13544

042044

Chemical:	**Metalaxyl**
PC Code:	**113501**
HED File Code	~~**11000 Chemistry Reviews**~~ 12000 Exposure Review
Memo Date:	**02/09/2002**
File ID:	***DPD280679***
Accession Number:	**412-02-0282**

HED Records Reference Center
05/22/2002

5

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 09, 2002

Memorandum

SUBJECT: Worker exposure to Apron® flowable while treating seed commercially.

FROM: Seyed Tadayon, Chemist
Chemistry Exposure Branch
Health Effect Division (7509C)

TO: Jeff Evans, Biologist
Chemistry Exposure Branch
Health Effect Division (7509C)

DP Barcode: D280679

EPA MRID No: 43080049

Attached is a review of the operator exposure to Apron® during seed treatment for two commercial seed treatment facilities in Indiana and Iowa. This review was completed by Versar, Inc. on January 4, 2002. It has undergone secondary review in HED and has been revised to reflect Agency policies.

Executive Summary

The data collected reflecting the operator exposure during commercial seed treatment with Apron® meet most of the criteria specified in OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure), and 875.1300 (inhalation exposure).

Summary

The study was conducted at two sites: a trial using Apron® FL took place in Indiana, and three trial using Apron® 25W (water soluble bags) were conducted in Iowa. The Bunker Hill, Indiana facility cleaned and treated the seed in a three story tall building. The building was divided into two areas. The smaller of the two areas contained the bagging and sewing machinery, empty seed bags, and stacked pallets. The larger area contained the seed cleaning machinery, a chemical mixing tank, the seed treater box, and seed-holding bins. The Belle Plaine, Iowa facility utilized two independent seed treatment systems and bagging and sewing areas. These two areas were located in separate rooms at opposite ends of a building that also served as a warehouse for bagged seed. The study consisted of a total of 15 mixer/operator, bagger, and bag sewer replicates using Apron® FL and 5 mixer/operator, bagger, and bag sewer replicates using Apron® 25W(wettable powder). Each trial consisted of 3 workers monitored 5 times per work function. The duration of a work replicate was a minimum of 3.5 hours. Trials 1 through 3 used Apron® FL and Trial 4 used Apron® 25W. The bagger and bag sewer could bag approximately 625 bags of seed per hour. However, the mixer/operator could only treat around 250 bags of seed in an hour because it takes longer to treat the seed than to bag it. The average amount of active ingredient handled per replicate for the mixer/operators working with Apron® FL ranged from 6.01 kg to 8.01 kg. The mixer/operator for Trial 4 using Apron® 25W handled an average of 6.12 kg active ingredient per replicate. The average amount of active ingredient handled per replicate for the baggers and sewers working with Apron® FL ranged from 4.69 kg to 7.45 kg. The baggers and sewers for Trial 4 using Apron® 25W handled an average of 5.98 kg active ingredient per replicate. The average duration of each replicate was 3.5 hours.

In addition to wearing long-sleeved shirts and long pants, mixer/operators wore goggles, chemical resistant gloves, and a chemical resistant apron. These personal protective equipment are consistent with the Apron® labels. The bagger and bag sewer wore long-sleeved shirts and long pants. The bagger and bag sewer for Trial 1 and the mixer/operator for Trials 2 and 4 also wore dust masks.

A portable Datalynx weather station was used to collect indoor environmental conditions during the study. Temperature and relative humidity were recorded at each site during each Trial. Temperatures ranged from 47.8 °F to 78.3 °F during Trial 1, from 39.6 °F to 49.7 °F for Trials 2 and 3, and from 46.6 °F to 54.7 °F for Trial 4.

Dermal exposure was measured using 100% cotton whole-body dosimeters (long underwear), detergent handwashes, and facial wipes. Inhalation exposure was monitored using personal air-sampling pumps calibrated to 1.5 liters per minute and attached to glass-fiber filters.

Raw residue data were corrected using the field fortification recoveries. Data only corrected for field recoveries less than 90%. Results for the dosimeter field fortification samples conducted concurrently with the study (Trials 1, 2, 3, and 4) were unacceptable due to an apparent extractability problem. Therefore, a second set of field fortifications, using an aqueous solution of Apron® FL, was prepared using whole body dosimeters at both sites. The results from these additional field fortification dosimeter samples were used to correct the dosimeter residues for each of the trials. These refortification dosimeters samples had an average recovery of 68.4% for the Indiana site (used to correct residue data for Trial 1) and 73.9% for the Iowa site (used to correct residue data for Trials 2 through 4). During Trial 1, recoveries for the air filter fortification samples ranged from 0 to 68% due to the acetone melting the air filter cassettes. Corrections for the air filter residues for Trial 1 were done using the average of the overall recoveries for Trials 2 and 4. Since Trials 2 and 3 were conducted simultaneously, Trial 2 field fortification data were used to correct both Trials 2 and 3. Tables 1 and 2 represents summary of total exposure (mg/lb ai handled) for each worker on trials1,2 and 3 (Apron® FL) and trial 4 (Apron ® 25W).

Conclusions

The operator exposure during commercial seed treatment study completed in support of the regulatory requirements met most of the series 875 Group A: Guidelines, 875.1300 (inhalation), and 875.1100 (dermal).

The overall average dermal exposure to Apron® FL was greatest for the mixer/operator followed by the bag sewer and the overall average inhalation exposure was greatest for the bag sewer followed by the mixer/operator. Overall average dermal exposure to Apron® 25W was greatest for the mixer/operator, and bagger, while the overall average inhalation exposure was greatest for the mixer/operator followed by the sewer. The use of wettable powder in water soluble bags resulted in greater average inhalation exposures to the mixer/operator than the use of the flowable formulation due to dust on the outside of the foil bags containing the water soluble bags, dust in the mixing tank, and dust arising when the compound was scraped off the mixing paddles.

Table 1.Total Exposure (mg/lb ai handled) for each Worker on Trial 1,2 and 3 (Apron® FL).

Replicates	Mixer/Operator		Bagger		Sewer	
	Dermal (mg/lb ai)	Inhalation (mg/lb ai)	Dermal (mg/lb ai)	Inhalation (mg/lb ai)	Dermal (mg/lb ai)	Inhalation (mg/lb ai)
1	1.2E-03	9.0E-04	5.2E-03	2.7E-04	1.4E-01	7.0E-03
2	3.6E-03	1.8E-04	9.9E-03	3.3E-03	4.8E-02	4.2E-02
3	7.5E-03	1.8E-04	6.7E-03	7.1E-04	3.7E-02	2.8E-02
4	2.3E-03	1.8E-04	5.5E-03	1.9E-04	2.3E-02	8.9E-03
5	3.5E-02	5.9E-04	4.4E-03	2.3E-04	2.6E-02	4.8E-03
6	1.0E-01	9.3E-04	1.2E-02	3.2E-04	7.2E-03	1.1E-03
7	8.7E-02	5.3E-03	3.8E-03	2.2E-04	4.0E-03	5.8E-04
8	3.5E-02	2.3E-03	6.0E-03	2.6E-04	8.5E-04	1.6E-03
9	8.1E-02	2.2E-04	6.6E-03	1.0E-03	3.4E-03	2.5E-04
10	4.9E-02	2.8E-04	2.6E-03	2.3E-04	3.0E-03	2.3E-04
11	1.5E-02	2.2E-04	1.0E-02	3.3E-04	1.8E-03	2.6E-04
12	2.2E-02	1.6E-04	9.6E-03	2.7E-04	1.3E-02	2.7E-04
13			1.8E-02	3.6E-04	2.2E-03	3.6E-04
14	5.2E-03	2.0E-04	1.4E-02	4.3E-04	2.2E-03	3.1E-04
15			2.1E-02	2.2E-04	2.2E-03	2.2E-04
Arithmetic Mean	**3.4E-02**	9.0E-04	**9.0E-03**	5.6E-04	2.1E-02	6.3E-03
Geometric Mean	1.6E-02	**4.3E-04**	7.7E-03	3.7E-04	**7.3E-03**	1.3E-03
Median	2.2E-02	2.2E-04	6.7E-03	**2.7E-04**	4.0E-03	**5.8E-04**
Distribution Type	normal	lognormal	normal	not normal or lognormal	lognormal	not normal or lognormal

Table 2. Total Exposure (mg/lb ai handled) for Each Worker at Trial 4 (Apron® 25W).

Worker	Rep.	Inhalation Exposure (mg/lb ai handled)	Total Dermal Exposure (mg/lb ai handled)	Total Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)
Mixer/Op	1	0.00862	6.69E-02	7.55E-02	0.0353	0.0275
	2	1.18E-02	1.16E-02	2.34E-02		
	3	1.19E-03	6.67E-03	7.86E-03		
	4	5.56E-04	2.46E-02	2.51E-02		
	5	8.79E-03	0.036	4.47E-02		
Bagger	1	6.73E-03	7.72E-03	1.45E-02	0.0178	0.017
	2	3.43E-04	1.92E-02	1.96E-02		
	3	2.50E-04	1.56E-02	1.58E-02		
	4	3.08E-04	2.75E-02	2.78E-02		
	5	0.00019	1.14E-02	1.15E-02		
Sewer	1	4.33E-04	3.51E-03	3.94E-03	0.0055	0.0049
	2	4.07E-04	7.20E-03	7.61E-03		
	3	1.91E-03	6.08E-03	7.99E-03		
	4	3.20E-04	5.63E-03	5.95E-03		
	5	2.03E-04	1.79E-03	1.99E-03		

Reviewer: Teri Schaeffer/Marit Espevik **Date January 4, 2002**

STUDY TYPE: Mixer/Operator, Bagger, and Bag Sewer Passive Dosimetry Study Using Whole Body Dosimetry and Personal Air Sampling.

TEST MATERIAL: Apron® is a systemic fungicide produced by Ciba-Geigy Corp. The two formulations used in this study were: (1) an Apron® Flowable liquid formulation containing 33.3% of the active ingredient metalaxyl and (2) an Apron® 25W wettable powder in water soluble bags containing 25% of the active ingredient metalaxyl.

SYNONYMS: Metalaxyl; N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester; (CAS # 57837-19-1).

CITATION:

Authors:	Leah A. Rosenheck - Pan-Agricultural Laboratories Larissa Schuster - Pan-Agricultural Laboratories
Study Director:	Frank B. Selman - Ciba Plant Protection
Title:	*Worker Exposure to Apron® Flowable While Treating Seed Commercially.*
Report Date:	March 15, 1993
Laboratory:	Pan-Agricultural Laboratories, Inc. 32380 Avenue 10 Madera, California 93638
Identifying Codes:	Pan-Ag Study Number AE-91-512; MRID 43080049; Unpublished.

