1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 31, 2006

Memorandum

SUBJECT: HED's Review of *Exposure of Workers During the Mixing and Loading of ORTHENE® 97 – a Pelletized Formulation of Acephate.* MRID 455970-01, DP Barcode D281186, [TAF Study No. 1-18]
PC Code: 103301

FROM: Matthew Lloyd, Industrial Hygienist
Reregistration Branch 1
Health Effects Division (7509C)

THROUGH: Whang Phang, Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Susan Bartow, Chemical Review Manager
Special Review Branch
Special Review and Reregistration Division (7508C)
And
Meridith Law, Branch Chief
IRB
Registration Division (7505C)

This document summarizes the findings of the study "Exposure of Workers During the Mixing and Loading of ORTHENE® 97 – a Pelletized Formulation of Acephate." A primary evaluation of the protocol and guideline compliance was performed by Versar Inc. (10/31/05), under supervision of HED, and the review is attached. It has undergone secondary review in HED and reflects current Agency policy.

APR 1 1 2006

Introduction

This report contains the review of a worker mixer/loader exposure study using three different mixing/loading systems for acephate, as submitted by Valent USA Corporation. The requirements for this worker dermal and inhalation exposure study are specified by the EPA's OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 and 875.1300. The results of this study are of sufficient scientific quality to be used to determine worker mixer/loader exposure.

Summary

Acephate is a highly water soluble organophosphorus pesticide and is used on a variety of crops to control a number of insect pests. The purpose of this study was to determine dermal and inhalation exposure to agricultural workers performing mixing and loading of acephate formulated as a pelletized granular (ORTHENE® 97). Dermal exposure was assessed using whole-body dosimetry, hand washes, and face/neck wipes. The air concentration of acephate in the workers breathing zone was also measured by drawing air from the workers breathing zones through an inhalation tube containing a quartz filter and chemical adsorbent that to trap acephate.

The field phase portion of the study took place at two cotton growing regions in southern California (El Centro & Blythe) and one in western Arizona (Stanfield). Fifteen experienced agricultural workers participated in the study, yielding 15 replicates. Each worker wore label specific PPE (long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves). The workers mixed and loaded enough product to treat 100 acres of cotton for aerial application. Each worker handled 100.49 lb product (97.4 lb ai). Exposure times varied between 23 and 89 minutes.

Three sites were selected to obtain a variety of mixing and loading equipment that would represent typical equipment for U.S. agriculture. Some of the relevant site characteristics include:

- **El Centro, CA:** Mobile mixing system; flat-bed truck fitted with 300 gallon tank with mechanical agitation; opening for the mix tank located just below waist level for the workers
- **Blythe, CA:** fixed mixing system on steel platform; two 240 gallon tanks with bypass agitation; opening for the mix tank located at ankle level for the workers
- **Stanfield, AZ:** fixed mixing system; 300 gallon uncovered tank with bypass agitation; opening for the mix tank located at chest level for the workers

Versar calculated all exposures in μg/lb ai handled. The exposures were adjusted for average field fortification recoveries less than 90%. Recovery adjustment factors were based on the average *of each site* by fortification level and matrix. The adjustment factor for the field fortification level closest to the raw value was used. The midpoint between successive fortification levels was selected as the breakpoint for applying the recovery adjustment factor. The Registrant calculated dermal exposure in μg and inhalation exposure in μg/lb ai handled. The Registrant corrected the raw field data for average field fortification recoveries of *all site combined* and corrected the raw data for all recoveries, even those greater than 100%. Additionally, the Registrant did not take the worker's inhalation rate into account when calculating the inhalation exposure. The Registrant used a 25 L/min breathing rate to calculate total inhalation exposure. Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities (mixer/loader handling containers < 50 lbs) to calculate inhalation exposure.

The overall geometric mean for total dermal exposure (inner dosimeter, hands, and face/neck) is 4.5 ug/lb ai handled (for all 3 sites combined), and 4.2 ug/lb ai handled, 2.0 ug/lb ai handled, and 11.0 ug/lb ai handled for El Centro (CA), Blythe (CA), and Stanfield (AZ), respectively.

Inhalation exposures were measured for each worker using a personal air sampling pump placed near each worker's breathing zone from the amount of acephate found in the OVS tubes. The overall geometric mean for inhalation exposures at all sites was 0.026 ug/lb ai handled. The geometric mean for inhalation exposures at each site were 0.011 ug/lb ai handled, 0.02 ug/lb ai handled, and 0.082 ug/lb ai handled at El Centro (CA), Blythe (CA), and Stanfield (AZ) respectively.

The overall arithmetic mean for inhalation exposures at al sites was 0.061 ug/lb ai handled. The geometric mean for inhalation exposures at each site were 0.015 ug/lb ai handled, 0.031 ug/lb ai handled, and 0.137 ug/lb ai handled at El Centro (CA), Blythe (CA), and Stanfield (AZ) respectively.

The slurry tank opening closest to the workers breathing zone could explain the higher measured air concentrations since pouring the product occurred closest to the workers breathing zones at the Stanfield, AZ test site. The values (in terms of ug/lb ai handled) for inhalation exposure range from 0.004 to 0.41 ug/lb ai handled. There were two replicates from the inhalation exposure portion of the study that displayed high exposures compared to the other replicates. Both samples were from the Stanfield, AZ study. The Study Report suggests that the location of the mixing tank (chest level) at this site may have been a factor in these results, as no other remarkable differences could be found in their work activities.

The data presented in this study met the majority of the pertinent Group A, 875.1100 and 875.1300 guidelines. However, the Agency notes the following issues of concern: (1) Trapping efficiency, breakthough, and stability tests were not reported in the Study Report (2) the registrant corrected all raw data for average recoveries which ranged from 76.5 to 110%. *The data presented in this review for recoveries which were <90% and used average recoveries for each site rather than all sites combined.* (3) the personal monitoring pump was calibrated to an airflow of 1.5 L/min (4) less than seven determinations for each laboratory fortification level were made for the face/neck, hand wash, and inhalation matrices.

Note:

This pelletized formulation of acephate contains significantly less dust than the current soluble powder formulations. The unit exposure figures for PHED Scenario Number 2 are based on "traditional", older granular formulations. Dustiness is the primary cause of exposure for granular formulations. The study data indicate that this particular formulation indicates approximately a 98% reduction in dustiness from the PHED Scenario Number 2 inhalation unit exposure value.

Table 1. Total Dermal Exposure for All Sites (ug/lb ai handled)

Replicate	Inner Dosimeter Residue (ug)	Face/Neck Residue (ug)	Total Hand Washes Residue (ug)[h]	Total Dermal Residue (ug)[a]	lb ai handled	Total Dermal Exposure[b] (ug/lb ai handled)
El Centro, CA						
1	89[c]	3.2	7.56	100	97.4	1.02
2	329[c]	8.21	31.9	369	97.4	3.79
3	720[c]	7.19	2.61	730	97.4	7.49
4	291[c]	2.47	8.36	302	97.4	3.10
5	1328[c]	5.6	5.92	1340	97.4	13.75
Arithmetic Mean						5.8
Geometric Mean						4.2
Standard Deviation						5.0
Blythe, CA						
6	49.6[d]	1.03	0.5[e]	51	97.4	0.52
7	170[d]	2.93	5.08	178	97.4	1.83
8	88[d]	0.5[e]	167.83[f]	256	97.4	2.63
9	225[d]	5.05	18.5	249	97.4	2.55
10	452[d]	1.07	1.25	454	97.4	4.66
Arithmetic Mean						2.4
Geometric Mean						2.0
Standard Deviation						1.5
Stanfield, AZ						
11	478[g]	13.6	27.8	519	97.4	5.33
12	17246[g]	72.3	215.5[h]	17534	97.4	180.02
13	287[g]	88.5	3.6	379	97.4	3.89
14	622[g]	13.8	181.8[h]	818	97.4	8.39
15	359[g]	6.5	131.3[h]	497	97.4	5.10
Arithmetic Mean						40.5
Geometric Mean						11.0
Standard Deviation						78.0
Overall Arithmetic Mean						16.3
Overall Arithmetic Standard Deviation						45.4
Overall Geometric Mean						4.5
Overall Geometric Standard Deviation						3.70

