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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 11, 2002

Memorandum

SUBJECT: Assessment of Worker Exposure to a Commercial Seed Treatment in Seed-Treating Plants

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

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

DP Barcode: D281597

EPA MRID No: 44731501

Attached is a review of the applicator exposure during dry seed treatment of grain with Vitavax® RS Flowable which was submitted by Uniroyal Chemical, Ltd. This review was completed by Versar, Inc. on June 02, 1999, under supervision of HED. It has undergone secondary review in the HED and has been revised to reflect Agency policies.

Executive Summary

The purpose of this study was to quantify inhalation and dermal exposure to workers operating commercial seed treating equipment using the active ingredients lindane, thiram and carbathiin, formulated as Vitavax® RS. The potential exposure was assessed during seed treatments of canola, mustard and cole crops. Although the study data do not meet all of the criteria specified in Subdivision K (currently referred to as Series 875 .1100 and 875.1300 Group B), the data are of sufficient scientific quality to be used to determine exposure to workers operating seed treating equipment.

Summary

This study was conducted at three seed-treatment plants in Ontario, Canada. These facilities were representative of large, medium, and samll seed treating operation with diffrent seed treatement equipment. A total of nine replicates were monitored in the study. Four of the replicates were monitored as loader/applicators and the remaining five workers were monitored as seed handlers. The sampling period consisted of one 8 hour work day.

Site 1 treated 165000 lbs of seed per day for 60 days/year. Five workers were evaluated at this site. These workers included a loader/applicator, a bagger, a sewer and two stacker/forklift drivers. Site 2 treated 22000 lbs of canola seed per day for 25 days/year. Three workers, representing a normal crew involved in the treatment of canola seeds were monitored. Site 3 treated 22000 lbs of canola seed for 42 days/year. One worker performed the entire process of seed-treatment. The maximum application rate for seed treatment of approximately 2.25 L formulated product per 100 kg (220 lbs) seed was applied at each site. Various type of PPE was used at each site, Table 1 represents a summary of PPE used.

Site/Rep#	Job	PPE	Gloves	Respirator
Site 1 - Camrose				
1	Loader /Applicator	coveralls	nitrile	full face
2	Sewing bags		latex	full face
3	Catching &Stacking bags		rubber	none
4			rubber	
5	Filling bags		latex	full face
Site 2 - Kelsey				
6	All tasks except driving forklift	coveralls	nitrile	mouth/nose respirator when filling, sewing, and stacking bags
7	All tasks	coveralls	nitrile	none
8	All tasks except pumping chemical		none	mouth/nose respirator when filling, sewing, and stacking bags
Site 3 - Forestburg				

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Site / Rep #	Job	PPE	Gloves	Respirator
9	All tasks	coveralls	nitrile	none

Dermal exposure was monitored using facial washes, hand washes, glove washes, ten dosimeter patches for Rep 1 at site 1, and full body dosimeters. The whole body dosimeter consisted of a one piece 100 percent cotton long underwear garment and a pair of 100 percent cotton socks worn underneath work clothes. Inhalation exposure was monitored using sampling tubes containing XAD and glass fiber filters.

Field fortified samples were run in order to demonstrate the stability of the test chemical, as well as extraction efficiency. The field spikes were fortified at two levels using Vitavax® RS Flowable and lindane/carboxin analytical standards for every matrix used in the study. The lindane recoveries ranged from 30 to 688 percent. The carbathiin recoveries ranged from 9 to 52 percent. Results appeared to suggest that lindane may have absorbed to the container walls and carbathiin may have hydrolyzed in the soap solutions. High recoveries for lindane and the low recoveries for carbathiin in the air samples were observed .

Conclusions

The samples were not analyzed for thiram because a viable analytical method is currently not available for the various matrices used in this exposure study. Instead, an estimate of the exposure to thiram was done based on the ratio of thiram to lindane (48.7 percent lindane : 6.43 percent thiram).

The largest amounts of lindane were found on the gloves, the second largest amounts were found on the dosimeters (specifically the lower arms, upper arms and lower torso), then the socks and then the hand wash/rinses. The gloves of the loader/applicators resulted in lindane levels of 463-1623 µg per kg ai (i.e. 211-738 µg per lb ai) handled, while hand rinse samples resulted in 7-28 µg per kg ai (i.e. 3.2-12.7 µg per lb ai) handled. Site 1 seed handlers hand wash levels, when gloves were worn, resulted in levels of 0.2-0.4 µg per kg ai (i.e. 0.09-0.18 µg per lb ai) handled. The seed handler who wore no gloves had levels of 13.8 µg per kg ai (i.e. 6.3µg per lb ai) handled.

Attachment

Attachment

Versar Review Memo dated June 2, 2002

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Versar inc.

