	89	90		
	2		115			
	3		b			
	4		73			
	5		83			

a The recoveries from these replicates were not included in the calculation of the mean recovery for inner dosimeters because assumed were outliers.

b The recoveries from these replicates were not included in the calculation of the mean recovery for urine because close interference peaks prevented accurate quantitation.

Formulation: Not reported.

Tank Mix: Triplicate tank mix samples were taken from the airplane spray tank during the applications at select sites. The amount of propanil found in the tank mix samples was close to the amount expected except for one sample at site 3 and all samples at site 10. Recoveries of propanil from the tank mix average 106% ± 38%.

Travel Recovery: At the field laboratory, duplicate control samples of the outer dosimeters, inner dosimeters, and patches were fortified with 1000 μg propanil. Duplicate samples of air filters and tubes were fortified with 25 μg propanil. Travel spikes were not weathered but were immediately placed in frozen storage. Travel spike recoveries ranged from 64% to 108%.

Storage Stability: Storage stability studies were performed for all matrices, except patches since the patch and dosimeter material is the same. Sample storage intervals for inner dosimeters, outer dosimeters, hand washes, hat patches, air tubes, air filters, and urine were 103, 104, 96, 89, 75, 71, and 73 days, respectively. The Study Report states that the inner and outer dosimeter storage stability studies are not complete and additional results will be added as an appendix. Table 8 provides a summary of the results.

Table 8. Storage Stability Results

Matrix	Days stored	Mean Recovery (%)	Standard Deviation (%)
Air Tubes	85	93	7
Air Filters	85	77	25
Hand Washes	119	88	6
Outer Dosimeters	43	86	27
Inner Dosimeters	43	71	8
Urine	115	92	9

10. Relevancy of Study to Proposed Use:

The study monitored handlers performing their normal duties while mixing/loading the test product and applying propanil formulations aerially.

II. RESULTS AND CALCULATIONS:

A. EXPOSURE CALCULATIONS:

The study author provided total exposure values expressed as μg/kg body weight/day and μg/kg a.i./day (Tables 9a-9c). Total exposure was calculated by summing the internal inhalation dose (assuming 100% lung absorption of the inhalation exposure) and the internal dermal dose (assuming 20% dermal penetration). The study author stated that residue values were corrected for field fortification recoveries if the recoveries were below 100%. It appears from review of the residue data provided that the study author used ½ LOQ for values below the LOQ. Versar estimated inhalation exposure values as μg/lb ai handled as per EPA's request. Versar has only estimated dermal exposure values for the pilots (applicators), per instructions from EPA. Versar corrected residue values for field fortification recoveries less than 90%. Versar also used ½ LOQ, for values below the LOQ, in their calculations.

Inhalation Exposure

Inhalation exposures were calculated by both the study author and Versar from the breathing-zone air concentrations determined from the amount of propanil found on the air-sampling tubes and filters and the volume of air sample. Inhalation exposure was calculated by the study author by dividing the micrograms of propanil found on the sample by the total volume of air that passed through the sample and then multiplying by 29 L/min and the actual time of inhalation monitoring during the replicate. The exposures for the air tube and air filter were combined.

Versar used the NAFTA recommended values for breathing rates to calculate the air concentration in $\mu g/m^3$ and ultimately the inhalation exposure in µg/lb ai handled. The new NAFTA recommended inhalation rates are 8.3, 16.7 and 26.7 L/min for sedentary activities (e.g., driving a tractor), light activities (e.g., flaggers and mixer/loaders <50 lbs containers), and moderate activities (e.g., loading >50 lb containers, handheld equipment in hilly conditions), respectively. Versar assumed that the activities performed by the mixer/loaders fell under the light activities category (16.7 L/min), and the activities performed by pilots fell under the sedentary activities category (8.3 L/min). For the mixer/loader/pilot, Versar weighted the breathing rate by the relative time spent mixing/loading versus applying (16.7 L/min x 25 minutes mixing/loading plus 8.3 L/min x 78 minutes applying divided by total handling time of 103 minutes). Table 10 provides Versar's calculated inhalation exposures. The average inhalation exposure for mixer/loaders was 1.37E-02 µg/lb a.i. handled, for pilots was 2.04E-03 µg/lb a.i. handled, and for the mixer/loader/pilot was 6.94E-04 µg/lb a.i. handled.

Dermal Exposure

Dermal exposure was calculated by the study author. First, a penetration factor was derived by dividing the amount of residue on the inner dosimeter (tee shirt and briefs) by the residue on the torso section of the outer dosimeter. Then outer dosimeter residues for arms, legs, and torso were multiplied by the penetration factor. The study author indicates that this method provides an estimate of the amount of residue that would penetrate the outer dosimeter and be deposited on the skin of the torso, arms, and legs.

The amount of propanil on the head, face and neck was estimated by the study author by multiplying the hat/helmet patch residue by a factor of 10.7, which was derived from EPA's estimated face, head and neck area of 2210 cm^2 divided by the surface area of the two hat/helmet patches (206.5 cm^2).

The amount of propanil on the hands was estimated by the study author by multiplying the hand residue by the sample volume of 500 mL.

The study author then calculated total dermal exposure by summing the estimated residues on the head/face/neck area, with the estimated hand residues, and with the estimated residues on the skin of the torso, arms, and legs. The study author did not calculate individual hand exposures or head/face/neck exposures. Only residue values were provided in the Study Report, which were then incorporated into the calculation of dermal exposure.

Versar calculated hand exposures (under chemical-resistant gloves) which are reported in Table 11. For mixers/loaders, hand unit exposures averaged 0.61 ± 1.41 µg/lb ai handled. For pilots, hand unit exposures averaged 0.46 ± 0.72 µg/lb ai handled. (Versar notes that in two of the study replicates (V28 and V32), the pilots wore flight gloves throughout the replicate.) For the mixer/loader/pilot, hand unit exposures were 0.75 µg/lb ai handled.