SPONSOR: Ciba Plant Protection
Ciba-Geigy Corporation
410 Swing Road
Greensboro, North Carolina 27409-8300

EXECUTIVE SUMMARY:

The purpose of this study was to determine the amount of metalaxyl residues that mixer/operators, baggers, and bag sewers are exposed to during commercial seed treatment with Apron® Flowable (FL) and Apron® 25 Wettable Powder (25W). Inhalation exposure was monitored using personal air-sampling pumps and dermal exposure was estimated using 100% cotton whole-body dosimeters, detergent handwashes, and facial wipes. This study was conducted at two test sites: one trial using Apron® FL took place in Indiana, and three trials using Apron® 25W were conducted in Iowa. Each trial consisted of 3 workers monitored 5 times per work function which resulted in a total of 15 mixer/operator, bagger, and bag sewer replicates using Apron® FL and 5 mixer/operator, bagger, and bag sewer replicates using Apron® 25W. The average amount of active ingredient handled per replicate was 5.92 kg (13.04 lbs) with amounts ranging from 0 kg to 12 kg (26.46 lbs). The average duration of each replicate was 226.47 minutes (3.77 hours).

Raw residue data were corrected using the field fortification recoveries. For the purposes of this review, Versar only corrected data for field recoveries less than 90%. The registrant provided exposure values expressed as mg/kg ai handled. However, in this review Versar has provided exposure values as mg/lb ai handled as per EPA's request. Versar's estimated inhalation exposures were as follows: for Trial 1 inhalation exposures ranged from 1.82E-04 mg/lb ai handled (mixer/operator) to 4.15E-02 mg/lb ai handled (bag sewer); for Trial 2, inhalation exposures ranged from 2.19E-04 mg/lb ai handled (bagger) to 5.29E-03 mg/lb ai handled (mixer/operator); for Trial 3, inhalation exposures ranged from 1.56E-04 mg/lb ai handled (mixer/operator) to 4.32E-04 mg/lb ai handled (bagger): and for Trial 4, inhalation exposures ranged from 1.90E-04 mg/lb ai handled (bagger) to 1.18E-02 mg/lb ai handled (mixer/operator).

Dermal exposures were estimated for each replicate as the total amount of metalaxyl residues for all dermal measures (total dosimeter adjusted for feet, handwashes, and face/neck wipes). The geometric mean total dermal exposures for each worker type for Trial 1 were as follows: mixer/operator = 4.83E-03 mg/lb ai handled; bagger = 6.09E-03 mg/lb ai handled; and bag sewer = 4.34E-02 mg/lb ai handled. The geometric mean total dermal exposures for each worker type for Trial 2 were as follows: mixer/operator = 6.52E-02 mg/lb ai handled; bagger = 5.43E-03 mg/lb ai handled; and bag sewer = 3.01E-03 mg/lb ai handled. The geometric mean total dermal exposures for each worker type for Trial 3 were as follows: mixer/operator = 1.19E-02 mg/lb ai handled; bagger = 1.38E-02 mg/lb ai handled; and bag sewer = 3.00E-03 mg/lb ai handled. The geometric mean total dermal exposures for each worker type for Trial 4 were as follows: mixer/operator = 2.15E-02 mg/lb ai handled; bagger = 1.48E-02 mg/lb ai handled; and bag sewer = 4.34E-03 mg/lb ai handled.

Total exposure estimates were calculated by taking the sum of all exposure routes (total dermal and inhalation). The geometric mean total exposures for each worker type for Trial 1 were as follows: mixer/operator = 5.58 E-03 mg/lb ai handled; baggers = 6.77E-03 mg/lb ai handled; and bag sewers = 6.12E-02 mg/lb ai handled. The geometric mean total exposures for each worker type for Trial 2 were as follows: mixer/operator = 6.71E-02 mg/lb ai handled; baggers = 5.83E-03 mg/lb ai handled; and bag sewers = 4.03E-03 mg/lb ai handled. The geometric mean total exposures for each worker type for Trial 3 were as follows: mixer/operator = 1.21E-02 mg/lb ai handled; baggers = 1.42E-02 mg/lb ai handled; and bag sewers = 3.34E-03 mg/lb ai handled. The geometric mean total exposures for each worker type for Trial 4 were as follows: mixer/operator = 2.75E-02 mg/lb ai handled; baggers = 1.70E-02 mg/lb ai handled; and bag sewers = 4.90E-03 mg/lb ai handled.

According to both the Registrant's and Versar's calculations, the overall average dermal exposure to Apron® FL was greatest for the mixer/operator followed by the bag sewer and the overall average inhalation exposure was greatest for the bag sewer followed by the mixer/operator. Overall average dermal exposure to Apron® 25W was greatest for the mixer/operator, and bagger, while the overall average inhalation exposure was greatest for the mixer/operator followed by the sewer.

This study met most of the Series 875.1100 and 875.1300 Guidelines. The major issues of concern are: (1) the study was performed at only two test sites; (2) analysis dates were not provided for any of the samples in this study in order to verify storage stability results; (3) there was an insufficient number of replicates for each Method Validation fortification level for each medium; (4) the personal monitoring pumps were calibrated at an airflow of 1.5 L/min. instead of 2 L/min.; (5) overall field fortification recoveries per matrix were used to correct data instead of average field fortification recoveries for each level which corresponded to the residue concentration found; and (6) storage stability was not discussed in detail.

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 Sponsor stated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR part 160), with two exceptions: (1) the thermometers used to record ambient temperatures at field fortification (dosimeter) site were not calibrated; and (2) although formal methodology was in place and being followed, it was not amended to the study protocol prior to initiation of sample analysis.

GUIDELINE OR PROTOCOL FOLLOWED: OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure), and 875.1300 (inhalation exposure) were followed for the compliance review of this study.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	Apron® Flowable (FL) is a liquid formulation containing 33.3% active ingredient metalaxyl. Apron® 25 Wettable Powder (25W) is a water soluble powder formulation containing 25% active ingredient metalaxyl.
Lot/Batch # technical:	Metalaxyl: 587-1208; FL-911751; FL-921860.
Lot/Batch # formulation:	Apron® FL: M14011440; M11001440; M11001438. Apron® 25W: GP-920102
Purity in technical:	95.8%
CAS #(s):	The CAS number for metalaxyl is 57837-19-1.
Other Relevant Information:	Apron® FL and Apron® 25W are produced by Ciba-Geigy Corporation. The EPA Registration number for Apron® FL is 7501-42 and the EPA Registration number for Apron® 25W is 100-639.

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

The test products used in this study were the same proposed formulations available to commercial seed treatment facilities.

3. Packaging:

Apron® FL was packaged in 1-gallon plastic jugs with four jugs to a case.
Apron® 25W was packaged in 3-pound water soluble bags.

B. STUDY DESIGN

There were seven amendments and six deviations to the protocol. The amendments were: (1) location of the test sites were provided as an amendment because they were not specified in the protocol; (2) a decision was made to use two glass fiber filters to monitor inhalation exposure instead of a glass filter and support pad; (3) the addition of a fourth trial using Apron® 25W packaged in water soluble bags was included; (4) a decision was made that the mixer/operators were to wear goggles, chemical-resistant gloves, and a chemical-resistant apron while mixing and loading the test chemical to comply with PPE that will be added to future Apron® labels; (5) analytical method PALM-120 was attached; (6) 48 additional samples were to be collected at both test sites; and (7) correcting discrepancies in Amendment Number 6 involving numbering and descriptions of samples. The protocol deviations included: (1) field fortification samples were prepared using both formulated material and the analytical standard; (2) methods of analysis were not amended to the protocol soon after validation; (3) pilot study samples were not analyzed prior to study initiation; (4) analysis of study samples proceeded before validation was approved by the study director; (5) the day 14 time point of the

freezer storage stability study was missed; and (6) relative humidity data were not collected during the refortification event at the Bunker Hill, Indiana site. None of the amendments, revisions, or deviations were expected to have any adverse effects on the study integrity.

1. Number and type of workers and sites:

Four trials were conducted with a total of nine individuals (5 males and 4 females) participating in the study. Each trial consisted of five replicates per work function. Three workers, a mixer/operator, a bagger, and a bag sewer, were monitored in each trial. The three workers used in Trial 2 were also used in Trial 4. The women primarily worked as baggers and bag sewers. Only men performed the work as mixer/operators. All of the study participants were experienced in seed treatment and performed their normal daily work responsibilities throughout the study. Each participant signed a worker consent form prior to the initiation of the study after being provided the proper information regarding the study, products being used, and proper precautions. The body weight of each of the male workers ranged from 81.2 to 123 kg and the women ranged from 47.6 to 138 kg. The number of years experience for these workers ranged from 3 to 16 years.

The study was conducted in three commercial seed treatment facilities. Trial 1 was conducted at a seed treatment plant in Bunker Hill, Indiana and Trials 2, 3, and 4 were conducted at a commercial seed treatment plant in Belle Plaine, Iowa.

The Bunker Hill, Indiana facility cleaned and treated the seed in a three story tall building. The building was divided into two areas. The smaller of the two areas contained the bagging and sewing machinery, empty seed bags, and stacked pallets. The larger area contained the seed cleaning machinery, a chemical mixing tank, the seed treater box, and seed-holding bins. There was no heating system in the area where the seed was treated. The smaller room, where the bagger and bag sewer were located, was heated by two ceiling hoses blowing hot air. There were concrete floors in both areas.

The Belle Plaine, Iowa facility utilized two independent seed treatment systems and bagging and sewing areas. These two areas were located in separate rooms at opposite ends of a building that also served as a warehouse for bagged seed. Trials 2 and 4 took place in the southwest corner of the building. In this corner of the building, the chemical mixing tank and seed treatment drum were located in a small room adjacent to the bagging and sewing area. Trial 3 took place in the northeast side of the building. In this area the chemical mixing tank and seed treatment drum were located approximately three stories above the bagging and sewing area. The mixing area was fairly warm due to its location. The baggers and bag sewers were kept warm by heaters suspended above their work stations.

