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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: June 23, 2010

SUBJECT: Determination of Dermal and Inhalation Exposure of Workers during On-Farm Seed Piece Treatment of Potatoes

PC Code: 129099	**DP Barcode: D378750**
Decision No.:	**Registration No.:**
Petition No.:	**Regulatory Action: Study Review**
Risk Assessment Type: NA	**Case No.:**
TXR No.: NA	**CAS No.:**
MRID No.: 470547-02	**40 CFR: Part 160**

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Attached is a review of the study of "Determination of Dermal and Inhalation Exposure of Workers during On-Farm Seed Piece Treatment of Potatoes" submitted by Bayer CropScience. The study review was conducted by Versar, Inc. A secondary review was conducted by HED.

This report reviews a study titled "Determination of Dermal And Inhalation Exposure of Workers During On-Farm Seed Piece Treatment of Potatoes" submitted by Bayer CropScience . The purpose of the study was to determine The dermal and inhalation exposure of experienced agricultural workers performing on-farm liquid seed piece treatment to potatoes and the inhalation exposure of agricultural workers who were sorting and cutting the potato seed pieces near the treatment site.

The potato seed pieces were treated with imidacloprid, formulated as ADMIRE 240F, a flowable concentrate formulation containing 21.4% of the active ingredient. The study was conducted at eleven potato treating locations in the southern potato growing region of Manitoba, Canada and encompasses a range of personal protective equipment, treatment equipment, and other variables.

In all trials, potato seed pieces were treated with ADMIRE 240F at a rate not to exceed 0.250 lbs. ai/A/season when the potatoes were planted. Calculated potato seed piece application rates ranged from 2.4 g ai/100 lbs. potato seed pieces to 4.8 g ai/100 lbs. potato seed pieces (0.005 lbs. ai/100 lbs. potato seed pieces to 0.011 lbs. ai/100 lbs. potato seed pieces). After planting the potato seed pieces, the achieved maximum theoretical seasonal application rates in the field ranged from 0.098 lbs. ai/A to 0.220 lbs. ai/A.

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, face/neck wipes, and hand washes. Total dermal exposures of treaters ranged from 19.6 µg/lb ai handled (Replicate NT024) to 296.2 µg/lb ai handled (Replicate NT036). The overall geometric mean for total dermal exposure was 99.0 µg/lb ai handled. Inhalation exposures for treaters were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of imidacloprid found in the OVS tubes. The personal monitoring pumps were set at an airflow of 2.0 L/min. Both the Registrant and Versar used the NAFTA recommended inhalation rate of 0.0167 m3/min for light activities when calculating the inhalation exposure. Inhalation exposures ranged from 0.80 µg/lb ai handled (Replicate NT028) to 20.90 µg/lb ai handled (Replicate NT031) for treaters. The overall geometric means for inhalation exposures were 3.87µg/lb ai handled for treaters. The inhalation exposures for cutter/sorters were expressed as daily exposure (µg/day), since cutter/sorters were not handling active ingredient directly and no correlation could be made with pounds active ingredient handled. Inhalation exposures ranged from 4.87µg/day (Replicate NT029) to 447.22 g/day (Replicate NT032) for cutters/sorters. The overall geometric means for inhalation exposures were 47.40µg/day for cutters/sorters.

Conclusion

The objective of this study was to determine the dermal and inhalation exposure of workers performing on-farm liquid seed piece treatment to potatoes and the inhalation exposure of workers who were sorting and cutting the potato seed pieces near the treatment site. The study was conducted with many variables, including equipment type and location and personal protective equipment. The results presented from combining all of the replicates are to be used with caution and for tier one assessment only. The standard deviation values are quite high, demonstrating the variability in the results. Therefore, the data has been analysed to assist assessors determining whether the variable significantly affects the exposure levels.

STUDY TYPE: Mixer/Loader/Applicator Passive Dosimetry Study Using Inner Whole Body Dosimetry, Face/Neck Wipes, Hand Washes and Personal Air Sampling; OPPTS 875.1100 and OPPTS 875.1300

PC CODE: 129099

TEST MATERIAL: ADMIRE 240F, a flowable concentrate formulation containing 21.4% of the active ingredient, imidacloprid.

SYNONYMS: 1-(6-Chloro-3-pyridinyl)methyl-*N*-nitroimidazolidin-2-ylideneamine; 1-[(6-Chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine; AE 1303004; AE 1304248; AE B143387; AE F106464; CAS # 138261-41-3.