Versar also calculated head, face, and neck exposures which are reported in Table 12. For mixers/loaders, these unit exposures averaged 9.4 ± 23.0 µg/lb ai handled. For pilots, these unit exposures averaged 0.58 ± 1.0 µg/lb ai handled. For the mixer/loader/pilot, the head, face, and neck unit exposure was 74.58 µg/lb ai handled.

Versar calculated dermal unit exposure to the torso, arms, and legs for the pilot scenarios only. Versar did not calculate dermal unit exposure to the torso, arms, and legs for the mixer/loader or for the mixer/loader/applicator scenarios, since an appropriate protection factor could not be calculated from the data as presented in the study. Versar calculated this unit exposure using the same method as the study author. First, a penetration factor was derived by dividing the amount of residue on the inner dosimeter (tee shirt and briefs) by the residue on the torso section of the outer dosimeter. Then outer dosimeter residues for arms, legs, and torso were multiplied by the penetration factor. Dermal unit exposures averaged 1.05E-04 mg/lb ai for the arms, 4.82E-05 mg/lb ai for the legs, and 7.46E-05 mg/lb ai for the torso (see Table 13).

Versar then calculated total dermal unit exposure for pilots. Total dermal unit exposure estimates averaged 1.27E-03 mg/lb ai handled for the pilots. Table 14 provides the total dermal exposures for pilots. Total dermal exposure to mixers/loaders and to the mixer/loader/applicator were not calculated by Versar, since dermal exposure to the torso, arms, and legs was not calculated for these two scenarios, because an appropriate protection factor could not be calculated from the data as presented in the study.

Total Dermal + Inhalation Exposure

The study author calculated mean total unit exposures of 2.10 ± 3.80 μg/kg ai/day for mixer/loaders and 0.481 ± 0.905 μg/kg ai/day for pilots.

Total unit exposure was calculated by Versar for pilots by adding the dermal and inhalation exposures to pilots. Versar did not calculate total unit exposures to mixers/loaders or to the mixer/loader/applicator, since an appropriate protection factor could not be calculated from the data as presented in the study for dermal exposure to the torso, arms, and legs for these two scenarios. Versar's calculated average total unit exposure to pilots was 1.28 ± 2.63 μg/lb ai handled (see Table 15).

Biomonitoring

The study protocol required that handlers participating in the study would not have be exposed to propanil for at least 3 days prior to and at least 3 days following the day of the study. In the study itself, however, only two handlers out of the 30 participants were known to have had no exposure in the 3 days before and 3 days following the study. Six other handlers may not have had exposures in the 3 days before and 3 days following the study, but there was some uncertainty. The remaining 22 participants were known to have had exposures in one or more of the 3 days before and 3 days following the study.

The urine data collected for eight handlers who were presumed to have had no propanil exposures for three days before or three days after the study were input into a model to determine the half-life of the excretion of detectable urine residues. The half-life of the excretion of propanil metabolites was found to be 23.9 hours. Using a model to adjust for propanil residues that handlers may have received other than during the study, the study author calculated an approximate dose of propanil for each handler on day 0. The study author calculated exposures of 54.7 ± 120 μg/kg ai/day for mixer/loaders and 35.5 μg/kg ai/day for pilots. For both mixer/loaders and pilots, the exposure values obtained from biomonitoring are much higher than those obtained from whole body dosimetry. The study did not provide an explanation for this discrepancy.

III. DISCUSSION

A. LIMITATIONS OF THE STUDY:

The study met some of the Series 875.1200 and 875.1400 Guidelines. However, there are major issues of concern, including:

(1) Mixers/loaders in the study wore either a chemical-resistant apron or a Tyvek coverall over the "outer" dosimeter and also wore chemical-resistant footwear. In calculating potential dermal exposures to mixers/loaders, the study author does not factor in this additional personal protective equipment, which exceeds the requirements of the product labeling and makes the use of a protection factor infeasible;
(2) The average duration of each replicate was 2.2 hours for mixers/loaders and 1.7 hours for pilots, rather than the 6-12 hours stated in the study protocol;
(3) The average application rate used in the study was approximately 3 pounds active ingredient per acre, rather than the label maximum of 6 pounds active ingredient per acre on the STAM-M4 label;
(4) Trapping efficiency tests for the air monitoring media chosen were not documented;
(5) There was no mention of breakthrough tests being run on the air filters;
(6) No information was provided on how the air filters/tubes were stored after sample collection;
(7) There was no mention of preliminary hand rinse studies; and
(8) It was not mentioned if a sample history sheet had been prepared by the laboratory upon receipt of samples.

B. DISCUSSION OF DERMAL CALCULATIONS:

Versar calculated dermal exposures to the arms, legs, and torso for pilots only. Versar did not calculate dermal exposure to the torso, arms, and legs for the mixer/loader or for the mixer/loader/applicator scenarios, since an appropriate protection factor could not be calculated from the data as presented in the study. Tables 9, 10, and 11 summarize the study authors'data. Versar's issues include:

1. The study did not follow its protocol or the product label in determining the personal protective equipment worn by mixers/loaders. The protocol and label indicate that mixers/loaders would wear long-sleeved shirts, long pants, shoes, socks, and chemical-resistant gloves. However, in the study, the mixers/loaders wore chemical-resistant footwear – described as "boots" instead of shoes. In addition, the four mixers/loaders wore a Tyvek coverall over the long-sleeved shirt and long pants and the remaining eleven mixers/loaders wore a chemical-resistant apron over the long-sleeved shirt and long pants. Versar is concerned that the chemical-resistant boots will greatly alter the amount of residues measured on the lower legs area of the "outer" dosimeter. Similarly, Versar is concerned that the chemical-resistant apron or Tyvek coveralls greatly alter the amount of residue measured on the upper legs and torso area of the "outer" dosimeter. Versar notes that on page 133 of the study report, the residues found in/on Tvyek suits is reported. However, these data are not used in any of the dermal exposure calculations.