2. Meteorology:

A portable Datalynx weather station was used to collect indoor environmental conditions during the study. Temperature and relative humidity were recorded at each site during each Trial. Temperatures ranged from 47.8 °F to 78.3 °F during Trial 1, from 39.6 °F to 49.7 °F for Trials 2 and 3, and from 46.6 °F to 54.7 °F for Trial 4. Relative humidity ranged from 34.7% to 47.9% for Trial 1, from 36.1% to 51% for Trials 2 and 3, and from 38.4% to 47.8% for Trial 4.

3. Replicates:

This study consisted of a total of 15 mixer/operator, bagger, and bag sewer replicates using Apron® FL and 5 mixer/operator, bagger, and bag sewer replicates using Apron® 25W. Each trial consisted of 3 workers monitored 5 times per work function. The duration of a work replicate was a minimum of 3.5 hours. Trials 1 through 3 used Apron® FL and Trial 4 used Apron® 25W. The bagger and bag sewer could bag approximately 625 bags of seed per hour. However, the mixer/operator could only treat around 250 bags of seed in an hour because it took longer to treat the seed than it did to bag it.

Mixer/Operator: Trial 1 - The mixer/operator mixed the test product, colorant, and water to form a slurry in the open mixing system tank. Three gallons of Apron® FL and 1 quart of colorant were added to 18.5 gallons of water per slurry mixture. Once the mixing process was completed, the mixer/operator removed his protective gear and put on a pair of cotton gardening gloves for warmth. In addition to mixing the seed treatments, the mixer/operator checked the treater box, took quality control samples of nontreated seed, received and directed unloading and storage of bulk bean shipments, and oversaw the operation of the seed-cleaning machinery.

Trial 2 - The mixer/operator first added water directly into the tank and then added 1 gallon of Apron® FL at a time. Each jug was rinsed and the rinsate was poured into the tank. Each tank consisted of 5 gallons Apron® FL, two 1.3 pound bags of colorant, and 16 gallons of water for a total final volume of 21.5 gallons. The mixer/operator checked the treated seed for coverage by placing his gloved hands into the rotating treater to obtain a sample. Once the mixing process was complete, the mixer/operator resided in the office next to the treatment room and observed the bagging process while monitoring the treater.

Trial 3 - The mixer/operator first added water and colorant to the tank. Approximately three minutes later, 5 gallons of Apron® FL were added, 1 gallon at a time. The mixer/operator filled one of the empty Apron® FL containers with 1 gallon of water, shook it, poured half into the tank, shook it again, and then poured the remainder into the tank. This process was repeated with each empty Apron® FL jug. Each tank consisted of 5 gallons Apron® FL, two 1.3 pound bags of colorant and 15.4 gallons of water for a total volume of 20.9 gallons. Once the slurry was made, the mixer/operator removed his chemical-resistant apron, nitrile gloves, and protective goggles. In between mixing treatments, the mixer checked coverage of the treated seed by reaching his arm into the rotating treater and catching seed with a pan. Periodically he swept up loose beans, opened the mix tank lid to visually check the slurry volume, and mechanically check the amount by dipping a metal rod (while wearing a nitrile glove) into the slurry for a more accurate measurement.

Trial 4 - The mixer/operator first added water and the colorant to the tank. Once the colorant was dissolved, the mixer/operator opened the outside Apron® 25W foil pouches with a knife and removed the water soluble bags. Eighteen water soluble bags were added to the tank. During agitation, the mix tank lid was closed. Each tank mix consisted of 54 pounds of Apron® 25W, two 1.3 pound bags of colorant, and 21.2 gallons of water.

Bagger and Bag Sewer: The same basic bagging and bag sewing procedures were followed in all four trials. The bagger clamped one empty seed bag at a time onto the shaft of the bagging machine and the treated seed dropped into the bag. The seed flow automatically stopped when the bag reached the desired weight of 50 pounds and the bag dropped onto the conveyor belt. The bag sewer grabbed the bag, placed identification tags at the top left edge of the bag, and guided it through the sewing and stamping machines. Occasionally the bag sewer weighed a bag to verify the amount of seed being released.

The average amount of active ingredient handled per replicate for the mixer/operators working with Apron® FL ranged from 6.01 kg to 8.01 kg. The mixer/operator for Trial 4 using Apron® 25W handled an average of 6.12 kg active ingredient per replicate. The average amount of active ingredient handled per replicate for the baggers and sewers working with Apron® FL ranged from 4.69 kg to 7.45 kg. The baggers and sewers for Trial 4 using Apron® 25W handled an average of 5.98 kg active ingredient per replicate. The average duration of each replicate was 3.5 hours.

4. Protective clothing:

In addition to wearing long-sleeved shirts and long pants, mixer/operators wore goggles, chemical resistant gloves, and a chemical resistant apron. These personal protective equipment are consistent with the Apron® labels. The bagger and bag sewer wore long-sleeved shirts and long pants. The bagger and bag sewer for Trial 1 and the mixer/operator for Trials 2 and 4 also wore dust masks.

5. Mixing/application method:

Trial 1 (Indiana site) - As per normal practice, seeds were cleaned by passing them through an aspirator, a Crippen air-screen cleaner, a spiral separator, and a gravity table before treatment. A seed treater box was located near the top of the building. When 4 pounds of seed filled the treater box, a counterweight shaft was tripped and approximately 15 cubic centimeters of slurry was released into the treater box and mixed with the seed. The test compound was mixed in a Gustafson open mixing system tank (Model PM 30, 30-gallon capacity). The tank was half filled with tap water measured using a precalibrated bucket. The colorant and Apron® FL were then added by pouring the entire contents of each container directly into the tank. The empty colorant and Apron® FL jugs were rinsed four to five times with water, the rinsate was poured into the precalibrated bucket, and the slurry was brought up to final volume of 21.7 gallons. Three gallons of Apron® FL and 1 quart of colorant were added to 18.5 gallons of water per slurry mixture. The treated seeds then fell into a holding bin until they were bagged.

Trial 2 (Iowa site) - As per normal practice, seeds were cleaned by passing them through an air-screen cleaner, a spiral separator, and a gravity table before treatment. The test chemical was mixed in a Gustafson open mixing system tank (60-gallon capacity). First, 10 gallons of water measured with a digital flow meter was added directly into the tank and then 1 gallon of Apron® FL was added at a time. Each jug was rinsed with water and the rinsate was poured into the tank. The colorant and remaining amount of water were added next. Each tank consisted of 5 gallons Apron® FL, two 1.3 pound bags of colorant, and 16 gallons of water for a total final volume of 21.5 gallons. The slurry delivery pump was a Digi-Staltic Digital Flow Controller. The slurry and seed were mixed together in a rotating treater adjacent to the mix tank. The treated seeds were then moved onto a leg elevator and deposited into a holding bin until bagged.

Trial 3 (Iowa site) - As per normal practice, seeds were cleaned by passing them through an air-screen cleaner, a spiral separator, and a gravity table before treatment. During this trial, the test material was mixed in a 60 gallon capacity Gustafson-type open mixing system tank. Water measured with a digital Sorenco flow meter was added directly to the tank followed by two 1.3 pound bags of colorant. Approximately three minutes later 5 gallons of Apron® FL were added, 1 gallon at a time. The Apron® FL containers were rinsed with water and the rinsate was poured into the tank. Each tank consisted of 5 gallons Apron® FL, two 1.3 pound bags of colorant and 15.4 gallons of water for a total volume of 20.9 gallons.

Trial 4 (Iowa site) - As per normal practice, seeds were cleaned by passing them through an air-screen cleaner, a spiral separator, and a gravity table before treatment. The mixing operation for this trial took place in the same location as Trial 2. However, the mixing procedure varied slightly due to the different formulation of Apron® being tested (wettable powder). During the first replicate, the mixer/operator added 15 gallons of water to the tank followed by two 1.3 pound bags of colorant. Once the colorant dissolved, he opened the outside Apron® 25W foil pouch with a knife and removed the water soluble bags. During agitation, one water soluble bag was added at a time, allowing each bag to dissolve before adding another. After ten bags had been added in this manner, the final eight bags were added simultaneously. The slurry was allowed to mix for approximately ten minutes before seed treatment. In the remaining 4 replicates for this trial, the mixer/operator first added 10 gallons of water and two 1.3 pound-bags of colorant. Once the colorant dissolved, all 18 bags of Apron® 25W were added to the tank. After five minutes of agitation, the remaining water was added. Each tank mix consisted of 54 pounds of Apron® 25W, two 1.3 pound bags of colorant, and 21.2 gallons of water.

6. Application Rate:

Apron® FL was applied during Trials 1, 2, and 3. Apron® 25W was applied during Trial 4. Apron® FL and Apron® 25W were applied to soybean seed at the maximum label rate of 1.5 fluid ounces (fl oz) per 100 pounds (lbs) of soybean seed and 2.0 fl oz/100 lbs soybean seed, respectively. The target slurry volumes for Trials 1 through 4 were 10.8 fl oz/100 lbs seed, 6.4 fl oz/100 lbs seed, 6.3 fl oz/100 lbs seed, and 7.4 fl oz/100 lbs seed. The total amount of Apron® FL and 25W applied was 76 gallons and 270 pounds, respectively.

7. Exposure monitoring methodology:

Dermal: Dermal exposure was measured using 100% cotton whole-body dosimeters (long underwear), detergent handwashes, and facial wipes.

Whole-Body Dosimeters - The whole-body dosimeters were worn over the worker's underwear and under the worker's clothing. The whole-body dosimeters used in Trial 1 were not pre-washed prior to use. The whole-body dosimeters used in Trials 2, 3, and 4 were pre-washed to help avoid potential interference during analysis. The whole-body dosimeters were changed after each replicate. The dosimeters were carefully removed by a study assistant wearing clean latex gloves to avoid contamination. Using solvent rinsed scissors, the garment was sectioned into four pieces: lower portion (just below the second button), arms, chest, and back. The sections were placed into separate pre-labeled metallic Kapak bags and heat sealed.

Handwashes - Hand exposure to metalaxyl was assessed by having each worker wash both hands twice in a soap solution. Each wash consisted of 300 mL of a 0.01% Aerosol OT solution in distilled water. The subject was asked to scrub both hands for 30 seconds in a 1 gallon bag containing 300 mL of the soap solution. This was

repeated with a second bag containing another 300 mL of soap solution. Both handwashes were combined in a large pre-labeled plastic bottle which was capped.