CITATION: Study Author: Sandra J.W. Mackie
Title: *ADMIRE 240F – Determination of Dermal and Inhalation Exposure of Workers During On-Farm Seed Piece Treatment of Potatoes*
Report Date: November 3, 2006 Performing

Laboratories: Field University of Guelph Centre for Toxicology Canadian Network of Toxicology Centres Bovey Building, Gordon Street Guelph, ON, Canada N1G 2W1

Analytical: Bayer CropScience Environmental Research Bayer Research Park
17745 South Metcalf Avenue Stilwell, KS 66085-9104

Identifying Codes: Bayer Study No. RANTY013; MRID 470547-02

SPONSOR: Bayer CropScience
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EXECUTIVE SUMMARY:

The objective of this study was to determine the dermal and inhalation exposure of experienced agricultural workers performing on-farm liquid seed piece treatment to potatoes and the inhalation exposure of agricultural workers who were sorting and cutting the potato seed pieces near the treatment site. The potato seed pieces were treated with imidacloprid, formulated as ADMIRE 240F, containing 21.4% of the active ingredient. The study was conducted at eleven potato treating cooperator locations in the southern potato growing region of Manitoba, Canada and encompasses a range of personal protective equipment, treatment equipment, and other variables.

Sixteen sampling trials were conducted. Each trial consisted of monitoring one treater for dermal and inhalation exposures and one cutter/sorter for inhalation exposures only. Dermal exposure was estimated using 100% cotton whole-body dosimeters (inner dosimeters only), detergent handwashes, and face/neck wipes. Inhalation exposure was monitored using a personal air-sampling pump connected to an adsorbent XAD-2 tube.

All workers wore a long-sleeved shirt and pants (over the inner dosimeter for the treaters), sneakers or boots, socks, and chemical resistant gloves. The chemical-resistant gloves were worn during mixing/loading activities and handling of treated potato seed pieces. In addition to the chemical-resistant gloves, seven treaters also wore cutter, leather or heavy nitrile gloves. Also, six treaters wore dust masks and three treaters wore two layers over the inner dosimeter - a t-shirt plus a sweater, a sweatshirt, or a hoodie.

The treater performed the mixing, loading and applying operations and also other treatment-related tasks, which often included assisting on the cutting/sorting table. Other treating responsibilities included nozzle cleaning, troubleshooting equipment, and overseeing other workers. Each treater applied the liquid test formulation to potato seed pieces using either a cannon style treater (n=8) or a barrel style treater (n=8). The shields on the cannon treater were open to the air, side-shielded, or side-shielded and covered. The shields on the barrel style treaters were exposed to the environment, shielded, or unshielded similar to the cannon-style treater. The cutter/sorters performed the cutting and sorting operations at each site. These activities were conducted just prior to treating and concurrently with the potato seed piece treating operation. Activities performed by the cutter/sorter included culling bad potato pieces, removing debris, and cutting large pieces to a smaller more uniform size. The cutter/sorters worked 2 to 40 feet from the treaters. Twelve of the treater replicates were conducted indoors and four were conducted outdoors. All of the cutter/sorter replicates were conducted indoors. Indoor ventilation conditions varied at each site.

The amount of ADMIRE 240F handled during a replicate ranged from 4 gallons (Replicate NT025) to 13 gallons (NT032), equating to 8 lbs. ai handled to 28 lbs. ai handled, respectively. The duration of the work day ranged from 405 to 612 minutes for the treaters and ranged from 346 to 607 minutes for the cutters/sorters.

In all trials, potato seed pieces were treated with ADMIRE 240F at a rate not to exceed 280 g ai/ha/season (0.250 lbs. ai/A/season) when the potatoes were planted. Calculated potato seed piece application rates ranged from 2.4 g ai/100 lbs. potato seed pieces to 4.8 g ai/100 lbs. potato seed pieces (0.005 lbs. ai/100 lbs. potato seed pieces to 0.011 lbs. ai/100 lbs. potato seed pieces). After planting the potato seed pieces, the achieved maximum theoretical seasonal application rates in the field ranged from 110 to 247 g ai/ha (0.098 lbs. ai/A to 0.220 lbs. ai/A).

Versar estimated dermal and inhalation exposure values for treaters as µg/lb ai handled. Average field fortification recoveries, calculated by fortification level and matrix from each of four locations were used to adjust the field residues if the recoveries were less than 90%. Ranges for the recovery adjustment factor were derived by taking the midpoint between adjacent fortification levels for each matrix type. The midpoint between adjacent spike levels was selected as the breakpoint for applying the recovery adjustment factor. To calculate the inhalation exposures, Versar adjusted the flow rate of each treater by an average breathing rate of 0.0167 m^3/min. for light activities. The inhalation exposures for the cutter/sorter replicates were expressed as daily exposure (µg/day), since cutter/sorters were not handling active ingredient directly and no correlation could be made with pounds active ingredient handled.

Total Dermal Exposures

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, face/neck wipes, and hand washes. Total dermal exposures of treaters ranged from 19.6 µg/lb ai handled (Replicate NT024) to 296.2 µg/lb ai handled (Replicate NT036). The overall geometric mean for total dermal exposure was 99.0 µg/lb ai handled.