2. Versar questions the validity of the study author's use of a protection factor to determine dermal exposure to mixers/loaders. The study author divides the residue in the inner dosimeter (tee shirt and briefs) by the residue in the torso section of the outer dosimeter to determine what percentage of residue penetrates the outer dosimeter. Then the study author applies this protection factor to the total residue measured on the outer dosimeter to estimate dermal exposure to the handlers' skin surface. Versar suggests that the use of a protection factor in this study is questionable due to the use of additional PPE over the "outer" dosimeter (see issue 1 above).

3. Versar questions the validity of using data from abbreviated handling times and lower than maximum application rates in determining dermal exposures to mixers/loader or pilots. It is Versar's understanding that penetration of a residue through a matrix is dependent on three factors: composition of the matrix, concentration of the residue on the matrix surface, and time of residue contact with the matrix surface. This study used application rates lower than the maximum 6 pounds active ingredient listed in the protocol and on the product labeling (STAM M4), with an average application rate in the study less than 3 pounds active ingredient per acre. In addition, this study involved much lower handling times than were listed in the protocol or are routinely found in other handler exposure studies. The average handling time for mixers/loaders was only 2.2 hours and for pilots was only 1.7 hours and the average dermal monitoring time was less than 4.5 hours for both handling tasks. The application-rate factor would be expected to result in less residue being deposited on the outer dosimeter and the handling time factor would be expected to result in less time for the residue to penetrate the outer dosimeter.

4. Versar questions the validity of combining dermal exposure data from mixers/loaders wearing aprons with mixers/loaders wearing Tyvek coveralls. Versar also questions the validity of using hand wash data for pilots who wore "flight gloves" throughout the replicate.

5. The study author chose to eliminate the head patch data for the mixer/loader portion of the mixer/loader/pilot replicate. Versar questions the validity of that decision, particularly since the head patch residues were very high for the mixer/loader portion of the replicate and very low for the pilot portion of the replicate.

6. The biomonitoring measurements in the study are complicated further by the fact that most mixers/loaders and pilots were exposed to propanil within 3 days prior to and/or within three days following day of the study. In addition, other mixers/loaders and pilots **may** have been exposed to propanil in the few days before and/or after the study date – their exposure during those days is unknown. The study authors adjusted the biomonitoring results for those handlers exposed within

3 days prior or 3 days following the study using a modeling program and basing the calculation of excretion half-life on only those handlers who had no propanil exposure, except on the day of the study. Twenty-two of the thirty participants had propanil exposures on days other than just the study day. Urine data from the remaining eight participants was used to calculate excretion half-life. However, two of those eight may have had multiple exposures to propanil – the study states "The amount applied is not sure. Exposure may happen." And four other of those eight are not explicitly known to have no exposures – the study states "No dates or amount applied in the record and is regarded as no exposure." The two remaining participants of those eight in the "single exposure" group both had exposure to propanil five days before the study date. Versar questions the validity of adjusting biomonitoring data on the basis of 8 replicates – some of which may not be single exposure at all. Versar notes that the results of the biomonitoring study indicate much higher exposure to propanil that the results of the passive dosimetry and personal air sampling study.

C. CONCLUSIONS:

Dermal and inhalation exposures to professional handlers were assessed during the mixing/loading and aerial application of propanil to rice fields. The study author calculated mean total exposures (doses) of 2.10 ± 3.80 μg/kg ai/day for mixers/loaders and 0.481 ± 0.905 μg/kg ai/day for pilots , using passive dosimetry and personal air sampling. The study author also calculated total exposures (doses) of 54.7 ± 120 μg/kg ai/day for mixer/loaders and 35.5 μg/kg ai/day for pilots using biomonitoring. This review found several concerns with this study.

Table 9a. Summary of Study Report Results for Mixer/Loader Replicates

Mixer/Loader Replicate	Loads per Day	Pounds AI Handled per Day	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE Worn	Exposed Just Before or Just After Study	Study Reported Total Internal Exposure (μg/kg ai/day)	
								Dosimetry + Air Sampling	Biomonitoring
V1	16	1328	3.43	6.2	6.7	apron, boots	Before	0.0911	6.82
V3	12	1080	2.33	4	4.3	apron, boots	No	0.253	2.16
V5	8	870	2.82	6.5	6.8	apron, boots	No	1.022	4.75
V7	5	644	2.38	2.5	2.8	apron, boots	Before	2.18	43.8
V9	16	1328	3.43	6.4	7.2	apron, boots	Before & After	1	28.4
V13	6	510	1.75	2.3	2.8	apron, boots	Before	0.0744	1.79
V15	6	510	1.75	2.3	2.7	apron, boots	Before & After	0.0138	2.23
V17	9	776	5.3	6.1	6.4	tyvek, boots	Before	6.50	11.2
V19 (repl #1)	2	138	0.32	1.9	2.3	apron, boots	Unknown	0.885	32.9
V19 (repl #2)	1	156	0.05						
V19 (TOTAL)	3	294	0.37						
V21	6	579	2.8	3.5	4.1	apron, boots	No	0.239	20.9
V23	2	196	0.53	1.4	1.8	apron, boots	Before	5.039	452

Mixer/Loader Replicate	Loads per Day	Pounds AI Handled per Day	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	PPE Worn	Exposed Just Before or Just After Study	Study Reported Total Internal Exposure (μg/kg ai/day)	
								Dosimetry + Air Sampling	Biomonitoring
V25 (repl #1)	4	600	1.63	3	no data	tyvek, boots	After	0.0142	11.3
V25 (repl #2)	2	204	0.78						
V25 (TOTAL)	6	804	2.41						
V27	3	576	1.32	2.9	5	apron, boots	Before & After	0.0967	3.78
V29	5	790	1.62	2.2	2.4	tyvek, boots	After	0.117	9.97
V31 (repl #1)	1	76	0.35	5.6	6	tyvek, boots	Before	13.9	189
V31 (repl #2)	2	192	0.82						
V31 (repl #3)	1	96	0.17						
V31 (TOTAL)	4	364	1.34						
Mean	**7.1**	**710**	**2.2**	**3.8**	**4.4**	N/A	N/A	**2.10**	**54.7**