Face/Neck Wipes - Face and neck exposure to metalaxyl was monitored by wiping the worker's face and neck area with a gauze pad (12-ply cotton, 7.5 cm x 7.5 cm) wetted with 4 to 7 mL of the 0.01% Aerosol OT solution. This was repeated with a second gauze pad, also wetted with the soap solution. Both pads were placed in a 6-ounce pre-labeled glass jar sealed with a foil-lined lid.

Inhalation: Inhalation exposure was monitored using personal air-sampling pumps calibrated to 1.5 liters per minute and attached to XAD-2 vapor-collection tubes and glass-fiber filters. Two glass fiber filters, each measuring 37 mm diameter and having a 1.0 um pore size, were placed in a plastic cassette sealed with a shrink band. The XAD-2 vapor collection tube contained 400 mg sorbent with a 200 mg breakthrough backup. A personal air sampling pump was hung on the worker's belt or jeans, and was attached by tygon tubing to the XAD-2 tube which, in turn, was connected to the cassette holding two glass fiber filters. The close-faced cassette was clipped to the worker's collar near his/her breathing zone.

Each air-sampling pump was calibrated to an airflow rate of 1.5 liters per minute with a Kurz Mass Flow Meter prior to placement on the worker. The pump was turned on at the start of the sampling replicate. At the end of the sampling period, the flow rate of the sampling train was again measured and recorded. The XAD-2 collection tube and cassette were removed from the tubing and each orifice capped. Preprinted labels were placed around each sample and each sample was placed in a recloseable bag.

Field monitoring was conducted at the Indiana site (Trial 1) from December 2, through December 5, 1991. Monitoring at the Iowa sites (Trials 2, 3, and 4) took place January 27 through January 31, 1992. Samples were placed in insulated cardboard boxes containing dry ice for shipment. Samples were shipped via Federal Express Next Morning Delivery to Pan-Ag Field Department on December 5, 1991 (Trial 1) and February 1, 1992 (Trials 2, 3, and 4). Samples were placed in the field walk-in freezer (temperatures ranging from 5 °F to 7 °F [Trial 1] and 9 °F to 15 °F [Trials 2, 3, and 4]) until they were transferred to the analytical laboratory of Pan-Ag Labs on December 9, 1991 (Trial 1) and February 4, 1992 (Trials 2, 3, and 4) and stored frozen.

8. Analytical Methodology:

Extraction method(s):

Air Filters - Filter samples were transferred to 4 ounce glass, screw cap bottles. Approximately 50 mL of hexane were added and the samples were shaken for approximately 15 minutes using a mechanical shaker set at low speed. Following the shaking process, the hexane extract was decanted through a funnel containing filter paper into a 125 mL evaporation flask. The extract was concentrated using rotary evaporation to approximately 1 mL and quantitatively transferred to a culture tube. Using a nitrogen stream, the hexane in the tube was evaporated to dryness and the sample rediluted in 0.5 mL of hexane and thoroughly mixed.

Facial/Neck Wipes - The gauze pads were transferred to 4 ounce glass, screw cap bottles. Approximately 50 mL of methylene chloride were added and the samples were shaken for approximately 15 minutes using a mechanical shaker set at low speed. Following the shaking process, the methylene chloride extract was decanted over a funnel containing sodium sulfate supported by a glass wool plug into a 250 mL evaporation flask. The extract was concentrated using rotary evaporation to approximately 1 mL and quantitatively transferred to a culture tube with hexane. Using a nitrogen stream, the hexane in the tube was evaporated to dryness and the sample rediluted in 0.5 mL of hexane and thoroughly mixed.

Handwash Solution - Prior to analysis, the total volume of each handwash sample was measured and recorded and 50 mL of the solution were transferred to a 125 mL separatory funnel. The samples were extracted with approximately 5 mL methylene chloride and approximately 20 mL of 10% NaCl by shaking for approximately 1 minute, venting when necessary. The methylene chloride extract was drained into a 15 mL culture tube and

evaporated to dryness using a stream of nitrogen. Following evaporation, the samples were rediluted in 1 mL of hexane and thoroughly mixed.

Vapor Tubes (XAD-2) - The vapor-collection tube was designed with two section of packing material separated by a glass wool plug. The section containing a larger amount of the packing material was designated as the front part of the tube while the remaining section was the back and was used to determine breakthrough. For analysis purposes, the "end" on the front of the tube was carefully snapped off and the packing material was transferred to a 15 mL culture tube. The tube was scored and snapped again at the glass wool plug separating the two sections so as to leave the back end of the tube intact. The front section was rinsed with 5 mL of acetone into the culture tube to further remove packing material which was attached to the inner surface of the tube. Once all samples were in the culture tubes, the sample were shaken on a mechanical shaker for approximately 15 minutes at high speed. Following the shaking process, the acetone extract was transferred to a clean labeled culture tube and evaporated to dryness using a gentle stream of nitrogen. The samples were rediluted in 2 mL of acetone, swirled to mix, and submitted fo GC analysis.

Whole-Body Dosimeters - The dosimeter sections were placed in 1 gallon glass, screw cap jars (all buttons were removed prior to extraction). Two liters of methylene chloride were added to each jar and the samples were shaken on a mechanical shaker for approximately one hour on low speed. Following shaking, 400 mL of the extract was transferred to a 1000 mL flat-bottom (evaporation) flask using a 500 mL graduated cylinder. The methylene chloride was evaporated to dryness using rotary evaporation. Once the sample was brought to dryness, the residues were quantitatively transferred with acetone to a 15 mL centrifuge tube (calibrated to 2 mL). The acetone was reduce to the 2 mL mark using a gentle stream of nitrogen and a 35 to 40 °C water bath. The sample was centrifuged to 30 minutes at approximately 35000 rpm and the acetone was transferred to a clean culture tube and submitted for GC analysis.

Detection method(s): See Table 1.

Table 1. Summary of GC Chromatographic Conditions

GC Column	Restex RTx-5 30 ml X 0.5 µm X 0.32 mm ID
Temperatures	Injector: 200 °C Detector: 200 °C Column: 130 °C 5 °C/min to 220 °C (hold 4.0 min) 20 °C/min to 280 °C (hold 7.0 min)
Injection Volume	1 µL
Retention Time	15 to 19 minutes

Method validation: The analytical method used in this study was validated prior to sample analysis for each matrix. The method was validated by analyzing duplicate control samples, duplicate low spikes, duplicate mid spikes, and duplicate high spikes. According to the guidelines, at least 7 samples per medium per fortification level should be collected to validate the study. The minimum quantifiable limit (MQL) was considered to be the lowest validated level. A Limit of Detection (LOD) was not provided. A summary of the validated levels are as follows:

Matrix	Low Level	Mid Level	High Level
Filters	0.05 µg	0.50 µg	5.00 µg
Facial wipes	0.20 µg	0.50 µg	5.00 µg

Handwash	1.00 µg	10.00 µg	100.00 µg
Vapor tubes	0.20 µg	2.00 µg	20.00 µg
Dosimeters	1.00 µg	10.00 µg	100.00 µg

All matrices had average recoveries ranging from 84.7 % to 112 % for metalaxyl fortifications. The average recoveries for the filters ranged from 98% to 115%. The average recoveries for the facial wipes ranged from 77% to 98%. The average recoveries for the handwash solutions ranged from 84% to 120%. The average recoveries for the vapor tubes ranged from 82% to 143%. The average recoveries for the dosimeters ranged from 81% to 110%. The highest recoveries were measured in the low level fortification samples.

Instrument performance and calibration: According to the study protocol, standard curves were to be prepared and were to include the range of residue levels expected for each sampling medium to be analyzed. The linear range of these standard curves were not provided in the study report but it was noted that four standards were used to generate the curve and the correlation coefficient of 0.990 was used as meeting curve criteria.

Quantification: Sample concentrations were calculated using the linear regression function of Maxima® 820 chromatography software from Waters Corporation. Concentrations of metalaxyl in the samples were determined directly from the standard curve.

9. Quality Control:

Lab Recovery: With each set of samples extracted, a control and two laboratory fortification samples were run concurrently. In all cases, laboratory controls were either not detected or were below the MQL. Table 2 provides a summary of the average percent recoveries for the laboratory fortified samples.

Table 2. Average Percent Recoveries for Metalaxyl in Laboratory Fortified Samples.

Matrix	Average Percent Recovery (%)	Standard Deviation
Filters	92.5	20.7
Vapor Collection Tubes	96.8	15.9
Handwash Solutions	91.8	16
Facial Wipes	79.1	17.4
Whole Body Dosimeters	81.1	19.4

Field blanks: Duplicate control samples of each matrix were placed in a corner of the sample handling room each day of the study. Air sampling media were attached to operating pumps set at 1.5 liters per minute. Samples were left out during the entire period that test subjects were being monitored. In the majority of the samples, residues were either not detected or were below the MLQ.

Field recovery: Handwash field fortification media consisted of 50 mL of 0.01% aqueous Aerosol OT solution. Facial/neck wipe field fortification media consisted of two gauze patches moistened with 0.01% Aerosol OT solution. Dosimeter field fortification media were comprised of half of a whole-body dosimeter. Air filter field fortification samples were fortified while attached to operating pumps (set at 1.5 liters per minute).

Both the formulated material (diluted in deionized water) and the technical material (diluted in acetone) were used to fortify sample media for field fortification samples during Trial 1. The technical material, diluted in methanol, was used to fortify sample media for field fortification samples during Trials 2, 3, and 4 because the technical material diluted in acetone melted the air filter cassettes in Trial 1 and rendered the fortification samples useless. During each day of the study, one sample of each matrix was fortified at one of three rates. The air filters were fortified at 0.25, 2.5, and 25 µg. The facial/neck wipes were fortified at 1, 10, and 100 µg. The whole body dosimeters and hand washes were fortified at 5, 50, and 500 µg. To prevent contamination, field fortification samples were prepared in a room away from the seed treatment and handling areas.

Once fortified, the whole body dosimeters were covered with one layer of clothing to simulate the long underwear being worn by the test subjects. Handwash solutions and gauze patches were capped ten minutes after fortification and then placed in a freezer. Fortified cloth dosimeters and air-sampling media remained exposed to the environment for the duration of a replicate (approximately 3.5 hours). Duplicate 2 mL samples of each fortification solution were collected each day of the study to confirm the integrity of each fortification solution over time.