Hand Exposures

Hand exposures were calculated based on hand wash solutions collected for each of the worker replicates. Hand exposures of treaters ranged from 3.18 µg/lb ai handled (Replicate NT027) to 165.46 µg/lb ai handled (Replicate NT029). The overall geometric mean for hand exposures was 33.75 µg/lb ai handled. Note: handwashes were performed on bare hands only. The gloved hands were not rinsed. Therefore, the unit exposure values for hands in this study represent exposure that would be expected if chemical-resistant gloves are worn during seed piece treatment.

Face/Neck Exposures

Face/neck exposures were based on wipes collected from each of the worker replicates. Face/neck exposures of treaters ranged from 0.58 µg/lb ai handled (Replicate NT032) to 10.31 µg/lb ai handled (Replicate NT026). The overall geometric mean for face/neck exposures was 2.27 µg/lb ai handled.

Inhalation Exposures

Inhalation exposures for treaters were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of imidacloprid found in the OVS tubes. The personal monitoring pumps were set at an airflow of 2.0 L/min. Both the Registrant and Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities when calculating the inhalation exposure. Inhalation exposures ranged from 0.80 µg/lb ai handled (Replicate NT028) to 20.90 µg/lb ai handled (Replicate NT031) for treaters. The overall geometric means for inhalation exposures were 3.87 µg/lb ai handled for treaters. The inhalation exposures for cutter/sorters were expressed as daily exposure (µg/day), since cutter/sorters were not handling active ingredient directly and no correlation could be made with pounds active ingredient handled. Inhalation exposures ranged from 4.87 µg/day (Replicate NT029) to 447.22 µg/day (Replicate NT032) for cutters/sorters. The overall geometric means for inhalation exposures were 47.40 µg/day for cutters/sorters.

Major Issues of Concern

The major issues of concern when reviewing this study for compliance with the Group A, 875.1100 (dermal exposure) and 875.1300 (inhalation exposure) Guidelines are:

1) The tests were conducted with many variables, including equipment type and location and personal protective equipment. It is not clear how all of these variables may have affected the exposure values of each individual worker. Versar has presented the dermal and inhalation exposure data for treaters and the inhalation exposure data for sorter/cutters by combining the replicates and calculating the mean, geomean, standard deviation, and coefficient of variability. The results we obtained from combining all of the replicates are of a concern, since standard deviation values are quite high, demonstrating the variability in the results. In addition, Versar has presented separate tables where some of the variables have been analyzed to assist HED in determining whether the variable significantly affects the exposure levels.

   Major Variables include:

   - **Treater Type:** Of the sixteen replicates, half were conducted using a cannon style treater and half were conducted with a barrel style treater.
   - **Nozzle Shields:** The shields on the cannon treater were open to the air, side-shielded, or side-shielded and covered. The shields on the barrel style treaters were exposed to the environment, shielded, or unshielded similar to the cannon-style treater.
   - **Number of Nozzles:** The number of nozzles on the treater equipment varied.

- **Flow Rate**: The nozzle flow rates of the treater equipment varied.
- **Treatment Location:** Twelve of the treater replicates were conducted indoors and four were conducted outdoors. (Note: All the sorter/cutters replicates were indoors.)
- **Indoor Ventilation:** The ventilation at the indoor sites varied.
- **Personal Protective Equipment:** Seven treaters also wore cutter, leather or heavy nitrile gloves in addition to the study-supplied chemical-resistant gloves. Six treaters wore dust masks and three treaters apparently wore two layers over the inner dosimeter - a t-shirt plus a sweater, a sweatshirt, or a hoodie.
- **Distance between Treatment Site and Cutter/Sorters:** The cutter/sorters worked 2 to 40 feet from the treaters.

2) Versar could not assume that the cutter/sorters were exposed to the same lbs. ai handled as the treater replicates. Therefore, in presenting the data for the cutter/sorters, Versar provided the cutter/sorter inhalation exposure data in µg/day rather than in µg/lbs. ai handled, as was done for the treater replicates.

3) The cutters/sorters were not monitored for dermal exposure. Since residues were detected from inhalation monitoring, it also would be expected that residues could be detected from dermal monitoring.

4) The handwashes were performed on bare hands only. The gloved hands were not rinsed. Therefore, the unit exposure values for hands in this study represent exposure that would be expected if chemical-resistant gloves are worn during seed piece treatment.

5) The hand washes were not immersed in Aerosol OT solution for 30 seconds at Trial NT028. The hand exposures were one of the lowest recorded at this site; however, inner dosimeter and face/neck exposures were also low for this worker.