Table 9b. Summary of Pilot (Applicator) Replicates

Pilot Replicate	Loads	Acres Treated per Replicate (total = acres/day)	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	Pounds AI per Acre	PPE	Exposed Just Before or Just After Study	Study Reported Total Internal Exposure (µg/kg ai/day)	
									Dosimtery + Air Sampling	Biomonitoring
V2	9	246	1.73	6.6	7.1	3	single layer, shoes, socks + gloves when entering or exiting	After	1.62	17
V4	6	240	1.48	4.2	4.7	2.25		No	0.0572	8.28
V6	8	334	1.72	6.2	6.5	3		No	0.0423	2.38
V8	7	197	1.75	6.6	6.8	3		After	3.41	69.3
V10	6	254	1.70	2.5	2.9	2		After	0.0221	3.81
V14 (repl #1)	4	137	1.3	3.2	3.9	4		Before	0.224	9.94
V14 (repl #2)	1	32	0.15			3				
V14 (TOTAL)	5	169	1.45			N/A				
V16 (repl #1)	2	72	0.38	2.8	3.1	1.9		Unknown	0.298	13.2
V16 (repl #2)	1	51	0.3			3.1				
V16 (TOTAL)	3	87	0.68			N/A				
V20 (repl #1)	2	73	0.53	NONE	4	3		No	0.0952	5.5
V20 (repl #2)	4	160	1.5			2.25				
V20 (TOTAL)	6	233	2.03			N/A				
V22	2	49	0.87	1.4	2.2	4		Before	0.423	208
V24 (repl #1)	4	200	1.17	3	3.2	3		After	0.0065	1.92
V24 (repl #2)	2	102	0.98		3.1	2				
V24 (TOTAL)	6	302	2.15		6.3	N/A				

Pilot Replicate	Loads	Acres Treated per Replicate (total = acres/day)	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	Pounds AI per Acre	PPE	Exposed Just Before or Just After Study	Study Reported Total Internal Exposure (µg/kg ai/day)	
									Dosimtery + Air Sampling	Biomonitoring
V26	3	129	1.28	2.3	5	4.5		Before	0.0157	0.495
V28 (repl #1)	6	240	2.62	6	6.3	1.9	wore "flight" gloves	Before & After	0.111	52.7
V28 (repl #2)	3	156	1.2			2				
V28 (TOTAL)	9	396	3.82			N/A				
V30	5	197.5	1.32	2	2.2	4	same as V2	After	0.0809	16.9
V32 (repl #1)	1	37.5	0.23	5	5.3	2	wore "flight" gloves	Before	0.453	105
V32 (repl #2)	3	138	1.22			2.1				
V32 (TOTAL)	4	175.5	1.45			N/A				
Mean	**5.6**	**218**	**1.7**	**4.0**	**4.5**	**2.8**	**N/A**	**N/A**	**0.481**	**35.5**

Table 9c. Summary of Mixer/Loader/Pilot Replicate

Mixer/Loader/ Pilot Replicate	Loads	Acres Treated per Load	Actual Time Spent in Handling Task (hours)	Inhalation Monitoring Time (hours)	Dermal Monitoring Time (hours)	Pounds AI per Acre	Exposure Just Before or Just After Study	Study Reported Total Internal Exposure (µg/kg ai/day)	
								Dosimetry + Air Sampling	Biomonitoring
V12 (mixing)	4	118	0.4	2.5	3.5	4	Before & Unknown After	0.351	18.3
V12 (applying)			1.4						
V12 (total)			1.8						

Table 10. Potential Inhalation (μg/lbs ai handled) Based on Residue Levels Found on Air Filters and Air Tubes

Site Number	Replicate No.	Flow Rate (L/min)	Combined inhalation residue (μg)[a]	Duration (min)	Concentration (μg/m³)[b]	lbs ai handled	Vent. Rate L/min *0.001 for m3/min at 16.7 l/min	Inhalation Exposure[c] (μg/lb ai handled)	Mean (μg/lb ai handled)	Geometric Mean (μg/lb ai handled)	Standard Deviation	CV (%)
Mixers/loaders												
1, 1A, 1B	3	1.9	0.038	242	0.08	1080	0.0167	3.11E-04	1.37E-02	6.08E-03	0.02	0.01
1, 1C, 1D	5	2	0.889	389	1.14	870	0.0167	8.53E-03				
2, 2A, 2B, 2C	1	1.5	0.401	374	0.71	1328	0.0167	3.36E-03				
2, 2A, 2B, 2C	9	1.5	0.556	381	0.97	1328	0.0167	4.66E-03				
3, 3A, 3B	13	2	0.050	139	0.18	510	0.0167	8.16E-04				
3, 3A, 3B	15	2	0.100	138	0.36	510	0.0167	1.63E-03				
4, 4A; 4, 4B	19	1.9	0.190	115	0.87	294	0.0167	5.68E-03				
6, 6A, 6B, 6C	7	1.9	0.951	152	3.29	156	0.0167	5.36E-02				
6, 6D, 6E	23	2	0.370	81	2.28	196	0.0167	1.58E-02				
7, 7A, 7B	21	2	0.170	208	0.41	579	0.0167	2.45E-03				
8, 8A	27	2	0.561	172	1.63	576	0.0167	8.13E-03				
9, 9A; 9, 9B	25	2	0.663	180	1.84	804	0.0167	6.89E-03				
10, 10A, 10B, 10C	17	2	0.822	364	1.13	776	0.0167	8.85E-03				
10, 10D; 10, 10E;	31	2	0.455	334	0.68	76	0.0167	5.00E-02				
11, 11A, 11B	29	2	1.546	131	5.90	364	0.0167	3.55E-02				
Pilots (Applicator)												
1, 1A, 1B	4	2	0.078	89	0.44	540	0.0083	6.02E-04	2.04E-03	9.26E-04	0.003	0.01
1, 1C, 1D	6	2	0.180	103	0.87	870	0.0083	8.59E-04				
2, 2A, 2B, 2C	2	1.9	1.435	104	7.26	738	0.0083	8.49E-03				
2, 2A, 2B, 2C	8	2	0.060	105	0.29	591	0.0083	4.23E-04				