Results for the dosimeter field fortification samples conducted concurrently with the study (Trials 1, 2, 3, and 4) were unacceptable due to an apparent extractability problem. Due to these poor results, a second set of field fortifications, using an aqueous solution of Apron® FL, was prepared using whole body dosimeters at both sites. These fortifications were prepared in the same locations and under the same conditions as the original procedure. Six pieces of long underwear were fortified at each rate (5.0, 50, and 50 µg) in Indiana while 12 pieces of long underwear were fortified at each rate in Iowa. Some of the spiked samples were analyzed shortly after arrival at the laboratory while the remaining spikes were stored frozen to provide storage stability data. The results from these additional field fortification dosimeter samples were used to correct the dosimeter residues for each of the trials. These refortification dosimeters samples had an average recovery of 68.4% for the Indiana site (used to correct residue data for Trial 1) and 73.9% for the Iowa site (used to correct residue data for Trials 2 through 4).

During Trial 1, recoveries for the air filter fortification samples ranged from 0 to 68% due to the acetone melting the air filter cassettes. Corrections for the air filter residues for Trial 1 were done using the average of the overall recoveries for Trials 2 and 4. Since Trials 2 and 3 were conducted simultaneously, Trial 2 field fortification data were used to correct both Trials 2 and 3. For recoveries greater than 100%, the registrant used a value of 100% to calculate field fortification recovery averages. Versar only corrected data for field recoveries less than 90%. Tables 3 through 5 provide a summary of the field fortification recovery results for each trial.

Table 3. Metalaxyl Field Fortification Recoveries for Trial 1

Sample Type	Fortification Level	Amount of Metalaxyl Applied (µg)	Average Metalaxyl Recovery per Level (%)	Overall Average (%)	Standard Deviation
Air Filters[1]	Low	0.25	93.24	74.79	16.11
	Medium	2.5	63.50		
	High	25	67.64		
Handwashes	Low	0.1	94.63	89.42	13.92
	Medium	10	99.98		
	High	100	73.64		
Facial/Neck Wipes	Low	0.1	80.63	69.51	12.97
		1	78.40		
	Medium	10	66.68		
	High	100	52.35		
Dosimeters[2]	Low	5	65.70	68.38	3.54
	Medium	50	72.40		
	High	500	67.05		

1 Air filter fortification recoveries were calculated for this trial by taking the average of each Trial 2 and Trial 4 fortification level recovery.
2 Dosimeter fortification recoveries are from the additional field fortification samples which were prepared at a later date (see page 80 in the Study Report).

Table 4. Metalaxyl Field Fortification Recoveries for Trials 2 and 3[1]

Sample Type	Fortification Level	Amount of Metalaxyl Applied (µg)	Average Metalaxyl Recovery per Level (%)	Overall Average (%)	StandardDeviation
Air Filters	Low	0.25	82.13	67.7	12.6
	Medium	2.5	62.10		
	High	25	58.87		
Handwashes	Low	0.1	87.50	86.79	2.67
	Medium	10	83.83		
	High	100	89.03		
Facial/Neck Wipes	Low	1	99.43	83.97	13.47
	Medium	10	77.63		
	High	100	74.83		
Dosimeters[2]	Low	5	70.15	73.68	3.06
	Medium	50	75.68		
	High	500	75.20		

1 - Trials 2 and 3 were done at the same time and in the same general location, therefore, the same field fortification samples were used.
2 - Dosimeter fortification recoveries are from the additional field fortification samples which were prepared at a later date (see page 80 in the Study Report).

Table 5. Metalaxyl Field Fortification Recoveries for Trial 4

Sample Type	Fortification Level	Amount of Metalaxyl Applied (µg)	Average Metalaxyl Recovery per Level (%)	Overall Average (%)	Standard Deviation
Air Filters	Low	0.25	109.90	85.43	22.51
	Medium	2.5	65.60		
	High	25	80.80		
Handwashes	Low	0.1	96.40	84.82	16.64
	Medium	1	92.30		
	High	10	65.75		
Facial/Neck Wipes	Low	1	132.50	114.83	16.62
	Medium	10	112.50		
	High	100	99.50		
Dosimeters[1]	Low	5	70.15	73.68	3.06
	Medium	50	75.68		
	High	500	75.20		

1 - Dosimeter fortification recoveries are from the additional field fortification samples which were prepared at a later date (see page 80 in the Study Report).

Formulation: According to the Registrant, determinations of strength, purity, composition, and stability were made of the test product prior to the study. A laboratory report with this information (other than purity) was not reported.

Tank Mix: The application rate was verified by collecting duplicate slurry (product, water, and colorant mixture), and duplicate treated seed samples from each slurry mixture. Approximately 20 mL per sample was collected using a plastic 10 mL syringe and placed in a 6 ounce preleabeled glass jar with a foil-lined lid. After every 54 bags, the Trial 1 bagger used a soup spoon to collect a sample of treated beans for quality control evaluation. In Trials 2, 3, and 4, after every other bag the hopper automatically released a quality control seed sample into a bucket hanging on the backside of the shaft. After 100 to 150 bags were filled, the bagger emptied this bucket into a seed bag. The seed samples were placed into two recloseable prelabeled plastic bags. The average percent of expected residues in seed treatment slurry samples was 57.7%, 47.1%, 38.2%, and 46.9% for Trials 1, 2, 3, and 4, respectively. The average percent of expected residues in seed samples was 85.2%, 92.5%, 35.9%, and 50.7% for Trials 1, 2, 3, and 4, respectively. The seed treatment slurry samples had lower recoveries than the seed samples which may be due to the uniformity of the slurry samples at the time they were sampled either in the field or in the laboratory.

Travel Recovery: Travel Recovery samples were not used in this study.

Storage Stability: A second set of field fortified dosimeters were prepared at each of the sites because the first set showed poor results. It was mentioned in the Study Report that these samples were fortified in the same locations and under the same conditions as the original procedure. Some of the spike samples were analyzed shortly after arrival at the laboratory while the remaining samples were stored frozen to provide storage stability data. The overall average field fortification recoveries were 68.38% for Trial 1 and 73.68% for Trials 2 through 4. The length of time field samples and field fortification samples were in storage was not reported.

10. Relevancy of Study to Proposed Use:

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

II. RESULTS AND CALCULATIONS:

A. EXPOSURE CALCULATIONS:

Limit of Quantitation (LOQ) and Limit of Detection (LOD) values were not provided in the study. However, a Minimum Quantitative Level (MQL) was provided. MQL values were used in calculations by the registrant when residue levels were less than MQL. Non-detect values were reported as 50% of the MQL for each matrix. For recoveries greater than 100%, the registrant used a value of 100% to calculate field fortification recovery averages. Versar only corrected data for field recoveries less than 90%. The registrant corrected the residues using the average field fortification recoveries. Versar corrected the residues using the field fortification recovery for the level that corresponded to the residue concentration. Residues detected on the whole-body dosimeters were adjusted using the average recoveries of the second set of dosimeter field spikes prepared in Indiana and Iowa (see field fortification section of this study review for explanation).

Total adjusted dermal exposure was calculated by the registrant to account for exposure to the workers' feet which were not monitored in the study. Surface areas were determined for the adult body to be in the following ratio: thigh 3,820 cm^2, lower leg 2,380 cm^2, feet 1,310 cm^2. Because feet residues were not measured, the dermal exposure to the feet was extrapolated from lower dosimeter values using these ratios.

The Registrant provided exposure values in mg/kg ai handled. Versar provided exposure values in mg/lb ai handled as per EPA's request (Tables 6 through 13).

Inhalation Exposure

Air concentrations were calculated by adding the air filter residues to the residues found in the air tubes. For the most part, residues were not detected in the air tubes. Therefore, a value of ½ the MQL was added to the air filter residue concentration to calculate air concentrations. The registrant used ½ the MQL for air filters (0.025 µg), but the MQL for air tubes was 0.20 µg. Therefore, Versar used ½ the MQL for air tubes (0.1 µg) when air tube residues were ND. Air residue values ranged from < MQL to 35.58 µg for Trial 1, from < MQL to 3.63 µg for Trial 2, from ND to 0.24 µg for Trial 3, and from < MQL to 8.21 µg for Trial 4. Residue values <MQL were treated as MQL (0.05 µg) and values which were ND were treated as ½ MQL (0.025 µg). The Registrant used 29 liters per minute to represent a light work inhalation rate. Versar's estimated inhalation exposures for Trial 1 ranged from 1.82E-04 mg/lb ai handled (mixer/operator) to 4.15E-02 mg/lb ai handled (bag sewer). The geometric mean inhalation exposures for each type of worker for Trial 1 was as follows: mixer/operator = 3.17 E-04 mg/lb ai handled; bagger = 4.88E-04 mg/lb ai handled ; and bag sewer = 1.28E-02 mg/lb ai handled. Versar's estimated inhalation exposures for Trial 2 ranged from 2.19E-04 mg/lb ai handled (bagger) to 5.29E-03 mg/lb ai handled (mixer/operator). The geometric mean inhalation exposures for each type of worker for Trial 2 was as follows: mixer/operator = 9.32 E-04 mg/lb ai handled; bagger = 3.35E-04 mg/lb ai handled; and bag sewer = 5.66E-04 mg/lb ai handled.Versar's estimated inhalation exposures for Trial 3 ranged from 1.56E-04 mg/lb ai handled (mixer/operator) to 4.32E-04 mg/lb ai handled (bagger). The geometric mean inhalation exposures for each type of worker for Trial 3 was as follows: mixer/operator = 1.88 E-04 mg/lb ai handled; bagger = 3.16E-04 mg/lb ai handled; and bag sewer = 2.80E-04 mg/lb ai handled.Versar's estimated inhalation exposures for Trial 4 ranged from 1.90E-04 mg/lb ai handled (bagger) to 1.18E-02 mg/lb ai handled (mixer/ooperator). The geometric mean inhalation exposures for each type of worker for Trial 4 was as follows: mixer/operator = 3.58 E-03 mg/lb ai handled; bagger = 5.07E-04 mg/lb ai handled; and bag sewer = 4.65E-04 mg/lb ai handled.