6) The following field fortification issues are noted:
- Field fortification samples were only collected at four of the eleven sites;
- For the field fortification samples, only three samples from three concentrations levels were prepared for each matrix at each site, with the exception of the OVS tube fortifications where six 1.00 µg samples were collected at the Glenboro test site and only two 1.00 µg samples were collected at the Portage La Prairie and Winkler sites;
- The Registrant corrected the field fortification recoveries for any interferences in corresponding control samples. Versar did not correct the recoveries for residues detected in the control samples;
- The Registrant corrected the raw field data for all field fortification recoveries, including recoveries over 100%. Versar only corrected raw field data for recoveries < 90%;
- The Registrant corrected the raw field data based on field fortification recoveries analyzed concurrently with each sample set. Since only one inner dosimeter fortification at each spike level could be manipulated through the analytical procedure in one day, recovery adjustment factors for inner dosimeters were not averages: the recovery adjustment factor was the recovery value for each spike level for the inner dosimeters analyzed that day. As Versar only corrected the raw field data for recoveries <90%, only the face/neck samples from three replicates required correction and the recovery adjustment factor was based on the average of three low level fortification samples from one site.

7) The study author corrected the method validation samples for residues detected in untreated control samples. The residues from the untreated controls were subtracted from the fortification sample before calculating percent recovery;

8) The full analytical method was not included in the study report. Raw data and an analytical method summary were provided; however, details of the LC/MS/MS equipment and conditions were not provided and could not be verified;

9) It is uncertain if breakthrough and trapping efficiency studies were conducted; however, breakthrough was examined during the study. A minimal amount of breakthrough was detected in some of the field samples;

10) A separate storage stability study was not conducted; however, the registrant verified storage stability using the field fortification samples. These samples were conducted concurrently with sample sets from initial generation through field storage, transport, storage at the analytical facility, and through the period of time between sample extraction and analysis; and

11) In lieu of laboratory fortification samples, a new method was utilized, spiking each field sample with a known aliquot of the imidacloprid [^{13}C-D_3] internal standard. The response of the analyte and the corresponding internal standard during LC/MS/MS analysis were measured and a relative response was calculated. The relative response of the analyte in the samples was then compared to the relative response of the analyte in the standard solutions. The ratio determined the amount of imidacloprid residues in the test samples. Since the test substance and radio-labelled standard are identical, 100% recovery is assumed with the standard and if there is any procedural loss, it will be proportional to both the field sample and the internal standard.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The

study sponsor and director stated that the study was conducted under EPA Good Laboratory Practice Standards (40 CFR part 160) with the following exceptions: 1) weather data were not collected under GLPs; and 2) there are at least 67 instances where 40 CFR 160.103(e) data recording requirements were not met (write-overs or double cross-outs) in the raw data for the field project.

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

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material:

Active ingredient: Imidacloprid
Purity: The purity of the reference test substance was 96.9%.
Formulation: ADMIRE 240F is a flowable concentrate containing a nominal 21.4% of the active ingredient, imidacloprid.
Lot/Batch # technical: Batch No.: 0126200521 (Expiration Date: November 20, 2007).
Lot/Batch # formulation: Batch No.: E160150-JF074 (Expiration Date: April 11, 2008) Analysis of this batch on April 11, 2006 resulted in a concentration of 21.45% imidacloprid (w/w) corresponding to 240 g/L.
CAS #(s):138261-41-3
Other Relevant Information:EPA Reg. No.: 264-758

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

According to the Study Report, the test product was ADMIRE 240F containing 21.45% of the active ingredient, imidacloprid. The test product used in this study is formulated the same as what is described on the ADMIRE 240F label (EPA Reg. No. 264-758).

3 Packaging:

The product was packaged in high density polyethylene 3.785 L (1 gallon) jugs. The jugs were opaque white with a pinch-handle and a custom wide mouth opening. The brimful capacity of each jug was 4.750 L (1.25 gallon). The white 63 mm tamper indicating screw cap on each jug was made of a polypropylene/polyethylene co-polymer and had a triseal trifol liner.

B. STUDY DESIGN:

There were two amendments to and three deviations from the analytical study protocol. The amendments included the following: 1) the air sampling pumps were checked periodically during the monitoring period to verify proper operation; and three blank control samples per matrix were processed with each set of field fortification samples which increased the total number of samples analyzed to 368 samples; and 2) the specific methods of analysis for the field samples were identified.

The deviations to the protocol included the following:

1) Several deviations are noted:
- At Trial NT024, the test substance was transported to the test site in the same vehicle used to collect and process the worker exposure samples (isolated in the front of the van);
- at trial NT024, the treater wore two layers of clothing over their inner dosimeter (t-shirt and hooded sweatshirt);
- during trial NT023, a face/neck wipe sample was not collected prior to the worker eating food at lunch time, but was collected at the end of monitoring period;
- during the first set of field fortifications at trial NT021, no high spike (50 µg/sample) OVS cartridges were collected;
- the second set of field fortifications at trial NT025 occurred when the fourth worker was monitored rather than for worker 5-8;
- face/neck wipe samples were transferred directly to amber glass jars rather than wrapped in aluminum foil and placed in plastic bags;
- at trial NT028, during one of the hand wash collections, the treater's hands were not immersed in the Aerosol OT solution for the prescribed 30 seconds; and
- at trial NT031, the final hand wash sample was collected before the treater removed their outer clothing;

2) the specific analytical method used was not identified in a protocol amendment prior to sample analysis; and

3) Two deviations are noted:
- at trial NT026 and NT031, the treaters were inexperienced in mixing/loading activities;
- at trials NT021, NT022, NT023, and NT031, the protocol-prescribed sample sequence (inhalation sample, hand wash sample, face/neck wipe, inner dosimeter) was not followed; and a summary statement signed by the facility QA Officer was not sent to the study director.