3, 3A, 3B	10	2.1	0.088	102	0.41	510	0.0083	6.78E-04				
4, 4A; 4, 4B	16	2	0.256	43	2.98	156	0.0083	6.81E-03				
6, 6A, 6B; 6, 6C	14	2	0.217	97	1.12	644	0.0083	1.40E-03				
6, 6D, 6E	22	2	0.015	52	0.15	196	0.0083	3.21E-04				
7, 7A; 7, 7B[d]	20											
8, 8A	26	2	0.142	77	0.92	576	0.0083	1.02E-03				
9, 9A; 9, 9B	24	2	0.030	129	0.12	804	0.0083	1.54E-04				
10, 10A, 10B; 10, 10C	28	2	0.661	229	1.44	776	0.0083	3.54E-03				
10, 10D; 10, 10E	32	2	0.189	87	1.09	364	0.0083	2.16E-03				
11, 11A, 11B	30	2	0.015	79	0.10	790	0.0083	7.97E-05				
Mixer loader and applicator												
5, 5A[e]	12	2	0.063	150	0.21	472	0.010339	6.94E-04	NA	NA	NA	NA

a Combined inhalation residue (μg) = Corrected air filters residue (μg) + Corrected air tubes residues (μg); Air filter residues corrected for 56% fortification recovery and air tube residues corrected for 80% fortification recoveries

b Concentration (μg/m3) = [Combined inhalation residue (μg) / (Flow rate (L/min) * Duration (min))]*1000

c Inhalation Exposure (μg/lb ai handled) = (Concentration (μg/m3) * Vent. Rate (m^3/min) * Duration (min))/lbs a.i. handled

d Replicate not included in calculations

e Inhalation ventilation rate calculated by weighting the ventilation rate for mixing/loading by the time spent mixing/loading and the ventilation rate for applying by the time spent applying.

Table 11. Summary of Hand Exposure (µg/lb ai handled) based on Hand Washes

Site Number	Replicate No.	Corrected residue (µg/mL)[a]	Sample volume (mL)	Concentration (µg)[b]	lbs ai handled	Hand exposure (µg/lb ai handled)[c]	Mean (µg/lb ai handled)	Geometric Mean (µg/lb ai handled)	Standard Deviation	CV (%)
Mixers/loaders										
1, 1A, 1B	3	1.0073	500	504	1080	0.466	0.61	0.09	1.41	0.02
1, 1C, 1D	5	0.0813	500	41	870	0.047				
2, 2A, 2B, 2C	1	0.1765	500	88	1328	0.066				
2, 2A, 2B, 2C	9	0.1055	500	53	1328	0.040				
3, 3A, 3B	13	0.0155	500	8	510	0.015				
3, 3A, 3B	15	0.0061	500	3	510	0.006				
4, 4A; 4, 4B	19	0.2359	500	118	294	0.401				
6, 6A, 6B, 6C	7	0.1476	500	74	156	0.473				
6, 6D, 6E	23	0.4301	500	215	196	1.097				
7, 7A, 7B	21	0.0938	500	47	579	0.081				
8, 8A	27	0.0140	500	7	576	0.012				
9, 9A; 9, 9B	25	0.0061	500	3	804	0.004				
10, 10A, 10B, 10C	17	1.2983	500	649	776	0.837				
10, 10D; 10, 10E	31	0.8426	500	421	76	5.543				
11, 11A, 11B	29	0.0123	500	6	364	0.017				
Pilot (Applicators)										
1, 1A, 1B	4	0.1000	500	50	540	0.093	0.46	0.14	0.72	0.02
1, 1C, 1D	6	0.0605	500	30	870	0.035				
2, 2A, 2B, 2C	2	2.9407	500	1470	738	1.992				
2, 2A, 2B, 2C	8	2.6268	500	1313	591	2.222				
3, 3A, 3B	10	0.0315	500	16	510	0.031				

4, 4A; 4, 4B	16	0.1160	500	58	156	0.372				
6, 6A, 6B; 6, 6C	14	0.4699	500	235	644	0.365				
6, 6D, 6E	22	0.1417	500	71	196	0.361				
7, 7A, 7B	20	0.1324	500	66	579	0.114				
8, 8A	26	0.0061	500	3	576	0.005				
9, 9A; 9, 9B	24	0.0061	500	3	804	0.004				
10, 10A, 10B; 10, 10C	28	0.2696	500	135	776	0.174				
10, 10D; 10, 10E	32	0.4133	500	207	364	0.568				
11, 11A, 11B	30	0.2549	500	127	790	0.161				
Mixer/Loader/Applicator										
5, 5A[d]	12	0.7068	500	353	472	0.75	NA	NA	NA	NA

a Corrected residue (µg/mL) = Hand wash residue (µg) * Field fortification recovery (82%)

b Concentration (µg) = Corrected residue (µg/mL) * Sample volume (mL)

c Hand exposure (µg/lb ai handled) = Concentration (µg)/lbs ai handled

d Hand exposure for person performing mixing/loading and applying tasks.