a Total Dermal Residue = inner dosimeter + hand residues +face/neck residues
b Total Dermal Exposure (ug/lb ai handled) = Total Dermal Residue (ug) / lb ai handled
c All inner dosimeter residues corrected for field fortification recovery
(<52.5 ug = 89.3%, 52.5 to 550 ug = 78.9%, and >550 ug = 77.0%)
d All inner dosimeter residues corrected for field fortification recovery
(<52.5 ug = 84.3%, 52.5 to 550 ug = 77.6%, and >550 ug = 76.0%)
e Value was below the MQL (1.00 ug/sample), there 0.5 MQL was used in the calculations
f Hand wash residue for replicate 8 was corrected for field fortification recovery of 85.8%.
g All inner dosimeter residues corrected for field fortification recovery
(52.5 to 550 ug = 81.9%, and >550 ug = 80.7%)
h Hand wash residue for replicates 12, 14 and 15 corrected for field fortification recovery of 89.1%.

Table 2. Potential Inhalation Exposure for All Sites, Based on Residue Levels Found in OVS Tubes

Replicate	Residue (ug)	Replicate Length (min)	Flow Rate (L/min)	Con-centration (ug/m3)	lb ai handled	Respiration Rate (m3/min)	Inhalation Exposure (ug/lb ai handled)
El Centro, CA							
1	0.0303	52	1.469	0.397	97.4	0.0167	0.00354
2	0.1085	48	1.478	1.529	97.4	0.0167	0.01259
3	0.0482	51	1.477	0.640	97.4	0.0167	0.00560
4	0.173	37	1.48	3.159	97.4	0.0167	0.02004
5	0.301	54	1.485	3.754	97.4	0.0167	0.03475
Arithmetic Mean							0.015
Arithmetic Standard Deviation							0.013
Geometric Mean							0.011
Geometric Standard Deviation							2.53
Blythe, CA							
6	0.0343	48	1.492	0.479	97.4	0.0167	0.00394
7	0.602	81	1.492	4.981	97.4	0.0167	0.06918
8	0.0754	59	1.501	0.851	97.4	0.0167	0.00861
9	0.385	89	1.497	2.890	97.4	0.0167	0.04410
10	0.257	73	1.512	2.328	97.4	0.0167	0.02914
Arithmetic Mean							0.031
Arithmetic Standard Deviation							0.027
Geometric Mean							0.020
Geometric Standard Deviation							3.28
Stanfield, CA							
11	1.352	27	1.501	33.360	97.4	0.0167	0.15444
12	3.562	31	1.495	76.858	97.4	0.0167	0.40852
13	0.404	23	1.513	11.610	97.4	0.0167	0.04578
14	0.437	31	1.495	9.429	97.4	0.0167	0.05012
15	0.2227	29	1.495	5.137	97.4	0.0167	0.02554
Arithmetic Mean							0.137
Arithmetic Standard Deviation							0.160
Geometric Mean							0.082
Geometric Standard Deviation							3.01
Overall Arithmetic Mean							0.061
Overall Arithmetic Standard Deviation							0.103
Overall Geometric Mean							0.026
Overall Geometric Standard Deviation							3.60

a Concentration ($\mu g/m^3$) = [(Residue (μg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (μg/lb ai handled) = [(Concentration ($\mu g/m^3$) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

d Residues in/on resin value was below the MQL (0.0200 μg/sample), therefore ½ MQL was added to residues in/on quartz filter value in calculations of total residues.

Reviewer: Amanda Jacob / Karie Riley **Date** October 31, 2005

STUDY TYPE: Mixer/Loader Passive Dosimetry Study Using Inner Whole Body Dosimetry, Face/Neck Wipes, Hand Washes and Personal Air Sampling

TEST MATERIAL: ORTHENE® 97 is a pelletized formulation containing 96.9% the active ingredient, acephate.

SYNONYMS: Ortho 12420; O,S-dimethyl acetylphosphoramidothioate; O,S- dimethyl acetylphosphoramidothioate; Acephate; Acephate ; Acetamidophos; Acetylphosphoramidothioic acid O,S-dimethyl ester; Asataf; Dimethyl acetylphosphoramidothioate; Kitron; Orthene; Orthene-755; Ortran; Phosphoramidothioic acid, N-acetyl-, O,S-dimethyl ester; CAS # 30560-19-1.

CITATION: Author: Eric D. Bruce-Data Analysis, Tami I. Belcher-Study Director, Leslie D. Dobbs-Principal Analytical Investigator

Title: *Exposure of Workers During the Mixing and Loading of* ORTHENE® 97 - a Pelletized Formulation of Acephate

Report Date: January 28, 2002

Performing Laboratory: Excel Research Services, Inc.
3201 W. Dakota Avenue, Suite 110
Fresno, California 93722

Identifying Codes: Laboratory Project Identification ERS20037;
MRID 455970-01

SPONSOR: Valent USA Corporation
1333 N. California Blvd., Ste. 600
Walnut Creek, CA 94596

EXECUTIVE SUMMARY:

The objective of this study was to determine the dermal and inhalation exposure of experienced agricultural workers performing mixing and loading of acephate, formulated as ORTHENE® 97. ORTHENE® 97 is a pelletized formulation containing 96.9% of the active ingredient, acephate. The field phase of the study was conducted in August of 2001 at test sites located in cotton-growing regions of the Imperial Valley in southern California (2 sites) and in western Arizona (1 site).

A total of 15 experienced workers participated in the study resulting in 15 completed replicates. Workers wore long-sleeved shirt, long pants, shoes and socks. Workers also wore Personal Protective Equipment (PPE) specified on the product label, which included chemical resistant (CR) gloves. Each worker mixed and loaded enough product to treat 100 acres of cotton by air at a rate of 1.0 lb. product per acre. Overall, each worker handled 100.49 lb product (97.4 lb ai). Exposure periods lasted approximately 23 to 89 minutes.

Dermal exposure was estimated by measuring residues on or in inner whole-body dosimeters, face/neck wipes, and hand washes. Inhalation exposure was monitored using an OSHA Versatile Sampler (OVS) tube containing a glass quartz filter and XAD-2 adsorbent. The tube was attached to an air sampling pump calibrated to deliver an air flow rate of approximately 1.5 liters per minute (LPM). Inhalation exposures were calculated from the breathing-zone air concentrations determined from the amount of acephate found in the OVS tubes.

Versar calculated all exposures in μg/lb ai handled. The exposures were adjusted for average field fortification recoveries less than 90%. Recovery adjustment factors were based on the average of each site by fortification level and matrix. The adjustment factor for the field fortification level closest to the raw value was used. The midpoint between successive fortification levels was selected as the breakpoint for applying the recovery adjustment factor. The Registrant calculated dermal exposure in μg and inhalation exposure in μg/lb ai handled. The Registrant corrected the raw field data for average field fortification recoveries of all site combined and corrected the raw data for all recoveries, even those greater than 100%. Additionally, the Registrant did not take the worker's inhalation rate into account when calculating the inhalation exposure. Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities.

Versar used the Shapiro-Wilks test on both non-transformed and log-transformed data to test for normality and lognormality, respectively (p 0.05 and p 0.01). Based on the results, the data are assumed to be lognormally distributed and therefore, the appropriate measure of central tendency is the geometric mean.