MEMORANDUM

TO: Seyed Tadayon

cc: 3771.101
D. Baxter
J. Becker

FROM: Teri Schaeffer/Susan Anderson

DATE: June 2, 1999

SUBJECT: Review of *Assessment of Worker Exposure to a Commercial Seed Treatment in Seed-Treating Plants (Vitavax® RS Flowable - Canola - Alberta, Canada)* (MRID No. 447315-01)

This report reviews the human exposure study entitled *Assessment of Worker Exposure to a Commercial Seed Treatment in Seed-Treating Plants (Vitavax® RS Flowable - Canola - Alberta, Canada)*, submitted in support of the registration requirements for the pesticide, Vitavax®. The requirements for this study were specified by the U.S. Environmental Protection Agency, under OPPTS Series 875 Group A (875.1100 and 875.1300 guidelines for indoor/outdoor dermal exposure and inhalation exposure) of the Pesticide Assessment Guidelines. The following information may be used to identify this study:

Title:	*Assessment of Worker Exposure to a Commercial Seed Treatment in Seed-Treating Plants (Vitavax® RS Flowable - Canola - Alberta, Canada)*, 272 pages.
Sponsor:	Rob Dupree Uniroyal Chemical, Ltd. Box 250, 25 Erb Street Elmira, ON N3B 3A3
Performing Laboratory: (Field Study)	Maureen D. Avakian Environmental Technologies Institute, Inc. (ETI) P.O. Box 13127 Research Triangle Park, NC 27709, USA
Analytical Laboratory:	Gary W. Bruns Enviro-Test Laboratories (ETL) 9936 67th Avenue Edmonton, Alberta T6E 0P5, Canada
Study Director:	Rob Dupree (i.e. 211-738 µg per lb ai) Uniroyal Chemical, Ltd.
Principal Authors:	Robert McK. Bird, Ph.D. Maureen D. Avakian, B.A.
Study Completion Date:	33668
Identifying Codes:	MRID # 447315-01; Uniroyal Study Number CPR-91001; Field Experiment Number ETI-911022.

Executive Summary

This report reviews a study submitted by Uniroyal Chemical quantifying dermal and inhalation exposure to the insecticide Vitavax® RS Flowable experienced by nine workers at three seed-treating facilities. The test substance is a water-based flowable seed treatment formulation containing three active ingredients, lindane (48.7 percent), thiram (6.43 percent), and carbathiin (a.k.a. vitavax and carboxin) (3.34 percent).

Key findings were: (1) the highest dermal exposure was to the gloves, followed by the lower arms, and (2) gloves provide approximately 98 percent protection.

The study is only partially compliant with OPPTS 875 Group A test guidelines. Key non-compliance and other issues identified included the following: (1) the field and analytical phases of the report lacked detailed descriptions of the sampling and analysis process, especially for field fortification samples, and also recoveries were provided in the tables with little or no discussion of table parameters, (3) insufficient number of replicates per test site, (2) details regarding the preparation and collection of field fortification samples and control samples were not provided, (4) laboratory recoveries were somewhat variable (i.e., 71 percent to 136 percent for lindane and 60 percent to 140 percent for carbathiin over all matrices), and (5) field fortified recoveries for all four matrices were extremely variable. Field soap sample recovery values ranged from 10 percent to 161 percent for lindane and showed 0 percent recoveries for carbathiin. Field pad sample recovery values ranged from 7 percent to 390 percent for lindane and 13 percent to 582 percent for carbathiin. Field fortified air sampling tube recovery values ranged from 30 percent to 688 percent for lindane and from 9 percent to 52 percent for carbathiin. According to the study author, "variations this great are not unusual for field-fortified matrices, and are attributed to the lack of solubility of the active ingredients in the spiking diluent." Another issue of concern is that sample receipt dates, extraction dates and analysis dates were not provided in the Study Report, and no mention was made in the Study Report of an LOD value. The LOQ was defined, however.

Study Background

Vitavax® RS Flowable is a systemic liquid seed protectant for canola, rapeseed, mustard and cole crops. It is a water-based flowable seed treatment formulation which contains the three active ingredients lindane (48.7 percent), thiram (6.43 percent), and carbathiin (a.k.a. vitavax and carboxin) (3.34 percent). The active ingredient lindane (CAS No. 58-89-9) is an insecticide and the active ingredients thiram (CAS No. 137-26-8) and carbathiin (CAS No. 5234-68-4) are fungicides. This product is registered for the protection of seeds and emerging seedlings only.

This study examined potential dermal and inhalation exposures of Vitavax® RS Flowable experienced by nine workers operating seed-treating equipment in three representative seed-treating plants. Uniroyal Chemical, Ltd. sponsored the study. Environmental Technologies Institute, Inc. presided over the field phase of the study and Enviro-Test Laboratories conducted the analytical phase of the study. Samples were collected between April 30, 1991 and May 2, 1991.

Study Replicates

This study was conducted at three seed-treatment plants in Ontario, Canada. The three facilities were representative of large, medium and small seed-treating operations and all sites used different seed treatment equipment. A total of nine replicates were monitored in the study. The guidelines suggests that at least 15 replicates be examined per study. Four of the replicates were categorized as loader/applicators and the remaining five workers were categorized as seed handlers. All workers evaluated in this study were experienced in performing the work functions associated with the treatment of high volumes of seed. Prior to participation in the study, each worker signed a consent form and was examined by a physician to insure that the worker was in good health. The sampling period consisted of one 8 hour work day.

Site 1 was a large facility located in Camrose, Alberta, Ontario. This facility usually treats 3000 25 kg-bags of seed per day for 60 days/year. Five workers were evaluated at this site. These workers represent a normal crew involved in the treatment of canola seeds at this facility, and included a loader/applicator, a bagger, a sewer and two stacker/forklift drivers. Rep 1 was the loader/applicator, Rep 5 was the bag filler, Rep 2 sewed the bags shut and applied the label, and Reps 3 and 4 shared the responsibilities of stacking the bags and driving the forklift. Reps 1, 2 and 5 wore respirators.