Table 12. Summary of Face/Neck Exposure (µg/lb ai handled) based on Hat Patches

Site Number	Replicate No.	Residue (µg/sample)	Patches surface area (cm^2)[a]	Residue (µg/cm^2)[b]	Fortification recovery	Corrected residue (µg/cm^2)[c]	Combine surface area of face/head/ neck (cm^2)	Total Concentration (µg)[d]	lbs ai handled	Face/Neck exposure (µg/lb ai handled)	Mean (µg/lb ai handled)	Geometric Mean (µg/lb ai handled)	Standard Deviation	CV (%)
Mixers/loaders														
1, 1A, 1B	3	2.4691	206.45	0.0120	0.73	0.0164	2210	36.21	1080	0.034	9.4	0.65	23.06	0.02
1, 1C, 1D	5	137.9199	206.45	0.6681	0.73	0.9151	2210	2022.47	870	2.325				
2, 2A, 2B, 2C	1	10.0646	206.45	0.0488	0.73	0.0668	2210	147.59	1328	0.111				
2, 2A, 2B, 2C	9	219.4563	206.45	1.0630	0.73	1.4562	2210	3218.12	1328	2.423				
3, 3A, 3B	13	1.117	206.45	0.0054	0.73	0.0074	2210	16.38	510	0.032				
3, 3A, 3B	15	0.1827	206.45	0.0009	0.73	0.0012	2210	2.68	510	0.005				
4, 4A; 4, 4B	19	8.2237	206.45	0.0398	0.73	0.0546	2210	120.59	294	0.410				
6, 6A, 6B, 6C	7	226.5144	206.45	1.0972	0.73	1.5030	2210	3321.62	156	21.292				
6, 6D, 6E	23	145.7732	206.45	0.7061	0.73	0.9673	2210	2137.63	196	10.906				
7, 7A, 7B	21	6.3378	206.45	0.0307	0.73	0.0421	2210	92.94	579	0.161				
8, 8A	27	20.8759	206.45	0.1011	0.73	0.1385	2210	306.13	576	0.531				
9, 9A; 9, 9B	25	14.535	206.45	0.0704	0.73	0.0964	2210	213.14	804	0.265				
10, 10A, 10B, 10C	17	793.6982	206.45	3.8445	0.9	4.2717	2210	9440.40	776	12.165				
10, 10D; 10, 10E	31	464.3179	206.45	2.2491	0.73	3.0809	2210	6808.79	76	89.589				
11, 11A, 11B	29	5.0092	206.45	0.0243	0.73	0.0332	2210	73.46	364	0.202				
Pilot (Applicators)														
1, 1A, 1B	4	0.2916	206.45	0.0014	0.73	0.0019	2210	4.28	540	0.008	0.58	0.05	1.0	0.03
1, 1C, 1D	6	1.495	206.45	0.0072	0.73	0.0099	2210	21.92	870	0.025				
2, 2A, 2B, 2C	2	43.5914	206.45	0.2111	0.73	0.2892	2210	639.23	738	0.866				
2, 2A, 2B, 2C	8	226.5144	206.45	1.0972	0.73	1.5030	2210	3321.62	591	5.620				
3, 3A, 3B	10	0.177	206.45	0.0009	0.73	0.0012	2210	2.60	510	0.005				
4, 4A; 4, 4B	16	7.9601	206.45	0.0386	0.73	0.0528	2210	116.73	156	0.748				

6, 6A, 6B; 6, 6C	14	0.8105	206.45	0.0039	0.73	0.0054	2210	11.89	644	0.018				
6, 6D, 6E	22	8.4006	206.45	0.0407	0.73	0.0557	2210	123.19	196	0.629				
7, 7A, 7B	20	6.30773	206.45	0.0306	0.73	0.0419	2210	92.50	579	0.160				
8, 8A	26	0.4091	206.45	0.0020	0.73	0.0027	2210	6.00	576	0.010				
9, 9A; 9, 9B	24	0.2244	206.45	0.0011	0.73	0.0015	2210	3.29	804	0.004				
10, 10A, 10B; 10, 10C	28	0.2261	206.45	0.0011	0.73	0.0015	2210	3.32	776	0.004				
10, 10D; 10, 10E	32	1.4476	206.45	0.0070	0.73	0.0096	2210	21.23	364	0.058				
11, 11A, 11B	30	0.438	206.45	0.0021	0.73	0.0029	2210	6.42	790	0.008				
Mixer/Loader/Applicator														
5, 5A (mix/load)[f]	12	2959.333	206.45	14.3344	0.9	15.9271	2210	35198.87	472	74.57	74.58	NA	NA	NA
5, 5A (apply)[f]	12	0.3464	206.45	0.0017	0.73	0.0023	2210	5.08	472	0.01				

a Two hat patches (one on front and one on back of cap or helmet) were 4"x4" (206.45 cm^2 total area).

b Residue ($\mu g/cm^2$) = Residue (μg/sample)/Patches surface area (cm^2)

c Corrected residue ($\mu g/cm^2$) = Residue ($\mu g/cm^2$)/Fortification Recovery (73% for residues closest to low level fortification and 90% for residues closest to high level fortification)

d Total Concentration (μg) = Corrected residue ($\mu g/cm^2$) * Combine surface area of face/head/ neck (cm^2)

e Face/Neck exposure (μg/lb ai handled) = Total Concentration (μg)/lbs ai handled

f Mixer/ loader/applicator replicate includes residue from patches while mixing/loading plus residues from patches while applying.