- The overall geometric means for total dermal exposure (inner dosimeter, hands, and face/neck) were 4.15 μg/lb ai handled, 1.97 μg/lb ai handled, and 11.0 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

- The overall geometric means for face/neck exposures were 0.050 μg/lb ai handled, 0.016 μg/lb ai handled, and 0.245 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

- The overall geometric means for hand exposures were 0.081 μg/lb ai handled, 0.065 μg/lb ai handled, and 0.566 μg/lb ai handled for El Centro, CA. Blythe, CA, and Stanfield, AZ, respectively.

- The overall geometric means for inhalation exposures were 0.0112 μg/lb ai handled, 0.0198 μg/lb ai handled, and 0.0820 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

This study met most of the Group A, 875.1100 (dermal exposure) and 875.1300 (inhalation exposure) Guidelines. The major issues of concern are: (1) preliminary studies of hand rinses were not discussed in the Study Report; (2) trapping efficiency, breakthrough and stability tests were not reported in the Study Report, (3) the Registrant corrected all raw data for recoveries which ranged from 76.5 to 110%; (4) the personal monitoring pump was calibrated to an airflow of 1.5 L.min; (5) it is not certain if the intake tube of the personal

monitor was positioned downward; and (6) less than seven determination for each laboratory fortification level were made for the face/neck, hand wash, and inhalation matrices.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were 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 six exceptions: (1) calibration of aircraft was not conducted since the application itself was not an exposure activity; (2) water pH and hardness were not collected under GLP; (3) the scale used to weigh the workers was not a GLP compliant instrument; (4) grower chemical batch orders for Replicates 6 through 10 were not collected under GLP; (5) off-site historical weather data were not collected under GLP; and (6) some late data entries were made as indicated in the field logbook.

GUIDELINE OR PROTOCOL FOLLOWED: The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure), and 875.1300 (inhalation exposure). A compliance checklist is provided in Appendix A.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	ORTHENE® 97 is a pelletized formulation containing 96.9% the active ingredient, acephate.
Lot #:	VKE-001PE-12
Purity:	The purity of the test substance was 96.9% (assay report date of May 10, 2001).
CAS #(s):	30560-19-1
Other Relevant Information:	The EPA Reg. No. is 59639-91.

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

According to the Study Report, the test product was ORTHENE® 97 containing 96.9% a.i. acephate. The test product used in this study is formulated the same as what is described on the ORTHENE® 97 label (EPA Reg. No. 59639-91).

3. Packaging:

The product was packaged in laminated plastic bags containing 7.73 pounds of product per bag.

B. STUDY DESIGN

There were eight amendments to and six deviations from the study protocol. The amendments involved the following changes: (1) the protocol section V was revised to clarify that protocol amendments can be signed by

the Study Monitor acting on behalf of the Sponsor representative; (2) a) Triton-X solution was used to prepare hand
wash and face and neck wipe samples instead of Aerosol OT-75, b) the protocol section II.B was revised to include additional field fortification samples to explore the effects of time on analytical recoveries, c) the protocol section I.D.1 was revised because temperature of the test substance was recorded daily, except on holidays and weekends if personnel were not available, d) the protocol section I.D.13 was revised to allow flexibility in test substance retention location, and e) the protocol section I.D.11 was revised to accommodate freezer conditions and temperature recording practices at the analytical laboratory; (3) the protocol section II.B was revised to increase the low from 0.05 µg/sample to 0.1 µg/sample and to explore the effect of time on analytical recoveries; (4) a) the protocol section I.D.6 was revised because the quartz filter was deemed more appropriate than the glass fiber filter, b) field fortification procedures to the protocol were amended, and c) the protocol section II.A was revised to increase the LOQ from 0.01 to 0.02 µg/sample and the low method validation level from 0.05 to 0.1 µg/sample; (5) analytical methods to the protocol were amended; (6) a) the protocol section I.D.3 was revised to allow the study to be conducted in Arizona, if necessary and b) the Approved Pesticide List found in Appendix C was revised to reflect the most current Approved Pesticide List; (7) Amendment No.5, Analytical Method, CCRL MTH-030, method page 11, Section L was revised and b) Amendment No. 5, Analytical Method, CCRL MTH-030, method page 2, Section B and method page 11, Section L was revised to change hand wash aliquot volume from 50 to 25 mL; and (8) the Quality Assurance Representative was change to Vincella J. Erickson in the protocol, page 2.

The deviations involved the following: (1) Sample number ERS20037-10-ID-UA consists of one upper arm segment because one was inadvertently dropped on the ground during sample collection; (2) fortified facial wipe and hand wash samples were not placed in frozen storage within 10 minutes of fortification for certain samples because additional time was required; (3) a) field fortification occurred on paper-lined tables, not foil-lined tables and b) the actual fortification weathering time was approximately 90 minutes instead of 2 hours; (4) the temperatures were not monitored during sample storage in the field or during shipment to the analytical laboratory since dry ice was used to freeze samples which may damage temperature recording devices; (5) only sample jars were packaged with a shock insulator (bubble wrap) during shipment to the analytical laboratory; and (6) the test substance was not in a temperature controlled area during transport to the field and while in the field. The study author reported that no deviations were expected to have an adverse impact.

1. Number and type of workers and sites:

A total of 15 male workers volunteered for the study. Five workers were monitored at each of the three test sites over three consecutive days for exposure while performing mixing and loading procedures. According to the Study Report, each volunteer signed a consent form prior to the initiation of the study after being provided the study objectives, procedures, possible risks, and statement of their rights. These volunteers consisted of agricultural workers ranging in age from 18 to 60 years and with experience applying pesticides ranging from 0 to 36 years.

The test sites used in the study were located in cotton-growing regions of the Imperial Valley in southern California and in western Arizona. Site 1 was located in El Centro, California (Replicates 1 through 5). Site 2 was located in Blythe, California (Replicate 6 through 10). Site 3 was located in Stanfield, Arizona (Replicates 11 through 15).

2. Meteorology:

An on-site Campbell Scientific 21X portable weather station (Excel Weather Station No. 2) was used to monitor environmental conditions. The station monitored wind speed and direction, air temperature, and relative humidity regularly during the mixing and loading activities at each site. There were no unusual weather conditions observed during the conduct of the study. Table 1 provides meteorological data pertinent to the study. The data represents conditions during each event, not for the entire day.

Table 1. Meteorological Data at Study Site

Test Location	Date (Replicate Nos.)	Max. Temp (°C)	Min. Temp (°C)	Max. Relative Humidity (%)	Min. Relative Humidity (%)	Average Wind Speed (mph)	Average Wind Direction (compass pt)[2]
Field Validation 1	8/30/00	26	21	63	44	2.04	241
Field Validation 2	9/27/00	30	20	66	32	2.02	316
Field Validation 3	4/17/01	26	23	39	29	2-10[1]	NW[3]
Field Experiment 1	10/23/00	23	17	55	32	1.37	272
El Centro, CA	08/08/01 (Reps. 1-5)	32	26	75	49	1.96	29
Blythe, CA	08/09/01 (Reps. 6-10)	33	27	89	54	1.11	291
Stanfield, AZ	08/10/01 (Reps. 11-15)	30	26	57	45	1.17	206

[1]Wind speed recorded with a hand-held instrument
[2]Represents predominant wind direction
[3]Wind direction based on visual observation

3. Replicates:

Five replicates were conducted at each of three sites, for a total of 15 replicates. Each replicate consisted of mixing and loading the test product for aerial application. Each worker handled 100.49 lb of material (3 bags), but only mixed and loaded 100 lb of material, the required amount to treat 100 acres of cotton at the maximum use rate of 1.0 pound product per acre. The mixing and loading process took from 23 to 89 minutes (reflecting the time when the air sampling pump was turned on and off). According to the Study Report, the large range is due to the fact that different size airplane tanks were used and most workers had to sit and wait for the plane to apply one load of product and return again so that same worker could complete the loading process.