Site 2 was a medium sized facility located in Kelsey, Alberta, Ontario. Usually 400 25-kg bags of canola seed are treated per day for 25 days/year at this facility. A total of three workers, representing a normal crew involved in the treatment of canola seeds at this facility, were evaluated at this site (Reps 6 through 8). Reps 6 and 7 applied the chemical to the seeds, Reps 6, 7 and 8 filled the bags, sewed the bags shut, attached the labels and stacked the bags, and Reps 7 and 8 drove the forklift. Reps 6 and 8 wore respirators.

Site 3 representing a small seed treating facility, was located in Forestburg, Alberta, Ontario. Usually 400 25 kg-bags of canola seed are treated per day for 42 days/year at this facility. The crew involved in treating seed at this site consisted of one worker (Rep 9). This

worker performed the entire process of seed-treatment.

Material and Application Information

The maximum application rate for seed treatment of approximately 0.562 L of formulated product per 25 kg seed or 2.25 L formulated product per 100 kg seed was applied at each site. Treated seed samples were collected twice at each test site to verify the actual application rate. Measurements at site 3 were approximate because the seed treating equipment at this site is calibrated only once/year. The seed treater at site 2 utilized a pump to dispense the test chemical which had been calibrated by the manufacturer. No mention is made as to when this calibration was performed. Table 1 shows the actual percent of the target application rate which was applied at each site. The seed sample percent target rates were calculated using the average of the reported percentage for the three active ingredients.

Table 1. Percent of Target Application Rate

	Site One	Site Two	Site Three
Kg Seed Treated	42600	14642	6250
Liters of Formulated Product Used	962.5	340	142
% of Target Rate			
Field Reading Basis	101.9	103.3	101.0
Sample 1 Analysis	101.7	106.8	94.0
Sample 2 Analysis	102.9	80.4	100.6

At site 1, the formulated product was transferred to a mixing/dispensing tank and the tote was triple rinsed with 75 kg water which was also added to the tank. A Gustafson Accu-Treat 8x10 film coater was used to blend the seed and the test chemical/water mixture. The application rate was determined by the rate the seed and the diluted test product were added to the tank. The mixing/dispensing tank contained two internal pumps. One for the seed and the other for the formulated test product. The operation rates (RPM) of these pumps were pre-determined and verified by results during operation. The RPM rate for each pump was set at the beginning of the treatment process and monitored throughout the day.

The seed-treating machines at sites 2 and 3 were filled with seed; the seed was weighed and an appropriate weight of Vitavax ® RS Flowable was added to the blender to treat the seed. An internal scale was used at site 2. The seed treater at site 2 was a modified fertilizer blender with a pump for the test chemical and a grain auger to load the seed. The blender unit contained a digital read-out scale which had been calibrated by the manufacturer. If necessary, minor adjustments could be made according to results during operation. The seed treater at site 3 was a Gustafson seed treater with a pump for the test chemical and a grain auger to load the seed. The blender unit contained an external scale which is calibrated on the first day of seed treatment each year by catching and measuring the chemical pumped while a set number of bags of seed passed through the apparatus. A table providing the manufacturers, model numbers, and serial numbers was provided on page 16 of the Study Report.

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Personal Protective Equipment

The label specifies use of rubber or butyl rubber gloves when handling Vitavax ® RS Flowable. The label also recommends use of goggles. Table 2 provides a summary of job description and protective clothing worn for each replicate. There was no mention of eye-protection worn by any of the workers.

Table 2. Summary of Job Descriptions and PPE Worn

Site / Rep No.	Job	Protective Clothing	Gloves	Respirator	Personal Clothing
Site 1 - Camrose					
1	Loader / Applicator	Tyvek® coveralls	nitrile	Airstream® full face	tennis shoes, blue jeans, flannel shirt
2	Sewing bags	A.W.P. coveralls	latex (sewer type)	Airstream® full face	tennis shoes, sweat pants, tee shirt
3	Catching & Stacking bags	A.W.P. coveralls	heavy rubber	none	tennis shoes, blue jeans, tee shirt
4	Catching & Stacking bags	A.W.P. coveralls	heavy	none	tennis shoes, sweat pants, tee shirt
5	Filling bags	A.W.P. coveralls	latex	Airstream® full face	tennis shoes, blue jeans, tee shirt
Site 2 - Kelsey					
6	All tasks except driving forklift	twill coveralls	nitrile gloves when pumping chemical	mouth/nose respirator when filling, sewing, and stacking bags	leather boots w/o laces, blue jeans, flannel shirt

Table 2. Summary of Job Descriptions and PPE Worn (continued)

Site / Rep No.	Job	Protective Clothing	Gloves	Respirator	Personal Clothing
Site 2 - Kelsey (continued)					
7	All tasks	twill coveralls	nitrile gloves when pumping chemical	none	tennis shoes, blue jeans, flannel shirt, jacket in the morning
8	All tasks except pumping chemical	coveralls	none used	mouth/nose respirator when filling, sewing, and stacking bags	leather boots w/o laces, blue jeans flannel shirt, jacket
Site 3 - Forestburg					
9	All tasks	coveralls	nitrile gloves when adjusting equipment	none	leather boots w/laces blue jeans, tee shirt flannel shirt jacket

Exposure Monitoring

During this study, workers were monitored for dermal and inhalation exposure during the loading, application, bagging, sewing, and stacking of canola seeds treated with Vitavax ® RS Flowable. The monitoring period lasted for one 8-hour work day. Table 3 provides a summary of the sampling events for each worker.