The study author indicated that no adverse impacts were expected from the deviations. Versar noted that in trial NT024 where two layers of clothing were worn over the dosimeter, the inner dermal dosimeter exposure values were the lowest. Similarly, at trial NT028 where one of the hand washes was not immersed in Aerosol OT solution for 30 seconds, the hand exposures were one of the lowest recorded.

1. Number and type of workers and sites:

The study was conducted at eleven potato treating cooperator locations in the southern potato growing region of Manitoba, Canada and encompasses a range of personal protective equipment, treatment equipment, and other variables. The participating facilities are provided in the table below.

Table 1. Details of Participating Test Site Facilities in Manitoba, Canada

Trial Number	Potato Farm	Nearest Town	Rural Municipality
NT021	Under the Hill	Glenboro	South Cypress
NT022	South River Farms	Portage La Prairie	Portage La Prairie
NT023	Marginet Potato Growers, Inc.	Holland	Victoria
NT024	Marginet Potato Growers, Inc.	Holland	Victoria
NT025	Grenville Farms, Ltd.	Portage La Prairie	Portage La Prairie
NT026	Spud Plains Farms, Ltd.	Wellwood	North Cypress
NT027	Northport Potato Growers	MacDonald	Portage La Prairie
NT028	South River Farms	Portage La Prairie	Portage La Prairie
NT029	Hespler Farms, Ltd.	Winkler	Stanley
NT030	Haskett Growers, Ltd.	Winkler	Stanley
NT031	Spud Plains Farms, Ltd.	Wellwood	North Cypress
NT032	Siemens Seed Potatoes	Rosetown	Rhineland
NT033	Siemens Seed Potatoes	Rosetown	Rhineland
NT034	Hespler Farms, Ltd.	Winkler	Stanley
NT035	Border Farms, Inc.	Rosetown	Rhineland
NT036	Swansfleet Farms, Ltd.	Bruxelles	Lorne

Sixteen treaters were monitored during the study. Two female and fourteen male workers ranging in age from 18 to 73 years and ranging in weight from 138 to 304 pounds volunteered to participate. Treater experience ranged from less than one year to 50 years. In addition, sixteen cutter/sorters were monitored for inhalation exposure only. Nine female and seven male workers ranging in age from 18 to 62 years and ranging in weight from 100 to 240 pounds volunteered to participate. Cutter/sorter experience ranged from less than one year to 22 years. A signed informed consent form was obtained from each worker prior to their participation in the study.

2. Meteorology:

Air temperature, relative humidity, rainfall, wind speed, wind direction and cloud cover were monitored on-site during each day of exposure monitoring. Equipment used to monitor the environmental conditions was not specified in the study report. Air temperatures ranged from 4.5°C (Replicate NT028) to 28.5°C (Replicate NT029) and relative humidity ranged from 5 percent (Replicate NT030) to 92 percent (Replicate NT025). Wind speeds ranged from 0 mph (Replicate NT032) to 16 mph (Replicate NT026). Wind direction and cloud cover varied by site. Rainfall was reported during five monitoring periods. A trace amount was recorded during Replicate NT021, a drizzle of rainfall was recorded during Replicate NT023, afternoon rainfall (exact amount not specified) was recorded during Replicate NT024, 7.6 mm of rain was recorded during Replicate NT025, and late morning rain (exact amount not specified) was recorded during Replicate NT027.

3. Replicates:

Sixteen sampling trials were performed. Each trial consisted of monitoring one treater and one cutter/sorter. The treater performed the mixing, loading and applying operations, and also other treatment-related tasks, which often included assisting on the cutting/sorting table. Other treating responsibilities may have included nozzle cleaning, troubleshooting equipment, and overseeing other workers. The cutter/sorters performed the cutting and sorting operations near the treatment site. These activities were conducted just prior to treating and in conjunction with the potato piece treating operation. Activities performed by the cutter/sorter included culling bad potato pieces, removing debris, and cutting large pieces to a smaller more uniform size. The distance between the treaters and the cutters/sorters ranged from 2 to 40 feet. Twelve of the treater replicates were conducted indoors and four were conducted outdoors. All of the cutter/sorter replicates were conducted indoors. Indoor ventilation conditions varied at each site. Details are provided in Table 2 in Section B.5 for each replicate.