Dermal Exposure

Dermal exposure estimates were calculated for each replicate as the total amount of metalaxyl residues for all dermal measures (total dosimeter adjusted for feet, handwashes, and face/neck wipes). Total adjusted dermal residues for Trial 1 ranged from 4.87 µg (bagger) to 2173.15 µg (bag sewer). Face/neck wipe residues for Trial 1 ranged from 0.95 µg (bagger) to 55.64 µg (bag sewer). Handwash residues for Trial 1 ranged from 2.04 µg (mixer/operator) to 483.43 µg (bag sewer). The geometric mean total dermal exposures for each worker type for Trial 1 was as follows: mixer/operator = 4.83E-03 mg/lb ai handled; bagger = 6.09E-03 mg/lb ai handled; and bag sewer = 4.34E-02 mg/lb ai handled. Total adjusted dermal residues for Trial 2 ranged from 6.77 µg (bagger) to 420.83 µg (mixer/operator). Face/neck wipe residues for Trial 2 ranged from < MQL (0.20 µg) (bag sewer) to 343.45 µg (mixer/operator). Handwash residues for Trial 2 ranged from < MQL (0.02 µg) (bag sewer) to 887.34 µg (mixer/operator). The geometric mean total dermal exposures for each worker type for Trial 2 was as follows: mixer/operator = 6.52E-02 mg/lb ai handled; bagger = 5.43E-03 mg/lb ai handled; and bag sewer = 3.01E-03 mg/lb ai handled. Total adjusted dermal residues for Trial 3 ranged from 6.22 µg (mixer/operator) to 200.09 µg (bagger). Face/neck wipe residues for Trial 3 ranged from < MQL (0.20 µg) (mixer/operator) to 8.13 µg (bagger). Handwash residues for Trial 3 ranged from < MQL (0.02 µg) (bag sewer) to 560.49 µg (mixer/operator). The geometric mean total dermal exposures for each worker type for Trial 3 was as follows: mixer/operator = 1.19E-02 mg/lb ai handled; bagger = 1.38E-02 mg/lb ai handled; and bag sewer = 3.00E-03 mg/lb ai handled. Total adjusted dermal residues for Trial 4 ranged from 13.38 µg (bag sewer) to 363.51 µg (mixer/operator). Face/neck wipe residues for Trial 4 ranged from 0.51 µg (mixer/operator) to 8.70 µg (mixer/operator). Handwash residues for Trial 4 ranged from < MQL (0.02 µg) (bag sewer) to 619.01 µg (mixer/operator). The geometric mean total dermal exposures for each worker type for Trial 4 was as follows: mixer/operator = 2.15E-02 mg/lb ai handled; bagger = 1.48E-02 mg/lb ai handled; and bag sewer = 4.34E-03 mg/lb ai handled.

Total Exposure

The total exposure estimate was calculated by taking the sum of all exposure routes (total dermal and inhalation). Tables 14 through 17 present total exposure across the exposure routes, as calculated by Versar. The geometric mean total exposures for each worker type calculated by Versar for Trial 1 were as follows: mixer/operator = 5.58 E-03 mg/lb ai handled; baggers = 6.77E-03 mg/lb ai handled; and bag sewers = 6.12E-02 mg/lb ai handled. The geometric mean total exposures for each worker type calculated by Versar for Trial 2 were as follows: mixer/operator = 6.71E-02 mg/lb ai handled; baggers = 5.83E-03 mg/lb ai handled; and bag sewers = 4.03E-03 mg/lb ai handled. The geometric mean total exposures for each worker type calculated by Versar for Trial 3 were as follows: mixer/operator = 1.21E-02 mg/lb ai handled; baggers = 1.42E-02 mg/lb ai handled; and bag sewers = 3.34E-03 mg/lb ai handled. The geometric mean total exposures for each worker type, calculated by Versar for Trial 4, were as follows:

mixer/operator = 2.75E-02 mg/lb ai handled; baggers = 1.70E-02 mg/lb ai handled; and bag sewers = 4.90E-03 mg/lb ai handled.

III. DISCUSSION

A. *LIMITATIONS OF THE STUDY:*

This study met most of the Series 875.1100 and 875.1300 Guidelines. The major issues of concern are: (1) the study was performed at only two test sites; (2) analysis dates were not provided for any of the samples in this study in order to verify storage stability results; (3) there was an insufficient number of replicates for each Method Validation fortification level for each medium; (4) the personal monitoring pumps were calibrated at an airflow of 1.5 L/min. instead of 2 L/min.; (5) overall field fortification recoveries per matrix were used to correct data instead of average field fortification recoveries for each level which corresponded to the residue concentration found; and (6) storage stability was not discussed in detail.

B. CONCLUSIONS:

The registrant provided exposure values expressed as mg/kg ai handled. Versar has provided exposure values as mg/lb ai handled as per EPA's request. Table 18 provides a comparison of the overall average dermal and inhalation exposures in mg/kg ai handled for each type of worker as calculated by the Registrant and Versar. According to both the Registrant's and Versar's calculations, the overall average dermal exposure to Apron® FL was greatest for the mixer/operator followed by the bag sewer, and overall average inhalation exposure was greatest for the bag sewer followed by the mixer/operator. Overall average dermal exposure to Apron® 25W was greatest for the mixer/operator, and bagger, while the overall average inhalation exposure was greatest for the mixer/operator followed by the sewer. The difference in estimated exposures between the registrant's calculations and Versar's was most noticeable with the inhalation exposure values. Two factors may have contributed to these differences: (1) for non-detect air tube residues, the registrant used ½ the MQL for air filters (0.025 µg), while Versar used ½ the correct MQL for air tubes (0.10 µg); and (2) Versar did not correct for field fortification recoveries >90%.

The use of wettable powder in water soluble bags resulted in greater average inhalation exposures to the mixer/operator than the use of the flowable formulation due to dust on the outside of the foil bags containing the water soluble bags, dust in the mixing tank, and dust arising when the compound was scraped off the mixing paddles.

Table 6. Inhalation Exposure (mg /lbs-ai handled) Based on Residue Levels Found on Air Filters for Trial 1 (Apron® FL).

Worker	Rep	Concentration (µg)	Duration (min)	Flow Rate (L/min)	Concentration (µg/m³)	kg ai handled	lbs ai handled	Vent. Rate[a]	Inhalation Exposure (µg/lb ai handled)	Inhalation Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.74	214	1.5	2.31	7.21	15.90	0.029	0.90	9.01E-04	0.000407	0.00032	0.00033
	2	0.15	223	1.5	0.45	7.21	15.90	0.029	0.18	0.000182			
	3	0.15	211	1.5	0.47	7.21	15.90	0.029	0.18	0.000182			
	4	0.15	217	1.5	0.46	7.21	15.90	0.029	0.18	0.000182			
	5	0.15	215	1.4	0.5	2.40	5.29	0.029	0.59	0.000587			
Bagger	1	0.22	214	1.5	0.68	7.11	15.67	0.029	0.27	2.70E-04	0.000946	0.00049	0.00135
	2	2.85	213	1.5	8.93	7.52	16.58	0.029	3.33	3.33E-03			
	3	0.55	211	1.5	1.72	6.69	14.75	0.029	0.71	0.000714			
	4	0.15	211	1.5	0.47	7.11	15.67	0.029	0.19	0.000185			
	5	0.24	231	1.5	0.68	8.83	19.47	0.029	0.23	2.33E-04			
Sewer	1	5.69	214	1.5	17.73	7.11	15.67	0.029	7.02	7.02E-03	0.0179	0.0128	0.016
	2	35.58	213	1.5	111.37	7.52	16.58	0.029	41.49	4.15E-02			
	3	20.95	211	1.5	66.18	6.69	14.75	0.029	27.46	2.75E-02			
	4	7.21	211	1.5	22.77	7.11	15.67	0.029	8.89	8.89E-03			
	5	4.50	231	1.4	13.91	8.83	19.47	0.029	4.79	4.79E-03			

a 29 L/min * 0.001 m^3/L.

Table 7. Inhalation Exposure (mg /lbs-ai handled) Based on Residue Levels Found on Air Filters for Trial 2 (Apron® FL).

Worker	Rep	Concentration (µg)	Duration (min)	Flow Rate (L/min)	Concentration (µg/m³)	kg ai handled	lbs ai handled	Vent. Rate[a]	Inhalation Exposure (µg/lb ai handled)	Inhalation Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.64	243	1.5	1.74	6.01	13.25	0.029	0.93	9.28E-04	0.00181	0.00093	0.00212
	2	3.63	268	1.5	9.02	6.01	13.25	0.029	5.29	0.00529			
	3	1.60	258	1.5	4.13	6.01	13.25	0.029	2.33	2.33E-03			
	4	0.15	257	1.5	0.39	6.01	13.25	0.029	0.22	0.000219			
	5	0.19	304	1.5	0.42	6.01	13.25	0.029	0.28	0.00028			
Bagger	1	0.15	224	1.4	0.48	4.41	9.72	0.029	0.32	0.00032	0.00041	0.00034	0.00035
	2	0.15	229	1.5	0.44	6.02	13.27	0.029	0.22	0.000219			
	3	0.15	219	1.5	0.46	5.04	11.11	0.029	0.26	0.000261			
	4	0.84	211	1.5	2.66	7.19	15.85	0.029	1.03	0.00103			
	5	0.15	241	1.4	0.44	6.25	13.78	0.029	0.23	0.000226			
Sewer	1	0.52	224	1.4	1.67	4.41	9.72	0.029	1.12	1.12E-03	0.000745	0.00057	0.00058
	2	0.40	229	1.5	1.15	6.02	13.27	0.029	0.58	5.77E-04			
	3	0.89	219	1.5	2.71	5.04	11.11	0.029	1.55	1.55E-03			
	4	0.21	211	1.5	0.65	7.19	15.85	0.029	0.25	2.52E-04			
	5	0.16	241	1.5	0.45	6.25	13.78	0.029	0.23	2.31E-04			

a 29 L/min * 0.001 m^3/L.

Table 8. Inhalation Exposure (mg /lbs-ai handled) Based on Residue Levels Found on Air Filters for Trial 3 (Apron® FL).