Dermal exposure monitoring was conducted using facial washes/rinses, hand washes/rinses, glove washes/rinses, ten dosimeter patches for Rep 1 at site 1, and full body dosimeters. The whole body dosimeter consisted of a one piece 100 percent cotton long underwear garment and a pair of 100 percent cotton socks worn underneath work clothes.

Facial washes and rinses were obtained by wiping the worker's neck, forehead and face with a gauze pad moistened with 5 mL 1 percent Ivory hand soap solution. Rinses were conducted using a gauze pad moistened with 5 mL of distilled water. The wipes were placed in a Zip-Lock® bag and placed in a cooler with ice.

Glove wash and rinses consisted of workers dipping their gloved-hands hands, into 500 mL of 1 percent Ivory soap solution contained in a Zip-Lock® bag. The worker then rinsed their gloves in another bag containing 500 mL distilled water. Hand wash and rinses were collected in

the same manner. The washes and rinses were placed in a cooler with ice.

For the one replicate wearing a Tyvek® suit, the ten dosimeter patches which were worn on the outside of the coveralls were removed from the suit at the end of the work day. Each patch was placed in an individual Zip-Lock® bag. Then the bags were rolled and placed together in one Zip-Lock® bag and stored in a cooler with ice.

The full body dosimeters were collected at the end of the work day. The workers went to a clean room to remove the dosimeters. The socks were placed in a labeled Zip-Lock® bag. Each pair of cotton long underwear was cut at the elbows and knees while still on the worker in order to distinguish correctly between upper and lower portions. The upper arm and upper leg sections were bagged separately from the lower arm and lower leg sections. The rest of the underwear was removed and cut into pieces and bagged and then placed in coolers with ice.

Inhalation exposure monitoring was conducted using sampling tubes containing XAD and glass fiber filters. These tubes were connected via plastic tubing to sampling pumps. The air sampling pumps were operated at a flow rate of 1 L/minute to obtain estimated unprotected inhalation exposure. The sampling tubes were removed and placed in a labeled Zip-Lock® bag. It is unclear if the tubes were sealed before placement in the Zip-Lock® bags. Detailed information on the placement and collection of these sample tubes was not provided in the Study Report.

Table 3 Summary of Sampling Events per Replicate at Each Site.

Site	Rep.	Sample Collected	Time Period
One	1, 2, 3, 4, 5	Facial wash/rinse	Beginning of work period Beginning of lunch break End of work period
	1[a], 2, 3, 4, 5	Hand wash/rinse	Beginning of work period Beginning of lunch break End of lunch break Beginning of 1st afternoon break End of 1st afternoon break End of work period
	1[a], 2, 3, 4, 5	Glove wash/rinse	Beginning of lunch break Beginning of 1st afternoon break End of work period
	1, 2, 3, 4, 5	Full body dosimeters	End of work period
	1	Dosimeter patches	End of work period
	1, 2, 3, 4, 5	Inhalation sampling tubes	Beginning of lunch break End of work period
	1, 2, 3	Gloves	End of work period

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Table 3. Summary of Sampling Events per Replicate at Each Site (continued)

Site	Rep.	Sample Collected	Time Period
Two	6, 7, 8	Facial wash/rinse	Beginning of work period Beginning of lunch break End of work period
	6[b], 7, 8	Hand wash/rinse	Beginning of work period Beginning of lunch break End of lunch break Beginning of 1st afternoon break End of 1st afternoon break End of work period
	6, 7	Glove wash/rinse[c]	Beginning of lunch break Beginning of 1st afternoon break End of work period
	6, 7, 8	Full body dosimeters	End of work period
	6, 7, 8	Inhalation sampling tubes	Beginning of lunch break End of work period
	6	Gloves	End of work period
Three	9	Facial wash/rinse	Beginning of work period Beginning of first morning break End of work period
	9	Hand wash/rinse	Beginning of work period Beginning of 1st morning break End of 1st morning break End of work period
	9	Glove wash/rinse	End of work period
	9	Full body dosimeters	End of work period
	9	Inhalation sampling tubes	Beginning of 1st morning break End of work period
	9	Gloves	End of work period

a Rep 1 did not take an afternoon break, therefore, samples were not collected for Rep 1 at beginning and end of 1st afternoon break.
b Rep 6 returned to work without providing sample at end of 1st afternoon break.
c No gloves were worn by Rep 8.

Quality Assurance & Quality Control (QA/QC)

Formulation testing

The commercial formulation used was obtained from Uniroyal Chemical Ltd.. The original sample had undergone 2 months of stability testing; the results of which are reported in

Appendix D of the Study Report (Appendix D, Section 3,Tables 18 - 21). It was determined that the samples were to be extracted no later than 5 to 6 weeks after receipt in order to avoid storage degradation. It is unclear why a 5 to 6 week timeframe was chosen, as results of samples stored for 2 months showed recoveries consistenly less than 80 percent. Sample extraction and analysis dates were not reported. Duplicate sample analysis of the formulated product confirmed that the product contained 3.34 ± 0.23 percent carbathiin, 6.43 ± 1.55 percent thiram, and 48.73 ± 2.37 percent lindane.

Sample History

Samples were collected between April 30 and May 2, 1991. Dated sample analysis documentation from Enviro-Test Laboratories was not provided. Dates for laboratory sample receipt, extraction and analysis are not known.