4. Protective clothing:

Workers wore cotton, whole-body inner dosimeters (long underwear) under long pants and long-sleeved shirts, all of which were provided by the researchers. The outer clothing consisted of a blue, 65% polyester and 35% cotton-blend long-sleeved shirt and tan, 65% polyester and 35% cotton poplin blend long pants that fit

appropriately. The shirt was tucked into the pants. As required by the product label, workers wore gloves while mixing and loading the product. The gloves were 100% natural latex, chemical resistant type gloves, 13 in. in length and 0.029 mil thickness. Workers were also required to wear their own shoes and socks. In addition, most workers chose to wear a hat and eye protection.

5. Mixing/loading Equipment and Method:

Mixing/loading Equipment

At Site 1, in El Centro, California a mobile mixing and loading facility parked at the end of an unpaved airstrip was used and included a 300-gallon stainless steel tank with a hinged lid, mechanical agitation (paddle), and a gasoline-powered pump system. The opening of the mixing tank was located just below waist level for the workers and a water tank supplied dilution water from an irrigation ditch.

At Site 2, in Blythe, California, the mixing facility included two 240-gallon stainless steel tanks with bypass agitation and a gasoline-powered engine hooked to a pump used to transfer spray solution to the plane. The mixing tanks were located below a steel platform that the workers walked on and under the overhang of the roof of a building at the end of a concrete airstrip and the tank opening was located at ankle level for the workers. Dilution water was obtained from an on-site well.

At Site 3, in Stanfield, Arizona, the mixing facility included a 300-gallon stainless steel tank with bypass agitation and an electric powered pump located at the end of a concrete airstrip. The tank was not covered, mounted on a concrete slab, and the opening was located at chest level for the workers. Dilution water was obtained from an on-site well.

Mixing/loading Method

In general, each worker obtained three full boxes of test substance (4 bags per box), plus a single bag. The boxes were opened and ORTHENE 97 bags were removed as needed. Each bag was opened by either using the integrated pull tab system or by cutting the bag just below the re-sealable zipper. Twelve of the bags were emptied entirely into a mixing tank containing half of the required circulating dilution water. Approximately one-half pound of product was removed from the thirteenth bag and the remainder was added to the mixing tank. After all the test substance was added to the tank, the remainder of the water was added. In total, 100 pounds of product were dissolved into the spray mixture which treats 100 acres of cotton at the maximum use rate of 1.0 pound product per acre. Each worker prepared and loaded 500 gallons of spray mixture, which required one to three loads depending on the size of the aircraft's spray tank and the commercial grower's batch order request. Multiple loads were required for Replicates 1 through 10 and a single load for Replicates 11 through 15. The fully diluted spray mixture was then pumped into fixed wing aircraft for application to cotton. The handling procedure also included disposal of the empty bags by placing them in a plastic garbage bag and tying the bag for disposal.

Additional products were added to some tank mix slurries, as required by the cotton grower's pest control needs. Most of the additional products were added by other workers that were not being monitored.

6. Application Rate:

Each worker was asked to mix and load enough product to treat 100 acres of cotton by air at a rate of 1.0 lb. product per acre. This is the maximum use rate on the ORTHENE® 97 label. Overall, workers handled 100.49 pounds of product (97.4 lb ai).

7. Exposure monitoring methodology:

Inner Dermal Dosimeters: Inner whole body dosimeters consisted of 100% cotton, rib knitted, white, long underwear that simulated the skin. These were dry-cleaned prior to use and were worn over the worker's undergarments and directly underneath the outer clothing. At the conclusion of the monitoring period, each worker was taken to a privacy area and his shoes, socks, and outer clothing were removed with assistance from researchers. The inner-whole body dosimeter was removed and care was taken to prevent unnecessary contamination. The dosimeters were cut into the following six sections after the mixing/loading activities were completed:

1. Left/Right Lower arms (elbow to cuff)
2. Left/Right Upper arms combined (shoulder to elbow)
3. Torso-Front (above the waist)
4. Torso-Rear (above the waist)
5. Left/Right Lower legs combined (knees to cuff)
6. Left/Right Upper legs combined (waist to knee)

Individual inner dosimeter samples were wrapped in aluminum foil prior to placement in labelled, plastic bags and then placed on dry ice for storage.

Face and Neck Wipes: Prior to each work period, the face/neck area of the worker was wiped and this face/neck wipe was discarded. No samples were collected during the work period since workers did not request a break. Final samples were collected at the end of the monitoring period. The worker's face and neck (front and back) were wiped two times with cotton gauze pads (4 x 4 in., 12-ply, 100% cotton pads) that had been wetted with approximately 4 mL of 0.01% of Triton-X (surfactant) solution in distilled water. Both end-of-monitoring wipe samples from each worker were placed in a pre-labeled glass jar with a Teflon®-lined lid and placed on dry ice for storage.

Hand Washes: Prior to beginning the work activity, the workers washed their hands and the wash was discarded. No samples were collected during the work period since workers did not request a break. Final hand wash samples were collected at the end of the monitoring period after the worker had rinsed his gloves under running water and removed the gloves. Workers washed both hands in a 0.01% Triton-X solution in distilled water. Each worker placed both hands in a plastic bag containing 250 mL of the surfactant solution and washed his hands for approximately 60 seconds. The 250 mL wash was poured into a pre-labeled glass jar. The washing process was repeated with another 250 mL solution in a new plastic bag. The second 250 mL wash was added to the first wash and the glass jar was sealed with a Teflon®-lined lid and placed on dry ice for storage.

Inhalation: Air concentrations of acephate were monitored in the worker's breathing zone utilizing OVS tubes with XAD-2 adsorbent. The OVS tubes consisted of 13 mm quartz filter secured with a retaining ring, followed by two sections of XAD-2 adsorbent (consisting of 270 mg in the primary adsorbent bed and 140 mg in the backup bed, separated by a small piece of polyurethane foam). The OVS tube was held in a plastic tube holder and clipped to the worker's shirt collar. Tygon tubing attached a personal air sampling pump to the OVS tube. The air sampling pump was calibrated to an airflow rate of approximately 1.5

liters per minute with a flow meter. Pumps were connected to a new OVS tube during the calibration process, which occurred at the beginning and end of the monitoring period. At the conclusion of the monitoring period, the OVS tube was removed from the Tygon® tubing, both ends of the OVS tube were capped, and the tube was placed in a pre-labeled plastic bag. The samples were placed on dry ice for storage.

Field monitoring was conducted on August 8, 9, and 10, 2001 for the El Centro, CA, Blythe, CA, and Stanfield, AZ sites, respectively. After collection, all of the samples were placed on dry ice for storage until receipt at the analytical laboratory. All of the worker samples were received on dry ice at the laboratory on August 13, 2001. Field validations for Field Validations 1, 2, and 3 were sampled and received at the laboratory on August 30, 2000, September 27, 2000, and April 17, 2000, respectively. The field experiment was sampled and received at the laboratory on October 23, 2000. All inhalation tube samples were analyzed within 10 days of being sampled. The dermal dosimeter samples were analyzed within 34 days of being sampled. The face/neck wipes and handwash samples were analyzed within 17 and 25 days of being sampled. Upon receipt at the laboratory, the field fortification samples were analyzed immediately following the completion of analysis for that particular matrix.

8. Analytical Methodology:

Extraction method(s): Inner Dosimeters - Dermal dosimeters were extracted in acetone overnight and an aliquot of extract solution was evaporated to dryness. Acephate residues were then picked up in 0.01% polyethylene glycol (PEG) in acetone.

Face and Neck Wipes - Face/neck wipe gauze pads were extracted in acetone for 20 minutes and an aliquot of extract solution was evaporated to dryness. Acephate residues were then picked up in 0.01% PEG in acetone.