Table 13. Summary of Arms, Legs, and Torso Exposure (µg/lb ai handled) to Pilots

Site Number	Replicate Number	Outer Dosimeter (coverall) Residues corrected for 77% Field Fortification Recovery (µg)			Penetration Factor[a]	"Inner dosimeter" residues (µg)			lbs ai handled	Dermal Exposures[b] (mg/lb ai)		
		Arm	Leg	Torso		Arm	Leg	Torso		Arm	Leg	Torso
1, 1A, 1B	4	134	183	344	0.016	2.1	2.9	5.5	540.0	3.93e-06	5.37E-06	1.01E-05
1, 1C, 1D	6	1242	586	3471	0.002	2.7	1.3	7.6	870.0	3.13E-06	1.48E-06	8.75E-06
2, 2A, 2B, 2C	2	3755	4618	819	0.061	230.5	283.5	50.3	738.0	3.12E-04	3.84E-04	6.81E-05
2, 2A, 2B, 2C	8	133855	20844	91493	0.005	622.4	96.9	425.4	591.0	1.05E-03	1.64E-04	7.20E-04
3, 3A, 3B	10	3.6	16.3	13.8	0.045	0.2	0.7	0.6	510.0	3.20E-07	1.45E-06	1.23E-06
4, 4A; 4, 4B	16	780	2493	3197	0.003	2.2	7.2	9.2	156.0	1.44E-05	4.61E-05	5.91E-05
6, 6A, 6B; 6, 6C	14	452	312	845	0.041	18.6	12.9	34.8	644.0	2.89E-05	2.00E-05	5.41E-05
6, 6D, 6E	22	743	324	1445	0.003	2.1	0.9	4.1	196.0	1.08E-05	4.72E-06	2.10E-05
7, 7A; 7, 7B*	20	87.5	97.7	3045.2	0.001	0.1	0.1	2.3	579.0	1.16E-07	1.30E-07	4.06E-06
8, 8A	26	5.6	13.5	39.1	0.033	0.2	0.4	1.3	576.0	3.21E-07	7.67E-07	2.22E-06
9, 9A; 9, 9B	24	1.8	13.9	6.0	0.104	0.2	1.4	0.6	804.0	2.31E-07	1.80E-06	7.77E-07
10, 10A, 10B; 10, 10C	28	223	264	1056	0.006	1.3	1.5	6.0	776.0	1.64E-06	1.95E-06	7.78E-06
10, 10D; 10, 10E	32	201	236	457	0.063	12.6	14.8	28.6	364.0	3.46E-05	4.05E-05	7.85E-05
11, 11A, 11B	30	34.8	45.5	132	0.053	1.8	2.4	7.0	790.0	2.32E-06	3.04E-06	8.81E-06
Mean										**1.05E-04**	**4.82E-05**	**7.46E-05**

a Penetration factor = Inner dosimeter (tee shirt and briefs) residue/Torso section of outer dosimeter

b Dermal Exposures = ("Inner dosimeter" (calculated using penetration factor)/lbs ai handled)/1000 µg/mg

Table 14. Summary of Total Dermal Exposures for Pilots (Applicators)

Site Number	Replicate	Hand exposure (mg/lb ai)	Face/Neck exposure (mg/lb ai)	Arm Exposure (mg/lb ai)	Leg Exposure (mg/lb ai)	Torso Exposure (mg/lb ai)	Total Dermal Exposure (mg/lb ai)
Pilots (Applicators)							
1, 1A, 1B	4	9.26E-05	7.92E-06	3.93E-06	5.37E-06	1.01E-05	1.20e-04
1, 1C, 1D	6	3.48E-05	2.52E-05	3.13E-06	1.48E-06	8.75E-06	7.33e-05
2, 2A, 2B, 2C	2	1.99E-03	8.66E-04	3.12E-04	3.84E-04	6.81E-05	3.62e-03
2, 2A, 2B, 2C	8	2.22E-03	5.62E-03	1.05E-03	1.64E-04	7.20E-04	9.78e-03
3, 3A, 3B	10	3.08E-05	5.09E-06	3.20E-07	1.45E-06	1.23E-06	3.89e-05
4, 4A; 4, 4B	16	3.72E-04	7.48E-04	1.44E-05	4.61E-05	5.91E-05	1.24e-03
6, 6A, 6B; 6, 6C	14	3.65E-04	1.85E-05	2.89E-05	2.00E-05	5.41E-05	4.86e-04
6, 6D, 6E	22	3.61E-04	6.29E-04	1.08E-05	4.72E-06	2.10E-05	1.03e-03
7, 7A; 7, 7B*	20	1.14E-04	1.60E-04	1.16E-07	1.30E-07	4.06E-06	2.78e-04
8, 8A	26	5.29E-06	1.04E-05	3.21E-07	7.67E-07	2.22E-06	1.90e-05
9, 9A; 9, 9B	24	3.79E-06	4.09E-06	2.31E-07	1.80E-06	7.77E-07	1.07e-05
10, 10A, 10B; 10, 10C	28	1.74E-04	4.27E-06	1.64E-06	1.95E-06	7.78E-06	1.89e-04
10, 10D; 10, 10E	32	5.68E-04	5.83E-05	3.46E-05	4.05E-05	7.85E-05	7.80e-04
11, 11A, 11B	30	1.61E-04	8.13E-06	2.32E-06	3.04E-06	8.81E-06	1.84e-04
Mean							**1.27e-03**
Standard Deviation							**2.63e-03**

Table 15. Total Dermal + Inhalation Exposures for Pilots (Applicators)

Site Number	Replicate	Inhalation Exposure (µg/lb ai)	Hand exposure (µg/lb ai)	Face/Neck exposure (µg/lb ai)	Arm Exposure (µg/lb ai)	Leg Exposure (µg/lb ai)	Torso Exposure (µg/lb ai)	Total Exposure (µg/lb ai)
Pilots (Applicators)								
1, 1A, 1B	4	6.02E-04	0.093	0.008	3.93E-03	5.37E-03	1.01E-02	0.12
1, 1C, 1D	6	8.59E-04	0.035	0.025	3.13E-03	1.48E-03	8.75E-03	0.07
2, 2A, 2B, 2C	2	8.49E-03	1.992	0.866	3.12E-01	3.84E-01	6.81E-02	3.63
2, 2A, 2B, 2C	8	4.23E-04	2.222	5.620	1.05E+00	1.64E-01	7.20E-01	9.78
3, 3A, 3B	10	6.78E-04	0.031	0.005	3.20E-04	1.45E-03	1.23E-03	0.04
4, 4A; 4, 4B	16	6.81E-03	0.372	0.748	1.44E-02	4.61E-02	5.91E-02	1.25
6, 6A, 6B; 6, 6C	14	1.40E-03	0.365	0.018	2.89E-02	2.00E-02	5.41E-02	0.49
6, 6D, 6E	22	3.21E-04	0.361	0.629	1.08E-02	4.72E-03	2.10E-02	1.03
7, 7A; 7, 7B*	20		0.114	0.160	1.16E-04	1.30E-04	4.06E-03	0.28
8, 8A	26	1.02E-03	0.005	0.010	3.21E-04	7.67E-04	2.22E-03	0.02
9, 9A; 9, 9B	24	1.54E-04	0.004	0.004	2.31E-04	1.80E-03	7.77E-04	0.01
10, 10A, 10B; 10, 10C	28	3.54E-03	0.174	0.004	1.64E-03	1.95E-03	7.78E-03	0.19
10, 10D; 10, 10E	32	2.16E-03	0.568	0.058	3.46E-02	4.05E-02	7.85E-02	0.78
11, 11A, 11B	30	7.97E-05	0.161	0.008	2.32E-03	3.04E-03	8.81E-03	0.18
Mean								**1.28**
Standard Deviation								**2.63**

Compliance Checklist

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Guidelines, 875.1400 (inhalation), and 875.1200 (dermal) is critical. The itemized checklist below describes compliance with the major technical aspects of OPPTS 875.1400, and 875.1200.