Twenty-seven facial wash and twenty-seven facial rinse samples were analyzed. Twenty-one glove wash and twenty-one glove rinse samples were analyzed. Forty-nine hand wash and forty-nine hand rinse samples were analyzed. Nine full body dosimeters were analyzed resulting in a total of sixty-three samples (one pair socks per worker plus each dosimeter cut into six sections totaling 63 samples in all). Eighteen inhalation sampling tubes were analyzed. Five pairs of gloves were analyzed. Ten dosimeter patches were analyzed.

Sample Storage and Handling

Samples were hand delivered by ETI personnel to the Enviro-Test Laboratory at the end of each sampling day. Samples were stored in coolers with ice for transport. Enviro-Test Laboratories stored the samples in walk-in refrigerators until analysis. According to the study protocol, a chain of custody for the transfer of the samples was to be fully documented. This chain of custody was not provided. It was also noted that daily refrigerator/freezer temperature logs were kept. All the samples with the exception of the soap solution samples and rinses, were stored in a walk-in freezer (<-15°C). The soap solution samples and the rinses were stored in a walk-in cooler (<3°C).

Analytical Methodology

All samples in the study were analyzed by Enviro-Test according to proprietary method Protocol No. UNR-1: Analytical Method for the Quantification of Lindane (gamma BHC) and Carboxin (Carbathiin) in Cotton Material, Water, Soap Solution and Air Filters. This method was provided in Appendix A of the Study Report. A Hewlett PackardModel 5890 GC-MSD fitted with a DB1701 column was used for all analyses. More detailed information on the GC/MS instrumentation parameters was provided on page 93 of the Study Report. Collected samples were not analyzed for thiram because a viable analytical method is currently not available for the various matrices used in this exposure study. Instead, an estimate of the exposure to thiram was made based on the ratio of thiram to lindane (48.7 percent lindane : 6.43 percent thiram).

The rinse/wash samples were shaken and aliquots removed. Equal volumes of 30 percent dichloromethane (DCM)/hexane were added to the aliquots. The samples were shaken and

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centrifuged. Using a syringe, only the DCM/hexane layers were removed and dried through sodium sulfate. This extraction procedure was repeated using the same aliquots and the combined organic extracts were concentrated on a rotary evaporator. The final extract was brought down to 1mL using nitrogen. The extraction and cleanup for the soap solutions (washes) were modified before the analysis of the samples began. An aliquot of the soap solutions (washes) was taken and combined with NaCl and a DCM/Ethyl Acetate (ETOAC)/hexane mixture (3:1:6). The samples were shaken and centrifuged. Using a syringe, only the DCM/ETOAC/hexane layers were removed and dried through sodium sulfate. This extraction procedure was repeated using the same aliquots and the combined organic extracts were concentrated on a rotary evaporator. The samples were taken down to their final volumes using a stream of nitrogen. The wash sample extracts were cleaned-up using a column of deactivated florisil.

The pads, gloves, and cotton material samples were soaked in 30 percent DCM/hexane, mixed and allowed to stand for 30 minutes. A solvent aliquot was decanted and concentrated on a rotary evaporator. The filters were analyzed as two samples. The first sample being the front part which contains the glass filter and XAD resin. The second sample was the back part of the filter. This was done to check for any break through. Both portions were desorbed using toluene by soaking and sonicating.

Method Validation Information

Method validation for spiked recoveries in soap solutions and air sampling tubes were reported to have been performed prior to sample analysis (Appendix D, pg. 152 of the Study Report). There was no mention of method validation for the gauze pads and cotton materials. Validation spikes were performed at two fortification levels in duplicate. According to Series 875 guidelines, acceptable recovery values are 70-120 percent.

The mean recovery of lindane in soap solutions was 101 percent (range 98-103 percent, standard deviation = $\pm$ 2 percent). Mean recovery of carbathiin in soap solutions was 90 percent (range 73-110 percent, standard deviation = $\pm$ 17). Mean recoveries of lindane and carbathiin from spiked air sampling tubes were 87 percent ± 8.8 and 90 percent ± 4.8, respectively. All recoveries were within the validation range (see Table 4 below). It was not clear if the in-house method validation air samples were exposed to a flow of air. Details on the process used to spike the method validation samples were not provided.

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Table 4. Method Validation Results

Matrices	LOQ (µg)	Fortification Range (µg)	Lindane Mean Recovery (%)[1]	Carbathiin Mean Recovery (%)
Air Filter	1	1.25 and 6.25	87± 8.8	90 ± 4.8
Soap Solution	1	6.25 and 25	101± 2	90 ± 17

1 Two samples analyzed per fortification level.

Limit of Detection (LOD) & Limit of Quantitation (LOQ)

The limit of quantitation is determined from the signal to noise for the detector and the magnitude of co-extractive peaks. The limit of quantitation was 1 µg for all matrices. Although the soaps were fortified at 5µg the minimum quantifiable limit was found to be 1µg. For samples in which low concentrations of residues could not be quantified, one-half of the limit of quantitation (LOQ) was used as an estimate of the residue. A limit of detection (LOD) was never mentioned in the Study Report. However, at the bottom of each Table in Section 3 of Appendix D, there is a row titled Detection Limit. It appears as though the study authors are using LOD and LOQ synonymously.