Hand Washes Aliquot of hand wash solutions were passed through an AC-2 cartridge and acephate was eluted from the cartridge with acetone. Ethyl acetate was added to the eluate and the solution was evaporated to dryness and acephate residues were picked up in 0.01% PEG in acetone.

OVS Tubes – OVS tubes were separated into two samples: the quartz filter with the retainer ring and both sections of adsorbent with the foam separator. During the methods validation, it was determined that acephate did not break through the first adsorbent bed (even at levels above what was measured in the field samples), so both resin sections from study samples were analyzed together. Acephate was extracted from each sample in acetone for 2 hours and an aliquot of extract solution was evaporated to dryness. Acephate residues were picked up in 0.01% PEG in acetone.

Detection method(s): All final extract solutions were analyzed by gas chromatography (GC) with a flame photometric detector (FPD) in phosphorous mode using method CCRL-MTH-30. If necessary, further dilution of the final solutions was made so that the acephate residue level would be within the range of analytical standards run concurrently with the worker samples. Table 2 provides a summary of the chromatographic conditions.

Table 2. Summary of GC Operating Conditions

GC Column	Restek Rtx®-200 (30 m x 0.53 mm id x 1.00 µm film)
Injector Temperature	Direct injection - 250 °C On-column injection – Oven tracking, runs 3° C higher than the oven temperature
Detector Temperature	280 °C
Gas Flow Rates	Helium (column) ~10 mL/min Helium (makeup) ~17 mL/min Septum Purge ~1.5 mL/min
Temperature	Initial Oven Temperature = 120 °C at 0.0 min Rate A = 20 °C/min Final Temperature A = 250 °C at 4.0 min Run Time = 10.5 min
Retention Time	~4.0 min
Injection Volume	1 µL (On-column Injection) 2 µL (Direct Injection)

Method validation: The analytical method CCRL-MTH-030 was used in this study. Prior to analysis of field samples, laboratory method validations were conducted to determine the efficiency of the method used for the analysis of acephate residues on worker exposure sampling media and field validations were also conducted to evaluate the recovery of acephate under simulated field conditions. Laboratory fortification and control samples were analyzed concurrent with each analytical set.

For the laboratory method validation results, the overall average recovery for the dermal dosimeter, face/neck wipes, and hand wash were 100%, 96.1%. and 98.0%, respectively. Overall average recoveries were 114% for the OVS Tube resin, 101% for the OVS tube glass filter and o-ring, and 99.0% for the OVS tube quartz filter and o-ring. The Study Report states that the analytical recoveries for each matrix were within the generally acceptable range of 70% to 120% recovery.

For the field method validation results, the overall average recovery for the dermal dosimeter, face/neck wipes, and hand wash were 89%, 93.4%, and 95.4%, respectively. Overall average recoveries were 76.7% for the OVS Tube with glass filter 91.8% for the OVS Tube with quartz filter. The Study Report states that the recoveries are all well above the minimum acceptable recovery of 50% specified in OPPTS testing guidelines.

The minimum quantifiable levels (MQLs) were 1.00 µg/sample for the dermal dosimeter, face/neck wipe, hand wash samples and 0.0200 µg/sample for the OVS tube samples.

Instrument performance and calibration: Calibration standards were injected every 2 to 3 sample injections, as well as at the beginning and end of the injection sequence. Five

concentrations were injected with each analytical set. Correlation coefficients were all greater than 0.999.

Quantification: Residues were quantified using a quadratic regression function by ChromPerfect® Chromatography Software. The concentration of acephate detected was interpolated from the standard calibration curve.

9. Quality Control:

Lab Recovery: Laboratory fortification and control samples were analyzed concurrent with each analytical set.

Each sample set included one laboratory control and two laboratory fortification samples. Two or three fortification levels were used per matrix, with 2 to 12 determinations per fortification level. The concurrent laboratory results were similar to those obtained during the method validation. All laboratory controls for each sample matrix were less than the MQL. Individual acephate laboratory recovery results for each matrix, including pertinent statistics for each fortification level, are provided in the Study Report (pages 296 through 301). Table 3 provides a brief summary of the overall average recoveries for each matrix.

Table 3. Summary of Laboratory Fortified Sample Recoveries for All Matrices

Matrix	Fortification Levels	Number of samples	Overall Average (%)	Standard Deviation (%)
Dermal Dosimeters	Low - 1.00 µg/sample High - 1,000 or 8,000 µg/sample	24	92.3	8.05
Face/Neck Wipes	Low -1.00 µg/sample High - 1,000 µg/sample	12	97.4	17.9
Hand Washes	Low -1.00 µg/ sample High - 1,000 µg/ sample	12	87.4	9.75
OVS Tubes- Resin	Low - 0.0200µg/ sample High - 1.0 or 10.0 µg/sample	12	95.5	7.79
OVS Tubes- Quartz Filter and O-ring	Low - 0.0200µg/ sample High - 1.0 or 10.0 µg/sample	12	97.6	6.2

Field blanks: One sample of each matrix was prepared for use as an unfortified control sample. The samples were set up and exposed similar to the methods described below for fortified samples. The exposed controls were located upwind from the field fortification samples. No residues were detected in the control samples above the MQL.

Field recovery: Triplicate field fortification samples were fortified on each day of exposure monitoring at three fortification rates. Dermal dosimeters, face/neck wipes, and handwash matrices were

fortified at 15.00 μg/sample (low level), 100 μg/sample (mid level) and 1000 μg/sample (high level). The inhalation tubes were fortified 0.100 μg/sample (low level), 0.500 μg/sample (mid level), and 1.00 μg/sample (high level).

The inner whole-body dosimeters and OVS tubes were exposed to ambient conditions for the full exposure monitoring period in a location upwind of the monitoring area. Fortified dosimeter samples were covered with cloth similar to the outer clothing used by workers and the OVS tubes were connected to an operating air sampling pump during the weathering period. The field fortification weathering period was approximately 90 minutes, exceeding the maximum length of times workers were monitored. Hand wash and face/neck wipe fortification samples were placed in storage within 18 minutes for fortification and were not weathered in the field.

Individual acephate field recovery results for each matrix, including pertinent statistics for each fortification level, are provided in the Study Report (pages 302 through 313). Table 4 provides a brief summary of the field fortification recoveries. The average field fortification recoveries per level and matrix ranged from 74.6% to 122%. No corrections were made to the field fortification samples for measured residues in laboratory or field control samples prior to calculation for field recovery.

The Registrant corrected all raw field data using the average recoveries for each fortification level of all three sites combined (range of 76.5% to 110%). Versar adjusted the raw field data using the average field fortification recoveries for each fortification level of each site separately. Additionally, Versar only corrected data when the average field fortification recoveries were below 90%. Adjustments were made based on the closest field fortification level to the raw value and the midpoint between successive fortification levels was selected as the breakpoint for applying the recovery adjustment factor.

Table 4. Field Fortification Recovery Results for Each of the Matrices.

Sample Type	Fortification Level (μg)	El Centro, CA			Blythe, CA			Stanfield, AZ		
		Average per Level (%)	Overall Average (%)	Std Dev	Average per Level (%)	Overall Average (%)	Std Dev	Average per Level (%)	Overall Average (%)	Std Dev
Dermal Dosimeters	5	89.3	81.7	6.13	84.3	79.3	4.45	90.3	84.3	4.98
	100	78.9			77.6			81.9		
	1,000	77.0			76.0			80.7		
Face/Neck Wipes	5	101	84.5	16.1	111	87.4	20.1	81.4	80.1	3.62
	100	77.8			76.4			78.8		
	1,000	74.8			74.6			80.1		
Hand Washes	5	104	89.6	12.0	98	88.2	9.06	94.4	86.7	10.5
	100	83.4			85.8			89.1		
	1,000	81.3			80.7			76.5		
OVS Tubes	0.100	96.1	105	16.6	95.9	96.5	9.33	98	97.9	6.24
	0.500	97.3			90.1			90.7		
	1.00	122			103			105		

Formulation: ORTHENE® 97 is a pelletized formulation containing 96.9% of the active ingredient, acephate (assay report date of May 10, 2001).