Worker	Rep	Concentration (µg)	Duration (min)	Flow Rate (L/min)	Concentration (µg/m³)	kg ai handled	lbs ai handled	Vent. Rate[a]	Inhalation Exposure (µg/lb ai handled)	Inhalation Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.15	217	1.5	0.46	6.01	13.25	0.029	0.22	0.000219	0.00019	0.00019	0
	2	0.20	214	1.4	0.67	12.00	26.46	0.029	0.16	0.000156			
	3	0.13	210	1.5	0.4	0.00	0.00	0.029	N/A	N/A			
	4	0.13	210	1.4	0.43	6.01	13.25	0.029	0.2	0.000195			
	5	0.15	323	1.5	0.31	0.00	0.00	0.029	N/A	N/A			
Bagger	1	0.15	210	1.4	0.51	4.30	9.48	0.029	0.33	0.000328	0.000324	0.00032	0.0001
	2	0.15	210	1.5	0.48	4.80	10.58	0.029	0.27	0.000274			
	3	0.15	111	1.4	0.97	3.87	8.53	0.029	0.36	0.000364			
	4	0.24	210	1.6	0.72	4.59	10.12	0.029	0.43	0.000432			
	5	0.15	315	1.5	0.32	5.88	12.96	0.029	0.22	0.000224			
Sewer	1	0.13	210	1.5	0.4	4.30	9.48	0.029	0.25	0.000255	0.000284	0.00028	0.0001
	2	0.15	210	1.5	0.48	4.80	10.58	0.029	0.27	0.000274			
	3	0.15	111	1.4	0.97	3.90	8.60	0.029	0.36	0.000361			
	4	0.17	210	1.6	0.51	4.60	10.14	0.029	0.31	0.000306			
	5	0.15	315	1.5	0.32	5.9	13.01	0.029	0.22	0.000223			

N/A - Mixer/Operator did not handle the test product during this replicate.

a 29 L/min * 0.001 m^3/L.

Table 9. Inhalation Exposure (mg /lbs-ai handled) Based on Residue Levels Found on Air Filters for Trial 4 (Apron® 25W).

Worker	Rep	Concentration (µg)	Duration (min)	Flow Rate (L/min)	Concentration (µg/m³)	kg ai handled	lbs ai handled	Vent. Rate[a]	Inhalation Exposure (µg/lb ai handled)	Inhalation Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	6.01	326	1.5	12.30	6.12	13.49	0.029	8.62	8.62E-03	0.00618	0.00358	0.00501
	2	8.21	240	1.5	22.80	6.12	13.49	0.029	11.76	1.18E-02			
	3	0.83	240	1.5	2.31	6.12	13.49	0.029	1.19	1.19E-03			
	4	0.36	261	1.4	0.99	6.12	13.49	0.029	0.56	5.56E-04			
	5	5.73	273	1.4	14.98	6.12	13.49	0.029	8.79	8.79E-03			
Bagger	1	4.35	212	1.5	13.69	5.67	12.50	0.029	6.73	6.73E-03	0.00156	0.00051	0.00289
	2	0.23	211	1.5	0.71	5.76	12.70	0.029	0.34	3.43E-04			
	3	0.17	212	1.5	0.53	5.96	13.14	0.029	0.25	2.50E-04			
	4	0.20	211	1.5	0.62	5.59	12.32	0.029	0.31	3.08E-04			
	5	0.15	226	1.5	0.44	6.94	15.3	0.029	0.19	0.00019			
Sewer	1	0.28	212	1.5	0.88	5.67	12.50	0.029	0.43	4.33E-04	0.000655	0.00047	0.00071
	2	0.27	211	1.5	0.84	5.76	12.70	0.029	0.41	4.07E-04			
	3	1.30	212	1.5	4.09	5.96	13.14	0.029	1.91	1.91E-03			
	4	0.20	211	1.5	0.64	5.59	12.32	0.029	0.32	3.20E-04			
	5	0.16	226	1.5	0.47	6.94	15.30	0.029	0.20	2.03E-04			

a 29 L/min * 0.001 m^3/L.

Table 10. Total Dermal Exposure for Each Worker at Trial 1 (Apron® FL).

Worker	Rep.	Total Dosimeter Residue Conc. (µg)	Face/Neck Residue Conc. (µg)	Hands Residue Conc. (µg)	Total Dermal Residue Conc. (µg)	kg ai handled	lbs ai handled	Dermal Exposure (µg/lb ai handled)	Dermal Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	14.03	2.79	2.04	18.86	7.21	15.90	1.19	1.19E-03	0.0098	0.0048	0.014
	2	21.53	21.75	14.40	57.67	7.21	15.90	3.63	3.63E-03			
	3	19.56	11.85	88.27	119.67	7.21	15.90	7.53	7.53E-03			
	4	8.91	5.10	23.20	37.21	7.21	15.90	2.34	2.34E-03			
	5	134.67	2.70	45.10	182.47	2.40	5.29	34.49	3.45E-02			
Bagger	1	30.64	1.18	49.80	81.61	7.11	15.67	5.21	5.21E-03	0.0064	0.0061	0.00216
	2	67.31	5.59	91.25	164.15	7.52	16.58	9.90	9.90E-03			
	3	8.25	0.98	89.76	98.99	6.69	14.75	6.71	6.71E-03			
	4	4.87	1.54	80.39	86.80	7.11	15.67	5.54	5.54E-03			
	5	9.03	0.95	75.37	85.34	8.83	19.47	4.38	4.38E-03			
Sewer	1	2173.15	54.44	24.60	2252.19	7.11	15.67	143.68	1.44E-01	0.0556	0.0434	0.0502
	2	381.04	12.31	406.03	799.38	7.52	16.58	48.22	4.82E-02			
	3	56.89	4.64	483.43	544.97	6.69	14.75	36.95	3.69E-02			
	4	36.96	20.25	308.26	365.46	7.11	15.67	23.32	2.33E-02			
	5	48.12	55.64	399.24	503.00	8.83	19.47	25.84	2.58E-02			

lbs ai handled = (kg ai *2.2046 to convert to lbs)

Table 11. Total Dermal Exposure for Each Worker at Trial 2 (Apron® FL).

Worker	Rep.	Total Dosimeter Residue Conc. (µg)	Face/Neck Residue Conc. (µg)	Hands Residue Conc. (µg)	Total Dermal Residue Conc. (µg)	kg ai handled	lbs ai handled	Dermal Exposure (µg/lb ai handled)	Dermal Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	412.91	23.06	887.34	1323.31	6.01	13.25	99.87	9.99E-02	0.0702	0.0652	0.0273
	2	174.84	343.45	629	1147.28	6.01	13.25	86.59	8.66E-02			
	3	120.08	2.86	334.72	457.66	6.01	13.25	34.54	3.45E-02			
	4	420.83	204.46	447.04	1072.33	6.01	13.25	80.93	0.0809			
	5	245.80	7.39	394.25	647.44	6.01	13.25	48.86	0.0489			
Bagger	1	41.46	13.40	63.35	118.20	4.41	9.72	12.16	0.0122	0.0062	0.0054	0.00369
	2	9.66	1.46	38.77	49.89	6.02	13.27	3.76	0.00376			
	3	6.77	0.67	59.64	67.09	5.04	11.11	6.04	0.00604			
	4	30.15	1.84	72.34	104.32	7.19	15.85	6.58	6.58E-03			
	5	8.75	1.14	26.01	35.90	6.25	13.78	2.61	2.61E-03			
Sewer	1	21.67	0.82	47.24	69.73	4.41	9.72	7.17	7.17E-03	0.0037	0.003	0.00228
	2	25.56	3.30	23.50	52.36	6.02	13.27	3.95	3.95E-03			
	3	8.75	0.70	0.02	9.47	5.04	11.11	0.85	8.52E-04			
	4	24.12	2.31	27.44	53.87	7.19	15.85	3.40	3.40E-03			
	5	12.75	0.20	28.51	41.46	6.25	13.78	3.01	3.01E-03			

lbs ai handled = (kg ai *2.2046 to convert to lbs)

Table 12. Total Dermal Exposure for Each Worker at Trial 3 (Apron® FL).

Worker	Rep.	Total Dosimeter Residue Conc. (µg)	Face/Neck Residue Conc. (µg)	Hands Residue Conc. (µg)	Total Dermal Residue Conc. (µg)	kg ai handled	lbs ai handled	Dermal Exposure (µg/lb ai handled)	Dermal Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	26.3	0.20	170.73	197.23	6.01	13.25	14.89	1.49E-02	0.014	0.0119	0.00835
	2	16.54	0.20	560.49	577.22	12.00	26.46	21.82	2.18E-02			
	3	17.81	0.20	32.69	50.69	0.00	0.00	N/A	N/A			
	4	6.22	0.24	62.34	68.80	6.01	13.25	5.19	5.19E-03			
	5	7.31	1.52	112.32	121.16	0.00	0.00	N/A	N/A			
Bagger	1	52.61	1.46	44.14	98.21	4.30	9.48	10.36	1.04E-02	0.0145	0.0138	0.00481
	2	46.12	1.64	53.32	101.08	4.80	10.58	9.55	9.55E-03			
	3	38.37	8.13	107.60	154.11	3.87	8.53	18.06	1.81E-02			
	4	77.08	3.25	58.93	139.25	4.59	10.12	13.76	1.38E-02			
	5	200.09	2.73	64.70	267.52	5.88	12.96	20.64	2.06E-02			
Sewer	1	15.90	0.88	0.02	16.80	4.30	9.48	1.77	1.77E-03	0.0043	0.003	0.00486
	2	15.05	0.68	121.31	137.04	4.80	10.58	12.95	1.29E-02			
	3	17.76	0.83	0.02	18.61	3.90	8.60	2.16	2.16E-03			
	4	22.41	0.27	0.02	22.70	4.60	10.14	2.24	2.24E-03			
	5	27.16	1.36	0.02	28.54	5.90	13.01	2.19	2.19E-03			

lbs ai handled = (kg ai *2.2046 to convert to lbs)
N/A - Mixer/Operator did not handle the test product during this replicate.

Table 13. Total Dermal Exposure for Each Worker at Trial 4 (Apron® 25W).

Worker	Rep.	Total Dosimeter Residue Conc. (µg)	Face/Neck Residue Conc. (µg)	Hands Residue Conc. (µg)	Total Dermal Residue Conc. (µg)	kg ai handled	lbs ai handled	Dermal Exposure (µg/lb ai handled)	Dermal Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	275.25	8.70	619.01	902.96	6.12	13.49	66.92	6.69E-02	0.0292	0.0215	0.024
	2	58.34	1.79	97.03	157.17	6.12	13.49	11.65	1.16E-02			
	3	49.66	0.51	39.80	89.97	6.12	13.49	6.67	6.67E-03			
	4	57.15	0.51	273.76	331.42	6.12	13.49	24.56	2.46E-02			
	5	363.51	1.90	119.70	485.10	6.12	13.49	35.95	3.60E-02			
Bagger	1	45.99	1.77	48.80	96.56	5.67	12.50	7.72	7.72E-03	0.0163	0.0148	0.00764
	2	224.56	2.58	16.80	243.94	5.76	12.70	19.21	1.92E-02			
	3	161.42	1.44	41.50	204.36	5.96	13.14	15.55	1.56E-02			
	4	315.11	1.31	23.00	339.42	5.59	12.32	27.54	2.75E-02			
	5	132.14	1.46	40.20	173.80	6.94	15.30	11.36	1.14E-02			
Sewer	1	26.01	1.15	16.70	43.86	5.67	12.50	3.51	3.51E-03	0.0048	0.0043	0.00217
	2	90.02	1.43	0.02	91.47	5.76	12.70	7.20	7.20E-03			
	3	49.53	1.02	29.30	79.85	5.96	13.14	6.08	6.08E-03			
	4	52.08	1.91	15.40	69.39	5.59	12.32	5.63	5.63E-03			
	5	13.38	1.57	12.40	27.35	6.94	15.30	1.79	1.79E-03			

lbs ai handled = (kg ai *2.2046 to convert to lbs)

Table 14. Total Exposure (mg/lb ai handled) for Each Worker at Trial 1 (Apron® FL).