875.1400

- *Investigators should submit protocols for review purposes prior to the inception of the study.* This criterion was met.
- *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* This criterion was met.
- *The test substance should be a typical end use product of the active ingredient.* This criterion was met.
- *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* This criterion was not met. The study protocol specified that the maximum label rate of 6 pounds active ingredient per acre would be used in the study. However, a range of application rates (1.9 to 4.5 lb ai/A) were used in the study, with the average at 2.8 lb ai/A.
- *Selected sites and indoor conditions of monitoring should be appropriate to the activity.* This criterion was met.
- *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was partially met. There were 15 mixer/loader replicates, but only 14 pilot replicates and 1 mixer/loader/pilot replicate.
- *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate.* This criterion was met.
- *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners.* This criterion was met.
- *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was not met. The protocol specified that mixers/loaders and pilots would be monitored for an entire workday and included hand washes that assumed a lunch break. For mixers/loaders, actual exposure times ranged from 0.37 to 5.30 (average = 2.2 hours), whereas dermal monitoring times ranged from 1.8 to 7.2 hours (average = 4.4 hours) and inhalation monitoring times ranged from 1.4 to 6.5 hours (average = 3.8 hours). For pilots, actual exposure times ranged from 0.68 to 3.82 hours (average = 1.7 hours), whereas dermal monitoring times ranged from 2.2 to 7.1 hours (average = 4.49 hours) and inhalation monitoring times ranged from 1.4 to 6.6 hours (average = 3.9 hours).
- *When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.* This criterion was met.
- *The analytical procedure must be capable of measuring exposure to 1 µg/hr (or less, if the toxicity of the material under study warrants greater sensitivity).* This criterion was met.
- *A trapping efficiency test for the monitoring media chosen must be documented.* This criterion was not met. Trapping efficiency tests were not documented for any of the media used in this study.
- *Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field.* This criterion was not met. There was no mention of any breakthrough tests being run on the air filters used in the study.
- *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified*

samples must be greater than 50% for the study. These criteria were partially met. Only five determinations were made for each matrix at each fortification level. Field fortification results were provided and all were greater than 50%.

- *If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples.* This criterion was met. A storage stability test was conducted, however, the final results for the inner and outer dosimeters were not reported in this Study Report. It was stated that they would be included in an appendix to this report.

- *A personal monitoring pump capable of producing an airflow of at least 2 L/min. should be used and its batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging. Airflow should be measured at the beginning and end of the exposure period.* This criterion was met. Personal monitoring pumps were calibrated to 2 L/min and airflow was measured at the beginning and end of the exposure period.

- *Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis.* This criterion was met. The study utilized personal air samplers containing Gelman filters and air tubes.

- *If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* It is unclear if this criterion was met. The Study Report does not provide information on how the filters and tubes were stored.

- *Personal monitors should be arranged with the intake tube positioned downward, as near as possible to the nose level of the subject.* This criterion was met.

- *Field calibration of personal monitors should be performed at the beginning and end of the exposure period.* This criterion was met.

- *Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same weather conditions.* These criteria were met. The study author stated that both field fortified samples and field blanks were collected.

- *Respirator pads should be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. The pads should be stored in a chest containing ice until they are returned to the laboratory, where they should be stored in a freezer prior to extraction.* This criterion was not applicable to this study.

- *Field data should be documented, including chemical information, area description, weather conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were met.

- *Analysis methods should be documented and appropriate.* This criterion was met.

- *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was not met.

875.1200

- *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.* This criterion was partially met. Pilots wore the personal protective equipment specified on the product labeling. However, mixers/loaders in the study wore either a chemical-resistant apron or a Tyvek coverall over the "outer" dosimeter and also wore chemical-resistant footwear – in calculating potential dermal exposures to mixers/loaders, the study author does not factor in this additional personal protective equipment, which exceeds the requirements of the product labeling;

- *Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require preextraction to remove substances that interfere*

with residue analysis. This should be determined prior to using the pads in exposure tests . This criterion probably was met through the use of 100% cotton dosimeters in this study.

- *Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would interfere with analysis and be preextracted if necessary.* This criterion is not applicable to this study.
-
- *A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing.* This criterion was partially met through the use of the whole body outer dosimeters in this study. However, the inner dosimeter covered the torso area only, and therefore did not allow determination of actual penetration of work clothing to arms and legs. Also, mixers/loaders wore either a chemical-resistant apron or Tyvek coveralls over the outer dosimeter – limiting the amount of residue on the outer dosimeter.

- *If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion probably was met. Dosimeters were stored in aluminum foil and placed in zip lock plastic bags.

- *Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present.* This criterion was not met. The study author made no mention of preliminary hand rinse studies.

- *The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm^2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity).* It is unknown if this criterion was met. The limit of quantitation was provided as ug/sample.

- *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were partially met. Only five determinations were made for each matrix at each fortification level. Field fortification results were provided and all were greater than 50%.

- *If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar weather conditions and for the same time period as those expected during field studies.* This criterion was partially met. A storage stability test was conducted, however, the final results for the inner and outer dosimeters were not reported in this Study Report. It was stated that they would be included in an appendix to this report.

- *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was met. The study author corrected data for all field recoveries less than 100%.

- *Field data should be documented, including chemical information, area description, weather conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were met.

- *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was not met.

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R100649

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PC Code:	**028201**
HED File Code	**12000 Exposure Reviews**
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