The amount of ADMIRE 240F handled ranged from 4 gallons (Replicate NT025) to 13 gallons (NT032), equating to 8 lbs. ai handled to 28 lbs. ai handled, respectively. The duration of the work day ranged from 405 to 612 minutes for the treaters and ranged from 346 to 607 minutes.

4. Personal Protective Equipment:

Treaters wore 100% cotton, rib knitted, white, long-underwear that served as the inner body dosimeter used to determine potential dermal exposure. All treaters wore a long-sleeved shirt and pants (over the long-underwear), sneakers or boots, socks, and chemical resistant gloves. The chemical resistant gloves were worn during mixing/loading activities and handling of the treated seed potato. In

addition to the chemical resistant gloves, seven treaters also wore cutter, leather or heavy nitrile gloves. Also, seven of the treaters wore a dust mask and three treaters apparently wore two layers over the inner dosimeter - a t-shirt plus a sweater, a sweatshirt, or a hoodie. Some of the treaters also wore head coverings and/or glasses. Table 2 highlights the specific treater replicates wearing extra layers of personal protective equipment (i.e. double gloves, dust mask, and extra layers of outer clothing).

Cutters/sorters wore long-sleeved shirt and pants, sneakers or boots, and socks. In addition, three of the cutter/sorters wore a dust mask. Some of the cutters/sorters also wore head coverings and/or glasses.

5. Mixing/loading/application method:

Treaters applied the test substance with typical equipment in their usual manner. The overall seed treating process was similar despite variations in the configuration of the potato seed piece treating equipment. Seed potatoes were sorted by size and cut into pieces by machine. Once cut, the potatoes were conveyed across a cutting/sorting table where workers removed debris and cut any remaining large potato seed pieces. Once sorted, the potatoes were transferred into the seed piece treating equipment. A Potato Seed Piece Applicator (PSPA), designed to specifically spray liquid treatments onto potato seed pieces, was used to deliver the tank mix to the seed piece treating equipment. The test substance was sprayed onto the seed pieces as they moved through an auger or drum. The augering or rotating drum provided mixing and a uniform coating of the test substance on the potato seed pieces which then received a fungicide dust treatment. The treated seed pieces were subsequently augered to a truck or conveyor for transport to the field or into storage.

The seed piece treating equipment was one of two styles: a cannon treater or a barrel treater. In the cannon-style treater, spray nozzles coat the potatoes with the ADMIRE 240F premix as they enter the treater equipment. The spray nozzles in this type of treater were either open to the air, side-shielded, or side-shielded and covered. The auger in the cannon treater propelled the treated potato seed pieces forward and underneath a dust hopper where they received the fungicide dust application. This augering process provided mixing and a somewhat uniform coating of the ADMIRE 240F and fungicide dust on the potato seed pieces. The barrel-style treater is similar in operation to a concrete mixer. The potatoes were either sprayed with the ADMIRE 240F premix as they entered the barrel or the spray nozzle was configured inside the barrel itself. Spray nozzles outside the barrel were exposed to the environment, shielded, or unshielded similar to the cannon-style treater. Spray nozzles configured within the barrel itself provided the best controlled environment for minimal worker exposure. The barrel was gently rotated to allow the ADMIRE 240F premix to coat the potato pieces without bruising them.

Table 2 describes the treater equipment and study conditions at each site.

Table 2. Trial Site Conditions

Trial Number	Equipment Location	Type of Treater	Number of Nozzles	Nozzle Flow Rate (mL/min)	Nozzle Shield	Pounds Active Ingredient Handled	Ventilation	Handler Unit Exposure (µg/lb ai handled)		Approximate Distance to Cutter/ Sorter (ft)	Cutter/ Sorter Inhalation Exposure (µg/day)
								Dermal	Inhalation		
NT021	Indoor	Barrel	2	450	Partial (Tarp tent)	18.0	1 Open Door 4 Ceiling Fans	67.6 Wore cutter gloves and dust mask	4.39	30	40.14
NT022	Indoor	Cannon	1	222	Partial (Metal box with open top)	12.0	Transverse Open Doors	170.5 Wore leather gloves	1.09	3	19.02
NT023	Indoor	Cannon	1	173	Partial (Half barrel plastic shroud left open on one side)	12.6	Transverse Open Doors	92.4 Wore heavy nitrile gloves	3.43	30	11.14
NT024	Indoor	Cannon	1	268 - 300	Partial (Half barrel plastic shroud left open on one side)	14.0	Transverse Open Doors	19.6 Wore double layers (t-shirt and hoodie) over inner dosimeter	6.27	30 – 40	62.59
NT025	Indoor	Barrel	2	320	Partial (Plastic sheeting draped over nozzles)	8.0	1 Open Door	232.1 Wore cutter gloves and dust mask	13.12	2	316.05
NT026	Indoor / Outdoor	Barrel	1	333	Partial (Open air ≈ 2 hrs; cardboard shield ≈ 6 hrs)	10.0	Open Air	82.6 Wore cutter gloves and dust mask, also wore double layers (t-shirt and sweatshirt) over inner dosimeter	1.78	4	170.20
NT027	Indoor	Cannon	1	181	Enclosed (Enclosed in cannon treater)	12.0	Perpendicular Open doors & Floor Fan	32.6 Wore cutter gloves	1.03	6	8.92
NT028	Indoor	Cannon	1	215	Partial (Metal box with open top)	12.0	Transverse Open Doors	41.0 Wore double layers (t-shirt and sweatshirt) over inner dosimeter	0.80	3	NA
NT029	Indoor / Outdoor	Cannon	2	182 - 208	Partial (Plastic box, partial cover, plastic sheeting over opening)	12.0	Open Air	250.8 Wore dust mask	4.37	10 – 15 [a]	4.87
NT030	Indoor /	Cannon	2	540	Enclosed	28.1	Open Air	150.1	2.33	10 [a]	7.05