Worker	Rep.	Inhalation Exposure (mg/lb ai handled)	Total Dermal Exposure (mg/lb ai handled)	Total Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.000901	1.19E-03	0.00209	0.0102	0.00558	0.0141
	2	0.000182	0.00363	0.00381			
	3	0.000182	7.53E-03	0.00771			
	4	0.000182	2.34E-03	0.00252			
	5	0.000587	3.45E-02	0.0351			
Bagger	1	2.70E-04	5.21E-03	0.00548	0.00729	0.00677	0.00347
	2	3.33E-03	9.90E-03	0.0132			
	3	7.14E-04	6.71E-03	0.00743			
	4	0.000185	5.54E-03	0.00572			
	5	0.000233	0.00438	0.00462			
Sewer	1	7.02E-03	1.44E-01	1.51E-01	0.0735	0.0612	0.0496
	2	4.15E-02	4.82E-02	0.0897			
	3	2.75E-02	3.69E-02	0.0644			
	4	8.89E-03	2.33E-02	0.0322			
	5	4.79E-03	2.58E-02	0.0306			

Table 15. Total Exposure (mg/lb ai handled) for Each Worker at Trial 2 (Apron® FL).

Worker	Rep	Inhalation Exposure (mg/lb ai handled)	Total Dermal Exposure (mg/lb ai handled)	Total Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.000928	0.0999	1.01E-01	0.072	0.0671	0.0277
	2	5.29E-03	0.0866	0.0919			
	3	2.33E-03	0.0345	3.69E-02			
	4	0.000219	0.0809	0.0812			
	5	2.80E-04	0.0489	0.0491			
Bagger	1	0.00032	1.22E-02	0.0125	0.00664	0.00583	0.00377
	2	0.000219	3.76E-03	0.00398			
	3	0.000261	6.04E-03	0.0063			
	4	0.00103	6.58E-03	7.61E-03			
	5	0.000226	2.61E-03	0.00283			
Sewer	1	1.12E-03	7.17E-03	0.00829	0.00442	0.00403	0.00229
	2	5.77E-04	3.95E-03	4.52E-03			
	3	1.55E-03	8.52E-04	2.40E-03			
	4	2.52E-04	3.40E-03	3.65E-03			
	5	2.31E-04	3.01E-03	3.24E-03			

Table 16. Total Exposure (mg/lb ai handled) for Each Worker at Trial 3 (Apron® FL).

Worker	Rep.	Inhalation Exposure (mg/lb ai handled)	Total Dermal Exposure (mg/lb ai handled)	Total Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.000219	1.49E-02	0.0151	0.0142	0.0121	0.00833
	2	0.000156	2.18E-02	0.022			
	3	N/A	N/A	N/A			
	4	0.000195	5.19E-03	0.00539			
	5	N/A	N/A	N/A			
Bagger	1	0.000328	1.04E-02	0.0107	0.0148	0.0142	0.00479
	2	0.000274	9.55E-03	0.00983			
	3	0.000364	1.81E-02	0.0184			
	4	0.000432	1.38E-02	0.0142			
	5	0.000224	2.06E-02	0.0209			
Sewer	1	0.000255	1.77E-03	0.00203	0.00455	0.00334	0.00485
	2	0.000274	1.29E-02	0.0132			
	3	0.000361	2.16E-03	0.00253			
	4	0.000306	2.24E-03	0.00254			
	5	0.000223	0.00219	0.00242			

N/A - Mixer/Operator did not handle the test product during this replicate.

Table 17. Total Exposure (mg/lb ai handled) for Each Worker at Trial 4 (Apron® 25W).

Worker	Rep.	Inhalation Exposure (mg/lb ai handled)	Total Dermal Exposure (mg/lb ai handled)	Total Exposure (mg/lb ai handled)	Mean (mg/lb ai handled)	Geometric Mean (mg/lb ai handled)	Standard Deviation (mg/lb ai handled)
Mixer/Op	1	0.00862	6.69E-02	7.55E-02	0.0353	0.0275	0.026
	2	1.18E-02	1.16E-02	2.34E-02			
	3	1.19E-03	6.67E-03	7.86E-03			
	4	5.56E-04	2.46E-02	2.51E-02			
	5	8.79E-03	0.036	4.47E-02			
Bagger	1	6.73E-03	7.72E-03	1.45E-02	0.0178	0.017	0.00629
	2	3.43E-04	1.92E-02	1.96E-02			
	3	2.50E-04	1.56E-02	1.58E-02			
	4	3.08E-04	2.75E-02	2.78E-02			
	5	0.00019	1.14E-02	1.15E-02			
Sewer	1	4.33E-04	3.51E-03	3.94E-03	0.0055	0.0049	0.00253
	2	4.07E-04	7.20E-03	7.61E-03			
	3	1.91E-03	6.08E-03	7.99E-03			
	4	3.20E-04	5.63E-03	5.95E-03			
	5	2.03E-04	1.79E-03	1.99E-03			

Table 18. Comparison of the Registrant's and Versar's Calculated Exposure Values.

	Registrant's Values		Versar's Values	
	Average Dermal Exposure (mg/kg ai handled)	Average Inhalation Exposure (mg/kg ai handled)	Average Dermal Exposure (mg/kg ai handled)	Average Inhalation Exposure (mg/kg ai handled)
Apron FL (15 reps)				
Mixer/operator	6.10E-02	7.75E-04	0.0749	0.00198
Bagger	1.82E-02	5.18E-04	1.99E-02	1.24E-03
Sewer	3.46E-02	5.60E-03	4.67E-02	1.39E-02
Apron 25W (5 reps)				
Mixer/operator	0.0427	6.96E-03	6.43E-02	1.36E-02
Bagger	3.40E-02	7.63E-04	3.59E-02	3.45E-03
Sewer	0.0101	0.000889	1.07E-02	0.00144

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head,
Occupational Exposure Assessment Section

Date

Compliance Checklist

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

875.1300

- *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).* It is uncertain whether this criterion was met.

- A *trapping efficiency test for the monitoring media chosen must be documented.* This criterion was not met. There was no trapping efficient test documented 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.* It is uncertain whether this criterion was met. There was no specific mention of any breakthrough tests being conducted on the air filters used in the study. However, an air tube was connected inline with the air filters and the majority of them showed non-detectable levels of residue. Therefore, the glass fiber filters were effective at trapping the metalxyl residues.

- 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 met. With each set of samples extracted, a control and only two laboratory fortification samples were run concurrently. This resulted in more than 7 laboratory fortified samples for each fortification level for each matrix. All recoveries 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.* It is not certain if this criterion was met. There was no specific mention of a storage stability test being done for this study. However, there was mention that the second set of dosimeters which were collected after the original sampling was completed, were used to verify stability. The registrant did not provide sufficient information on sampling and analysis dates, and duration of storage for each sample. All of the average field fortification recoveries for the second set of dosimeters were above 65%.

- *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.* These criteria were mostly met. The personal monitoring pumps were calibrated at only 1.5 L/min, but they were capable of sustaining this airflow for at least 4 hours. Air flow was measured at the beginning and end of each 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 problems with poor recoveries at Trial 1 were not due to the air sampling media, but rather due to the use of acetone which melted the cassette which held the air sampling media.

- *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.* This criterion was not met. The registrant stated that after collection of the air samples, they placed in a pre-labelled reclosable bag.

- *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.* This criterion was met.

- *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was met. Residues for each matrix were corrected for field recoveries <100% by the registrant. Versar only corrected residue data for field recoveries < 90%.

- *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 met.

- *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.

875.1100

- *The monitoring period should be of sufficient duration to result in reasonable detectability on dosimeters. Monitoring should be conducted before residues have dissipated beyond the limit of quantification. Baseline samples should be collected before the exposure activity commences.* These criteria were met.

- *The sampling techniques (e.g., patches, whole-body dosimeters, hand rinse, gloves, fluorescent tracer) should be appropriate to the activities being monitored. The construction materials and location (i.e., inside or outside clothing) of monitoring devices and numbers (e.g., patches) should be appropriate to the use scenario. Hand rinse solutions must be appropriate to the pesticide being evaluated (i.e., selection of aqueous surfactants vs. isopropanol or other solutions, based on the physical chemical properties of the pesticide being evaluated.* These criteria were met. Dermal samples were collected using inner dosimeters, handwashes and face/neck wipes.

- *Sufficient control samples should be collected.* This criterion was probably not met. According to the guidelines, at least 7 samples per medium per fortification level should be collected to validate the study and at least 3 fortified samples per fortification level per medium should be used for the storage stability study and field fortification samples. Only two fortified samples per medium per fortification level were used to validate the study. There were at least 3 fortified samples per fortification level per medium used for the field fortification samples.

- *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analyses. Information of storage stability should be provided.* This criterion was partially met. The length of time samples were stored was not reported. A storage stability test was not discussed in the Study Report. However, it was stated that samples were kept cold after collection and on through to analysis to minimize the deterioration and loss of analytes. Not all field fortification recoveries provided support for the stability of metalaxyl in each of the matrices. It is preferable that field fortification recoveries be > 70% and the field fortification data presented in this study were not all above this percentage.

- *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery) and limit of quantification (LOQ) should be provided.* These criteria were mostly met. Method validation results were provided. Matrix LODs and LOQs were not provided. However, a minimum quantifiable level (MQL) value was provided. It was assumed that this value was the same as an LOQ.

- *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study.* This criterion was met.

- *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was met. Residues for each matrix were corrected for field recoveries < 100% by the registrant. Versar only corrected residue data for field recoveries < 90%.