Laboratory Recovery

Laboratory-fortified samples of each matrix used in the study were analyzed concurrently with field samples to monitor procedural recoveries. Fortification levels of 1 to 25 µg were used. The recovery data are presented in Tables 14 though 17 in Appendix D, Section 3 of the Study Report. The average percent recovery of lindane and carbathiin in laboratory-fortified soap solutions was 98 percent and 85 percent, respectively (see Table 14, Appendix D, Addendum #2 of the Study Report). The recoveries ranged from 71 to 132 percent for lindane and 60 to 115 percent for carbathiin. The average recovery of lindane and carbathiin in laboratory-fortified pads was 100 percent and 99 percent, respectively (see Table 15, Appendix D, Section 3 of the Study Report). The recoveries ranged from 91 to 112 percent for lindane and 84 to 112 percent for carbathiin. The average percent recovery of lindane and carbathiin in laboratory-fortified cotton/glove samples was 103 percent and 90 percent, respectively (Table 16, Appendix D, Section 3 of the Study Report). The recoveries ranged from 74 to 136 percent for lindane and 73 to 125 percent for carbathiin. The average recovery of lindane and carbathiin in laboratory-fortified air sampling tubes was 107 percent and 130 percent, respectively (Table 17, Appendix D, Section 3 of the Study Report). Recoveries ranged from 99 to 112 percent for lindane and 112 to 140 percent for carbathiin.

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Controls & Fortified Sample Recoveries

Control samples were collected at the test sites. The handling and placement of these samples at the test site was not discussed in the Study Report. A control air sampling tube, cotton pad and aliquot of soap solution were collected at site 1. Only control soap solution samples were collected at sites 2 and 3. Therefore, a total of three control soap solution samples, one air sampling tube and one cotton pad were analyzed. Lindane recoveries of 2.4 µg (site 1) and 3.1 µg (site 3) were detected in the soap solution and 3.8 µg (site 1) was detected in the cotton pad control sample. The remainder of the samples were clean. Carbathiin was not detected.

Field fortified samples were run in order to demonstrate the stability of the test chemical, as well as extraction efficiency. The field spikes were fortified at two levels using Vitavax® RS Flowable and lindane/carboxin analytical standards for every matrix used in the study. Recovery data are presented in Tables 11 through 13 in Appendix D, Section 3 of the Study Report. Collection times were not reported for these samples. It appears that field recovery data for soap solutions, pads, and air sampling tubes indicated a problem with homogeneity of the spiking solutions. Results also appeared to suggest that lindane may have absorbed to the container walls and carbathiin may have hydrolyzed in the soap solutions. See Table 5 of this Study Review. No explanation was provided for the high recoveries of lindane and the low recoveries of carbathiin in the air samples. The lindane recoveries ranged from 30 to 688 percent. The carbathiin recoveries ranged from 9 to 52 percent.

Table 5. Field Fortification Recoveries

Matrix	LOQ (µg)	Number of Samples	Lindane Fortification Level (µg)	Lindane Mean Recovery (%)	Carbathiin Fortification Level (µg)	Carbathiin Mean Recovery (%)
Soap Solutions	1	12	34068317.8	72	23 4.5 27 6.7	0
Pads	1	12	85 17 7.8 1.6	68	5.6 1.1 6.7 1.35	83
Air Sampling Tubes	1	6*	85 17 7.8 1.6	224	5.6 1.1 6.7 1.35	25

* Only six sample results were reported but eight samples were collected. No explanation was provided for the two missing samples from Site Three.

Storage Stability Recovery

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A freezer stability study was done to determine degradation or change over time to cotton pad, air filter, and soap solution samples. Pads, air filters, and soap solutions were spiked and analyzed at Day 0. A second set of pads and air filter samples were spiked and stored at -20°C for two months and then analyzed. A second set of soap solution samples were spiked and stored at 2°C for two months. Six of the test samples were re-extracted and analyzed after the analytical phase for the field samples was finished. The results were provided in Tables 18-21 in Appendix D, Addendum #2 (pages 230 -233) of the Study Report. The results showed that lindane appeared to be unstable in water or soap solutions. It was suggested that lindane would absorb to the container walls and re-equilibrate with time. Carbathiin appeared to be hydrolyzed with the soap solution. The recovery values at 2 months were consistently less than 80 percent.

Results

Exposures were reported by body part for each worker in order to estimate regional deposition of the residues. The laboratory-fortified results were used to adjust the residues reported. This is not standard practice. Field fortification results were highly variable. As was stated earlier, the samples were not analyzed for thiram because a viable analytical method is currently not available for the various matrices used in this exposure study. Instead, an estimate of the exposure to thiram was done based on the ratio of thiram to lindane (48.7 percent lindane : 6.43 percent thiram). Tables with measured and calculated exposures were provided on pages 43 through 61 of the study report. For samples in which low concentrations of residues could not be quantified, one-half of the limit of quantitation (LOQ) was used as an estimate of the residue. The total µg (daily) dermal exposure, total µg dermal exposure per kg ai handled, and total unprotected inhalation exposure was reported for each worker.

The total µg (daily) dermal exposure and micrograms dermal exposure per kg ai handled were broken down into head and neck, body, hands if bared, hands if gloved, total with bare hands, and total with gloved hands. The unprotected inhalation exposure was given as total micrograms and per kg ai handled.