Tank mix: Tank mix samples were not collected.

Travel Recovery: Information on travel recovery is not provided in the Study Report.

Storage Stability: Information on storage stability is not provided in the Study Report.

10. Relevancy of Study to Proposed Use:

The study design and the proposed uses for this chemical are similar.

II. RESULTS AND CALCULATIONS:

The Registrant provided dermal exposure values expressed as μg/sample and inhalation exposure values expressed as μg/lb ai handled. The Registrant corrected the raw field data based on average field fortification recoveries from all three sites combined (ranging from 76.5 to 110%). Adjustments were made based on the closest field fortification level to the raw value. The midpoint between successive fortification levels was selected as the breakpoint for applying the recovery adjustment factor. The Registrant did not take the worker's respiratory rate into account when calculating the inhalation exposure. For those values below the MQL, the Registrant used ½ MQL in the calculations. Additionally, the Registrant did not calculate total exposure (dermal plus inhalation exposure).

Versar estimated dermal and inhalation exposure values as μg/lb ai handled. Average field fortification recoveries, calculated by fortification level and matrix from each site separately were used to adjust the field residues if the recoveries were less than 90%. The midpoint between adjacent fortification levels was selected as the breakpoint for applying the recovery adjustment factor. To calculate the inhalation exposures, Versar adjusted the flow rate of each worker by an average breathing rate of 0.0167 m^3/min for light activities. For those values below the MQL, Versar used ½ MQL in the calculations.

Versar used the Shapiro-Wilks test on both non-transformed and log-transformed data to test for normality and lognormality, respectively (tested for p 0.05 and p 0.01).These tests were conducted for total dermal exposure, hand exposure, face/neck exposure, and inhalation exposure (all expressed in terms of ug/lb ai) at each site. At the p 0.05 significance level, 3 of the 12 data sets had significant non-normality(total dermal exposure at Stanfield, AZ, CA, hand exposure at Blythe, CA and inhalation exposure at Stanfield, AZ) and 1 of the 12 data sets had significant non-log normality (total dermal exposure at Stanfield, AZ). At the p 0.01 significance level, 2 of the 12 data sets had significant non-normality (total dermal exposure at Stanfield, AZ and hand exposure at Blythe, CA), while none of the data sets had significant non-lognormality. The results of normality testing suggest that the data are lognormally distributed, therefore, the appropriate measure of central tendency is the geometric mean.

Total Dermal Exposures

Dermal exposure was estimated by measuring residues on or in inner whole-body dosimeters, face/neck wipes, and hand washes. Tables 5 through 7 provide the Versar-calculated dermal exposures for each of the three sites. Total dermal exposures ranged from 1.02 to 13.8 μg/lb ai handled for worker replicates at the El Centro, CA site, from 0.53 to 4.66 μg/lb ai handled for worker replicates at the Blythe, CA site, and from 3.89 to 180 μg/lb ai handled for worker replicates at the Stanfield, AZ site. Dermal exposure for worker 12 at the Blythe, CA site was very high. Observations of worker 12 during mixing and loading activities did not indicate any unusual practices that could lead such an increase of exposure and there were no apparent problems with the analysis of this worker's samples.

The overall geometric means for total dermal exposure were 4.15 μg/lb ai handled, 1.97 μg/lb ai handled, and 11.0 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

Hand Exposures

Versar calculated hand exposures based on hand wash solutions collected for each of the worker replicates and these are reported in Tables 8 through 10. Hand exposures ranged from 0.027 to 0.33 μg/lb ai handled for worker replicates at the El Centro, CA site, from 0.0051 (<MQL) to 1.72 μg/lb ai handled for worker replicates at the Blythe, CA site, and from 0.036 to 2.21 μg/lb ai handled for worker replicates at the Stanfield, AZ site.

The overall geometric means for hand exposures were 0.081 μg/lb ai handled, 0.065 μg/lb ai handled, and 0.566 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

Face/Neck Exposures

Versar calculated face/neck exposures based on wipes collected from each of the worker replicates. These are reported in Tables 11 through 13. Face/neck exposures ranged from 0.025 to 0.084 μg/lb ai handled for worker replicates at the El Centro site, from 0.0051 (<MQL) to 0.052 μg/lb ai handled for worker replicates at the Blythe, CA site, and from 0.066 to 0.91 μg/lb ai handled for worker replicates at the Stanfield, AZ site.

The overall geometric means for face/neck exposures were 0.050 μg/lb ai handled, 0.016 μg/lb ai handled, and 0.245 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

Inhalation Exposures

Inhalation exposures were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of acephate found in the OVS tubes. The personal monitoring pumps were set at an airflow of 1.5 L/min. The Registrant did not take the worker's inhalation rate into account when calculating the inhalation exposure. Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities.

Tables 14 through 16 provide the Versar-calculated potential inhalation exposures for all three sites. Inhalation exposures ranged from 0.00354 to 0.03475 μg/lb ai handled for worker replicates at the El Centro, CA site, from 0.00394 to 0.06918 μg/lb ai handled for worker replicates at the Blythe, CA site, and from 0.02554 to 0.40852 μg/lb ai handled for worker replicates at the Stanfield, AZ site.

The overall geometric means for inhalation exposures were 0.0112 μg/lb ai handled, 0.0198 μg/lb ai handled, and 0.0820 μg/lb ai handled for El Centro, CA, Blythe, CA, and Stanfield, AZ, respectively.

III DISCUSSION

A. LIMITATIONS OF THE STUDY:

This study met most of the Group A, 875.1100 (dermal exposure) and 875.1300 (inhalation exposure) Guidelines. The major issues of concern are: (1) preliminary studies of hand rinses were not discussed in the Study Report; (2) trapping efficiency, breakthrough and stability tests were not reported in the Study Report, (3) the Registrant corrected all raw data for average recoveries which ranged from 76.5 to 110%; (4) the personal monitoring pump was calibrated to an airflow of 1.5 L/min; (5) it is not certain if the intake tube of the personal monitor was positioned downward; and (6) less than seven determination for each laboratory fortification level were made for the face/neck, hand wash, and inhalation matrices.

B. CONCLUSIONS:

Dermal and inhalation exposure of experienced agricultural workers performing mixing and loading of acephate was determined in this study. The highest dermal and inhalation exposure was at the third site in Stanfield, AZ, the lowest dermal exposure was at the second site in Blythe, CA, and the lowest inhalation was at the first site in El Centro, CA. The Registrant stated that the location of the mixing tanks may have accounted for the differences, as the mixing tank was at ankle level at El Centro, CA, just below the waist at Blythe, CA, and at chest level at Stanfield, AZ. The lower level of the mixing tank may reduce contact between the body and pesticide packaging, with the product as it is poured into the tank, with spilled product, and with the mixed pesticide solution in the tank. According to the Registrant, dermal exposure was highest to the forearms, followed by front torso and hands.

Table 5. Total Dermal Exposure for El Centro, CA Site (μg/lb ai handled)

Replicate	Inner Dosimeter Residue[c] (μg)	Face/Neck Residue (μg)	Total Hand Washes Residue (μg)	Total Dermal Residue[a] (μg)	lb ai handled	Total Dermal Exposure[b] (μg/lb ai handled)
1	89	3.20	7.56	99	97.4	1.02
2	329	8.21	31.90	369	97.4	3.79
3	720	7.19	2.61	730	97.4	7.49
4	291	2.47	8.36	302	97.4	3.10
5	1328	5.60	5.92	1339	97.4	13.8
Arithmetic Mean						5.83
Geometric Mean						**4.15**
Standard Deviation						5.01
Coefficient of Variation (%)						85.9

a Total Dermal Residue = inner dosimeter residues + hand residues + face/neck residues

b Total Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) /lb ai handled

c All inner dosimeter residues corrected for field fortification recovery (<52.5 μg = 89.3%, 52.5 to 550 μg = 78.9%, and > 550 μg = 77.0%).