Trial Number	Equipment Location	Type of Treater	Number of Nozzles	Nozzle Flow Rate (mL/min)	Nozzle Shield	Pounds Active Ingredient Handled	Ventilation	Handler Unit Exposure (µg/lb ai handled)		Approximate Distance to Cutter/ Sorter (ft)	Cutter/ Sorter Inhalation Exposure (µg/day)
								Dermal	Inhalation		
	Outdoor				(Metal box with plastic top)						
NT031	Indoor	Barrel	1	500	None	18.0	1 Open Door	123.5	20.90	3 – 6	216.76
NT032	Indoor	Barrel	1	135	Enclosed (Fully contained in barrel treater)	26.1	Transverse Open Doors	58.0 Wore cutter gloves	2.31	4	447.22
NT033	Indoor	Barrel	1	135	Enclosed (Fully contained in barrel treater)	24.1	Transverse Open Doors	146.4	3.84	4	232.50
NT034	Indoor / Outdoor	Cannon	2	182	Partial (Plastic box, partial cover, plastic sheeting over opening)	16.0	Open Air	207.5 Wore dust mask	2.53	10 – 15 [a]	5.84
NT035	Indoor	Barrel	1	150	Enclosed (Fully contained in barrel treater)	16.0	1 Open Door	66.0 Wore dust mask	19.42	18	106.58
NT036	Indoor	Barrel	1	60 - 120	Enclosed (Fully contained in barrel treater)	14.0	Transverse Open Doors	296.2 Wore dust mask	13.97	35	111.12
Arithmetic Mean								**127.3**	**6.35**	**13.25**	**117.33**
Geometric Mean								**99.0**	**3.87**		**47.40**
Std. Dev.								**84.6**	**6.65**		**134.51**
C.V.								**66%**	**105%**		**115%**
Replicates								**16**	**16**	**16**	**15**

a Treating equipment was outside in the open air; cutter/sorter was inside barn.

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6. Application Rate:

In all trials, potato seed pieces were treated with ADMIRE 240F at a rate not to exceed 280 g ai/ha/season (0.250 lbs. ai/A/season) when the potatoes were planted. Calculated potato seed piece application rates ranged from 2.4 g ai/100 lbs. potato seed pieces to 4.8 g ai/100 lbs. potato seed pieces (0.005 lbs. ai/100 lbs. potato seed pieces to 0.011 lbs. ai/100 lbs. potato seed pieces). After planting the potato seed pieces, the achieved maximum theoretical seasonal application rates in the field ranged from 110 to 247 g ai/ha (0.098 lbs. ai/A to 0.220 lbs. ai/A).

The amount of ADMIRE 240F handled ranged from 4 gallons (Replicate NT025) to 13 gallons (NT032), equating to 8 lbs. ai handled to 28 lbs. ai handled, respectively.

7. Exposure monitoring methodology:

Dermal: Dermal exposures were monitored using whole body dosimeters, which consisted of 100% cotton, rib knitted, white, long underwear. These were worn directly underneath the outer shirt and pants. At the end of each monitoring period, workers were taken to a central staging area where the outer layer of clothing was removed and set aside. The inner dosimeter was then removed carefully with the assistance of a member of the exposure monitoring team to avoid contamination from the surrounding environment. Care was taken to ensure that the outer work garments did not contaminate the inner dosimeters. The field investigator assisting the worker put on a new pair of nitrile gloves prior to removal of the inner dosimeters. Buttons were removed from the inner dosimeter and the dosimeter was cut into the following six sections:

1. Left/Right Upper arms combined (elbow to shoulder seam)
2. Left/Right Lower arms combined (elbow to cuff)
3. Left/Right Upper legs combined (waist to knee)
4. Left/Right Lower legs combined (knees to cuff)
5. Torso – front (above the waist)
6. Torso – back (above the waist)

Scissors used to cut the dosimeter sections were rinsed with acetone between replicates. All dosimeter samples were wrapped in aluminum foil and placed in pre-labeled plastic re-sealable bags which were double-bagged in another plastic re-sealable bag. All six sections were then placed in one large plastic bag and placed into temporary frozen storage as soon as possible for transport to the analytical facility. Samples were maintained in frozen storage until analysis.