Each worker (Rep) was categorized as belonging to one of two work groups. The loader/applicators were workers who pumped and otherwise directly handled the test substance. There were four workers in this group. The five remaining workers were categorized as seed handlers. These workers were those involved with seed treatment operations other than test substance handling. The dermal exposure total gloved and the unprotected inhalation exposure estimates were used in a statistical analysis which generated the means, standard deviations, coefficient of variations, geometric means and geometric standard deviations for the two groups of workers. This information was provided in Table 18 (page 41) of the Study Report.

Table 6 is a summary of the lindane results provided in the tables found in the Study Report. Table 7 is a summary of the carbathiin results provided in the tables found in the Study Report. These tables show the number of detects, the range of corrected recoveries, and the lab-fortified recovery used to correct the field sample recoveries. The dosimeters in these two tables refer to the full body dosimeters. Residues were calculated for lower arms, upper arms, lower torso, upper torso, lower legs, and upper legs (not shown in Tables 6 and 7).

The largest amounts of lindane were found on the gloves, the second largest amounts

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were found on the dosimeters (specifically the lower arms, upper arms and lower torso), then the socks and then the hand wash/rinses. The gloves of the loader/applicators resulted in lindane levels of 463-1623 µg per kg ai handled, while hand rinse samples resulted in 7-28 µg per kg ai handled. Site 1 seed handlers hand wash levels, when gloves were worn, resulted in levels of 0.2-0.4 µg per kg ai handled. The seed handler who wore no gloves had levels of 13.8 µg per kg ai handled. The gloves provided about 98 percent protection.

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Table 6. Summary of Lindane Exposure Values - Loader/Applicators and Seed Handlers

	Sample/Matrix	No. Positive Detects/ Total n	Range Corrected Positive Values (ug)	Lab Recovery Correctional Factor Applied (%)
Loader/ Applicators	**Hand Wash**	20/20	64.3 - 2755	98
	Hand Rinse	20/20	32.7 - 500	98
	Glove Wash	36474	7551 - 147959	98
	Glove rinse	36442	1734.7 - 6836.7	98
	Facial Wash	36444	5.1 - 264	100
	Facial Rinse	36475	3.6 - 93	100
	Unprotected Inhalation	36379	1.0 - 48.6	107
	Socks	36253	196.1 - 2549	102
	Dosimeters	24/24	127.4 - 33333.3	102
	Gloves	36221	60648.1 - 148148.1	108

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Table 6. Summary of Lindane Exposure Values - Loader/Applicators and Seed Handlers (continued)

	Sampling Matrix	No. Positive Detects/ n=No.	Range (Corrected Positive Values) (µg)	Lab Recovery Correction Factor Applied (%)
Seed Handlers	**Hand Wash**	34/34	4.1 - 1000	98
	Hand Rinse	35/37	1.02 - 408.2	98
	Glove Wash	36538	5.31 - 1020.4	98
	Glove rinse	36537	1.6 - 132.7	98
	Facial Wash	14/15	1.8 - 30	100
	Facial Rinse	36478	1.8 - 19	100
	Unprotected Inhalation	36412	1.0 - 24.3	107
	Socks	36222	205.9 - 774.5	102
	Dosimeters	30/30	46.1 - 2156.9	102
	Gloves	36192	10185.2 - 25000	108

Table 7. Summary of Carbathiin Exposure Values - Loader/Applicators and Seed Handlers

	Sampling Matrix	No. Positive Detects / Total No.	Range Corrected Positive Values (µg)	Field Recovery Correction Factor Applied (%)
Loader/ Applicators	Hand Wash	15/20	1.3 - 470.6	85
	Hand Rinse	36210	2.1 - 8.9	85
	Glove Wash	36474	235.3 - 18823.5	85
	Glove Rinse	36412	62.4 - 705.9	85
	Facial Wash	36291	1.0 - 29.3	99
	Facial Rinse	36383	1.7 - 11.1	99
	Unprotected Inhalation	36167	1.3	130
	Socks	36284	5.1 - 206.5	92
	Dosimeters	19/24	1.1 - 98.9	92
	Gloves	36221	637.5 - 16250	80
Seed Handlers	Hand Wash	13/34	1.3 - 38.8	85
	Hand Rinse	2/37	5.9 - 20	85
	Glove Wash	14/14	2.1 - 72.9	85
	Glove rinse	0	-	85
	Facial Wash	36233	1.2 - 2.1	99
	Facial Rinse	36174	5	99
	Unprotected Inhalation	0	-	130
	Socks	36254	2.4 - 14.1	92
	Dosimeters	15/30	1.3 - 21.7	92
	Gloves	1/2	375	80

In several facial rinses, the recoveries for carbathiin were larger than those for lindane. The lab-fortified sample recoveries showed more variation for carbathiin (80-130 percent) than for lindane (98-107 percent).

Rep 1 at site 1 wore dosimeter patches on the outside of the Tyvek® coveralls. Analysis of these patches showed that the highest concentration of residues were found on the left thigh

and lower leg and on the front of the neck (ranging 9,200-15,000 total µg of lindane). The lowest concentrations were found on the shoulder and back of the neck (58-150 µg of lindane). (These results can be found in Tables 12 and 28 of the Study Report).

Due to the fact that the workers at the three sites handled substantially different amounts of the test substance (963 L, 340 L and 142 L at sites 1, 2, and 3, respectively), the exposure values per kg AI are thought to be the best exposure estimates per work group. Table 8 shows the mean total dermal exposure of each work group assuming gloves were worn.