Table 6. Total Dermal Exposure for Blythe, CA Site (μg/lb ai handled)

Replicate	Inner Dosimeter Residue[d] (μg)	Face/Neck Residue (μg)	Total Hand Washes Residue (μg)	Total Dermal Residue[a] (μg)	lb ai handled	Total Dermal Exposure[b] (μg/lb ai handled)
6	49.6	1.03	0.50[c]	51	97.4	0.53
7	170	2.93	5.08	178	97.4	1.82
8	88	0.50[c]	167.83[e]	257	97.4	2.64
9	225	5.05	18.50	248	97.4	2.55
10	452	1.07	1.25	454	97.4	4.66
Arithmetic Mean						2.44
Geometric Mean						**1.97**
Standard Deviation						1.50
Coefficient of Variation (%)						61.6

a Total Dermal Residue = inner dosimeter residues + hand residues + face/neck residues

b Total Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) / lb ai handled

c Value was below the MQL (1.00 μg/sample), therefore ½ MQL was used in calculations.

d All inner dosimeter residues corrected for field fortification recovery (<52.5 μg = 84.3%, 52.5 to 550 μg = 77.6%, and >550 μg = 76.0%).

e Hand wash residue for Replicate 8 was corrected for field fortification recovery of 85.8%.

Table 7. Total Dermal Exposure for Stanfield, AZ Site (μg/lb ai handled)

Replicate	Inner Dosimeter Residue[d] (μg)	Face/Neck Residue[e] (μg)	Total Hand Washes Residue[f] (μg)	Total Dermal Residue[a] (μg)	lb ai handled	Total Dermal Exposure[b] (μg/lb ai handled)
11	478	13.6	27.8	519	97.4	5.33
12[c]	17246	72.3	215.5	17534	97.4	180
13	287	88.5	3.6	379	97.4	3.89
14	622	13.8	181.8	818	97.4	8.40
15	359	6.5	131.3	496	97.4	5.10
Arithmetic Mean						40.5
Geometric Mean						**11.0**
Standard Deviation						78.0
Coefficient of Variation (%)						192

a Total Dermal Residue = inner dosimeter residues + hand residues + face/neck residues

b Total Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) / lb ai handled

c Dermal exposure for worker 12 was very high. Observations of worker 12 during mixing and loading activities did not indicate any unusual practices that could lead such an increase of exposure and there were no apparent problems with the analysis of his samples.

d All inner dosimeter residues corrected for field fortification recovery (52.5 to 550 μg = 81.9%, and > 550 μg = 80.7%)

e Face/neck residues for Replicates 11, 14 and 15 corrected for field fortification recovery of 81.4%. Face/neck residues for Replicates 12 and 13 corrected for field fortification recovery of 78.8%.

f Hand wash residue for Replicates 12, 14, and 15 corrected for field fortification recovery of 89.1%.

Table 8. Hand Exposures For El Centro, CA Site (μg/lb ai handled) Based on Hand Washes

Replicate	Hands Residue (μg)	lb ai handled	Hand Exposure[a] (μg/lb ai handled)
1	7.56	97.4	0.078
2	31.9	97.4	0.33
3	2.61	97.4	0.027
4	8.36	97.4	0.086
5	5.92	97.4	0.061
Arithmetic Mean			0.116
Geometric Mean			**0.081**
Standard Deviation			0.121
Coefficient of Variation (%)			104.18

a Hand Exposure (μg/lb ai handled) = Hand residue (μg) /lb ai handled

Table 9. Hand Exposures For Blythe, California Site (μg/lb ai handled) Based on Hand Washes

Replicate	Hands Residue (μg)	lb ai handled	Hand Exposure[a] (μg/lb ai handled)
6	0.5[b]	97.4	0.0051
7	5.08	97.4	0.052
8	167.8[c]	97.4	1.72
9	18.5	97.4	0.19
10	1.3	97.4	0.013
Arithmetic Mean			0.397
Geometric Mean			**0.065**
Standard Deviation			0.745
Coefficient of Variation (%)			188

a Hand Exposure (μg/lb ai handled) = Hand residue (μg) / lb ai handled

b Value was below the MQL (1.00 μg/sample), therefore ½ MQL was used in calculations.

c Residue corrected for field fortification recovery of 85.8%.

Table 10. Hand Exposures For Stanfield, AZ Site (μg/lb ai handled) Based on Hand Washes

Replicate	Hands Residue (μg)	lb ai handled	Hand Exposure[a] (μg/lb ai handled)
11	27.8	97.4	0.29
12	215.5[b]	97.4	2.21
13	3.55	97.4	0.036
14	181.8[b]	97.4	1.87
15	131.3[b]	97.4	1.35
Arithmetic Mean			1.150
Geometric Mean			**0.566**
Standard Deviation			0.958
Coefficient of Variation (%)			83.3

a Hand Exposure (μg/lb ai handled) = Hand residue (μg) /lb ai handled

b Residue corrected for field fortification recovery of 89.1%.

Table 11 Face/Neck Exposures For El Centro, CA Site (μg/lb ai handled) Based on Face/Neck Wipes

Replicate	Face/Neck Residue (μg)	lb ai handled	Face/Neck Exposure[a] (μg/lb ai handled)
1	3.20	97.4	0.033
2	8.21	97.4	0.084
3	7.19	97.4	0.074
4	2.47	97.4	0.025
5	5.60	97.4	0.057
Arithmetic Mean			0.055
Geometric Mean			**0.050**
Standard Deviation			0.025
Coefficient of Variation (%)			46.44

a Face/Neck Exposure (μg/lb ai handled) = Face/neck residue (μg) /lb ai handled

Table 12. Face/Neck Exposures For Blythe, CA Site (μg/lb ai handled) Based on Face/Neck Wipes

Replicate	Face/Neck Residue (μg)	lb ai handled	Face/Neck Exposure[a] (μg/lb ai handled)
6	1.03	97.4	0.011
7	2.93	97.4	0.030
8	0.5[b]	97.4	0.0051
9	5.05	97.4	0.052
10	1.07	97.4	0.011
Arithmetic Mean			0.022
Geometric Mean			**0.016**
Standard Deviation			0.019
Coefficient of Variation (%)			88.90

a Face/Neck Exposure (μg/lb ai handled) = Face/neck residue (μg) / lb ai handled

b Value was below the MQL (1.00 μg/sample), therefore ½ mQL was used in calculations.

Table 13. Face/Neck Exposures For Stanfield, AZ Site (μg/lb ai handled) Based on Face/Neck Wipes

Replicate	Face/Neck Residue [b] (μg)	lb ai handled	Face/Neck Exposure[a] (μg/lb ai handled)
11	13.6	97.4	0.14
12	72.3	97.4	0.74
13	88.5	97.4	0.91
14	13.8	97.4	0.14
15	6.47	97.4	0.066
Arithmetic Mean			0.400
Geometric Mean			**0.245**
Standard Deviation			0.394
Coefficient of Variation (%)			98.6

a Face/Neck Exposure (μg/lb ai handled) = Face/neck residue (μg) / lb ai handled

b Face/neck residues for Replicates 11, 14 and 15 corrected for field fortification recovery of 81.4%. Face/neck residues for Replicates 12 and 13 corrected for field fortification recovery of 78.8%.

Table 14. Potential Inhalation Exposure For El Centro, CA Site, Based on Residue Levels Found in OVS Tubes

Replicate	Residue (μg)	Replicate length (min)	Flow Rate (L/min)	Concentration[a] (μg/m^3)	lb ai handled	Respiration Rate[b] (m^3/min)	Inhalation Exposure[c] (μg/lb ai handled)
1	0.0303[d]	52	1.469	0.3967	97.4	0.0167	0.00354
2	0.1085[d]	48	1.478	1.5294	97.4	0.0167	0.01259
3	0.0482[d]	51	1.477	0.6399	97.4	0.0167	0.0056
4	0.1730[d]	37	1.48	3.1592	97.4	0.0167	0.02004
5	0.3010[d]	54	1.485	3.7536	97.4	0.0167	0.03475
Arithmetic Mean							0.0153
Geometric Mean							**0.0112**
Standard Deviation							0.0127
Coefficient of Variation (%)							82.7133

a Concentration (μg/m^3) = [(Residue (μg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (μg/lb ai handled) = [(Concentration (μg/m^3) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

d Residues in/on resin value was below the MQL (0.0200 μg/sample), therefore ½ MQL was added to residues in/on quartz filter value in calculations of total residues.

Table 15. Potential Inhalation Exposure For El Blythe, CA Site, Based on Residue Levels Found in OVS Tubes

Replicate	Residue (μg)	Replicate length (min)	Flow Rate (L/min)	Concentration[a] ($\mu g/m^3$)	lb ai handled	Respiration Rate[b] (m^3/min)	Inhalation Exposure[c] (μg/lb ai handled)
6	0.0343[d]	48	1.492	0.4789	97.4	0.0167	0.00394
7	0.6020[d]	81	1.492	4.9813	97.4	0.0167	0.06918
8	0.0754[d]	59	1.501	0.8514	97.4	0.0167	0.00861
9	0.3850[d]	89	1.497	2.8897	97.4	0.0167	0.0441
10	0.2570[d]	73	1.512	2.3284	97.4	0.0167	0.02914
Arithmetic Mean							0.0310
Geometric Mean							**0.0198**
Standard Deviation							0.0268
Coefficient of Variation (%)							86.3619

a Concentration ($\mu g/m^3$) = [(Residue (μg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (μg/lb ai handled) = [(Concentration ($\mu g/m^3$) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

d Residues in/on resin value was below the MQL (0.0200 μg/sample), therefore ½ MQL was added to residues in/on quartz filter value in calculations of total residues.

Table 16. Potential Inhalation Exposure For Stanfield, AZ Site, Based on Residue Levels Found in OVS Tubes

Replicate	Residue (μg)	Replicate length (min)	Flow Rate (L/min)	Concentration[a] ($\mu g/m^3$)	lb ai handled	Respiration Rate[b] (m^3/min)	Inhalation Exposure[c] (μg/lb ai handled)
11	1.3520	27	1.501	33.3605	97.4	0.0167	0.15444
12	3.5620	31	1.495	76.8584	97.4	0.0167	0.40852
13	0.4040	23	1.513	11.6095	97.4	0.0167	0.04578
14	0.4370[d]	31	1.495	9.4293	97.4	0.0167	0.05012
15	0.2227	29	1.495	5.1367	97.4	0.0167	0.02554
Arithmetic Mean							0.1369
Geometric Mean							**0.0820**
Standard Deviation							0.1599
Coefficient of Variation (%)							116.8443

a Concentration ($\mu g/m^3$) = [(Residue (μg))/(flow rate (L/min) x duration (min))]*1L/0.001m^3

b NAFTA recommended inhalation rate for light activities.

c Exposure (μg/lb ai handled) = [(Concentration ($\mu g/m^3$) x Respiration rate (m^3/min) x duration (min)]/lb ai handled

d Residues in/on resin value was below the MQL (0.0200 μg/sample), therefore ½ MQL was added to residues in/on quartz filter value in calculations of total residues.

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head,
Occupational Exposure Assessment Section

Date

APPENDIX A

Compliance Checklist for "Exposure of Workers During the Mixing and Loading of ORTHENE® 97 - a Pelletized Formulation of Acephate"

Compliance Checklist

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Guidelines, 875.1100 (dermal) and 875.1300 (inhalation) is critical. The itemized checklist below describes compliance with the major technical aspects of OPPTS 875.1100 and 875.1300.

Guidelines 875.1100

1. *Investigators should submit protocols for review purposes prior to the inception of the study.* It is uncertain if this criterion was met. It is not known if the protocol was submitted and reviewed by EPA. The Study Report stated that a protocol was reviewed by a Quality Assurance Representative on August 17, 2000 and approved by the Study Director on August 21, 2000 and the experimental phase started in August of 2001.

2. *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* This criterion was met.

3. *The test substance should be a typical end use product of the active ingredient.* This criterion was met.

4. *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 met.

5. *Selected sites and indoor conditions of monitoring should be appropriate to the activity.* This criterion was met.

6. *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For indoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was met. A total of 15 males were monitored, 5 each at three different sites.

7. *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate.* This criterion was met.

8. *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners.* This criterion was met.

9. *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.* This criterion was met.

10. *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* It is uncertain if this criterion was met.

11. *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 pre-extraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests.* This criterion was met through the use of the whole body inner dosimeter in this study.

12. *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 pre-extracted if necessary.* This criterion does not apply to this particular study review.

13. *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 met through the use of the whole body inner dosimeter in this study.

14. *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 does not apply to this study.

15. *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.* It is not certain if this criterion was met. The study report did not discuss this process in detail.

16. *The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity).* This criterion was met.

17. *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. For face/neck, OVS, and handwash matrices, only 2 to 6 fortified laboratory determinations were made per level. For the dermal dosimeters, 12 fortified laboratory determinations were made per level. All field fortification recoveries were greater than 50%.

18. *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 indoor conditions and for the same time period as those expected during field studies.* This criterion was met.

19. *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was partially met. The Registrant made adjustments based on the closest field fortification level and the midpoint between successive fortification levels was selected as the breakpoint for applying the recovery adjustment factor. The Registrant then corrected all of the raw data for the average recovery value (for each fortification level) based on all three sites (recoveries ranged from 76.5 to 110%). Versar corrected data only for recoveries which were <90% and used average recoveries for each site rather than all sites combined.

20. *Field data should be documented, including chemical information, area description, environmental conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* This criterion was met.

21. *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was met. A sample Chain-of-Custody was provided in the Study Report.

Guidelines 875.1300

1. *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.

2. *The analytical procedure must be capable of measuring exposure to 1 ug/hr (or less, if the toxicity of the material under study warrants greater sensitivity).* This criterion was met.

3. *A trapping efficiency test for the monitoring media chosen must be documented.* It is uncertain whether this criterion was met. Trapping efficiency testing was not mentioned in the Study Report.

4. *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.* It is uncertain whether this criterion was met. A breakthrough test was not discussed in the Study Report. However, according to the Study Report, breakthrough was not observed in the method validation test.

5. *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.* It is uncertain whether this criterion was met. Storage stability test were not mentioned in the report, however, this criterion may have been met through field fortification tests.

6. *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 partially met. The pump was calibrated to an airflow rate of approximately 1.5 L/min.

7. *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. Satisfactory fortified sample recoveries indicate the appropriate sampling media was selected.

8. *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 not certain if this criterion was met.

9. *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 mostly likely met. The intake tube was attached to the label on each subject, however, it is not certain if the intake tube was positioned downward.

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

11. *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.* This criterion was met.

12. *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 does not apply to this study.

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

13544

R125651

Chemical: Acephate

PC Code:
103301
HED File Code: 12000 Exposure Reviews
Memo Date: 3/31/2006
File ID: DPD281186
Accession #: 412-06-0193

HED Records Reference Center
7/18/2006