Table 8. Mean Exposures per kg Active Ingredient for Loader/Applicators and Seed Handlers

	Total Dermal Exposure-Gloved		Unprotected Inhalation Exposure	
	Count	Mean (lindane, carbathiin, thiram)	Count	Mean (lindane, carbathiin, thiram)
Loader/ Applicator	4	269.8 22.6 269.8	4	3.3 3.2 3.3
Seed Handler	4	5.1 0.9 5.1	5	0.9 1.2 0.9

In summary, key findings were: (1) the highest dermal exposure was to gloves, followed by the lower arms, and (2) gloves provide approximately 98 percent protection.

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Guideline Compliance

Compliance with OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A: Applicator Exposure Monitoring Test Guidelines (i.e. Subdivision U); Guidelines, 875.1000, 875.1100, and 875.1300, is critical for determining whether a study is acceptable to the Agency. The itemized checklist below describes compliance with the major technical aspects of these guidelines:

- *Prior "informed consent" must be obtained in writing from all subjects who will be exposed in the study.* The criterion was met.

- *All conditions specified on the pesticide product label must be observed, including whatever protective clothing is specified for workers to wear.* The criterion was met. The label did, however, recommend the use of goggles while handling the test product but there was no mention of goggles being worn by the workers. All other protective clothing specifications were met.

- *Studies must be designed so that an exposure is measured separately for each activity associated with an application.* This criterion was met.

- *Data collection in accordance with 40 CFR 160, Good Laboratory Practice standards.* The criterion was questionably met. According to the protocol, this criterion should have been met. A good portion of the data was not provided for review in the Study Report. It was noted, however, that the seed-treating facility was a non-GLP facility. GLP compliance sheets on pages 239 and 255 of the Study Report contain only one of the three required signatures.

- *Typical end use product of the active ingredient tested.* This criterion was met. Vitavax is a dual purpose seed treatment. Three active ingredients were analyzed (i.e., thiram, carbathiin (a.k.a. vitavax and carboxin), and lindane). The label was provided.

- *End use product handled and applied using recommended equipment, application rates, and typical work practices.* These criteria were met.

- *For indoor exposure monitoring at least five replicates at each of at least three sites for each job function should be monitored.* This criterion was not met. Series 875.1000 specifies a minimum of 15 replicates, and states that five replicates should be monitored at each of three sites for each job function. This study did not distribute five replicates per job function at any single site.

- *Monitoring period is sufficient to collect measurable residues, but not excessive so that residue loss occurs.* The criterion was met. The monitoring period was 4.1 hours for site 1, 6.5 hours for site 2, and 5.25 hours for site 3. Loader/applicators and seed handlers worked the same hours.

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- *Dermal and/or inhalation exposure must be monitored by validated methodologies.* This criterion was met. According to the Study Author, the extraction and analytical methods were validated prior to the extraction of the field samples.

- *Quantity of active ingredient handled and duration of monitoring period reported for each replicate.* This criterion was met. The amount handled and the duration of exposure were reported. Samples were collected at different times of the day for each of the workers. The author of the Study said that for purposes of calculation, a standard time period format was used.

- *Protective clothing worn by each study participant and location of dosimeters are reported.* These criteria were met. A one piece full body dosimeter was cut into pieces prior to extraction in order to distinguish potential exposures to separate body parts. One worker also wore dosimeter patches on the outside of his Tyvek® coveralls. The location of these patches was defined.

- *Quantitative level of detection is at least 1 μg/cm²*. This criterion is not applicable. Exposure results were reported as mass values and as "unit exposure" values (mass residue/pound a.i. handled).

- *Storage of samples consistent with storage stability data.* It is not clear whether this criterion was met or not. The author of the Study Report stated that due to the results of the storage stability data, the samples were to be extracted within 5-6 weeks of receipt. There are no dates indicating when sample extraction or sample analysis took place.

- *Efficiency of extraction in laboratory provided as mean plus or minus one standard deviation. Lower 95 percent confidence limit is not less than 70 percent based on a minimum of seven replications per fortification level or prior Agency approval of extraction methodology provided.* This criterion was met. Concurrent laboratory recovery controls, analyzed with field samples, were somewhat variable with mean recoveries ranging from 80-130 percent for all matrices. (See QA/QC section of Study Review)

- *At least one field fortification sample per worker per monitoring period per fortification level for each matrix. At least one field blank per worker per monitoring period for each matrix.* This criterion was not met. There were no details provided in the study review noting when the field-fortified samples were collected, and the number of field-fortified samples was deficient.

Additional Issues of Note

Additional issues and concerns not mentioned above are summarized below:

- The Vitavax® RS flowable label states that "due to the viscosity of the material, it should be kept above 10°C prior to and during application. At site 3, the test substance was stored between -4°C to 9°C, never lower, reaching the 10°C minimum storage temperature. Site 2 storage ranged from 0°C-12°C. Site 1 storage ranged from 7°C to 19°C.
- Pesticide usage history of pesticides other than Vitavax® RS flowable was not provided for any of the seed treatment facilities.
- Sample chain of custody was not provided with the Study Report therefore, the time the samples spent in transit is not known.
- Dates were not provided for the extraction and analysis of the method validation samples or for the field samples.
- Level of Detection (LOD) was never discussed in the text of the Study Report.
- The Study Report lacked organization and detailed information.
- The seed-treatment equipment was not calibrated before and after application at sites 2 and 3 as recommended in the guidelines.