Face and Neck: Face and neck exposure was measured by wiping exposed areas sequentially with two 4 x 4-inch, 4-ply, 100% cotton gauze pads moistened with 4 mL of 0.01% (v/v) Aerosol OT solution. Face/neck wipes were performed by a member of the exposure monitoring team wearing a fresh pair of nitrile gloves. The exposed face and neck of the treater were thoroughly wiped using both sides of each wetted gauze pad. The pad was then placed on aluminium foil. The process was repeated with a second pad, combining both pads on the same foil. The foil was then folded, placed in a re-sealable plastic bag, and stored frozen until analysis.

A face/neck wipe was conducted prior to the monitoring period to remove any pre-existing source of contamination. This wipe was discarded. One dermal face/neck wipe sample was collected from the treater prior to any eating event. A face/neck wipe was also collected at the end of the monitoring period before removal of the whole body inner dosimeter. All wipes collected during the exposure period were combined in the same container, resulting in a single sample per trial for analysis.

Hand: Hand washes were performed to evaluate potential dermal exposure to the hands. Each worker placed both hands over a stainless steel bowl as a member of the exposure monitoring team poured approximately 400 mL of 0.01% (v/v) Aerosol OT solution over the hands. The worker then rubbed his hands together in the wash solution for approximately 30 seconds. The worker then removed his hands from the solution and held them over the bowl while the researcher poured a final 100 mL of the 0.01% (v/v) Aerosol OT solution over the hands to rinse. The hands were allowed to drain for about 5 seconds. The workers dried their hands with paper towels, and then donned clean nitrile gloves before the inner dosimeters were removed.

Hands were washed just prior to the exposure monitoring period to remove any source of contamination. This rinsate was discarded. During the monitoring period, hand wash samples were collected in the central staging area away from any source of contamination whenever a worker would normally wash their hands (i.e., before eating, bathroom breaks, etc.). A final hand wash sample was collected at the end of the monitoring period. All hand wash samples collected were treated as separate samples.

Note: handwashes were performed on bare hands only. The gloved hands were not rinsed. Therefore, the unit exposure values for hands in this study represent exposure that would be expected if chemical-resistant gloves are worn during seed piece treatment.

Inhalation: Both treaters and cutter/sorters were monitored for inhalation exposure. Potential inhalation exposure was monitored using an OVS tube sample collector connected by Tygon-type tubing to a personal air sampling pump. The sample collector consisted of a glass fiber filter at the air inlet, followed by two sections of XAD-2 adsorbent (consisting of 270 mg and 140 mg separated by a foam plug) housed in a 13 mm diameter glass tube. The pumps were calibrated with the OVS-2 cartridge attached to a nominal flow rate of approximately 2.0 liters per minute (LPM) prior to being placed on a worker. Flow rates were measured before and after each exposure monitoring period. The OVS tube was clipped to the worker's outer shirt collar with the intake facing downward. The air sampling pumps operated for the total monitoring period.

At the end of the monitoring period, the workers were taken to the central staging area where the Tygon-type tubing, pump and OVS tube sample were removed from the worker and the airflow rate was measured. The OVS tube was then disconnected from the tubing, sealed at both ends, labeled, placed into a pre-labeled container, and placed in temporary frozen storage as soon as possible for transport to the analytical facility. Samples were maintained in frozen storage until analysis.

At trial NT027, the personal air sampling pump worn by the treater failed prior to the completion of the work day. The pump was immediately replaced with another pre-calibrated pump using the same OVS air sampling cartridge for the duration of the monitoring period.

At trial NT034, the OVS air sampling cartridge worn by the treater clogged with particulates approximately 1 hour and 10 minutes prior to the completion of the work day. The air sampling cartridge worn by the cutter/sorter also clogged approximately 3 hours and 50 minutes prior to the completion of the work day. Inhalation monitoring was terminated for the duration of the work day for these two workers. Inhalation exposure was normalized to the actual amount of imidacloprid active ingredient handled prior to the termination of the inhalation monitoring.

Field monitoring was conducted on April 27-28, 2006, May 1-6, 2006, May 8-9, 2006 and May 11, 2006. The inner dosimeter samples, face/neck wipe samples, and OVS cartridge samples were placed in field freezers (electric freezers kept in transport vehicles and plugged in at the field sites) upon collection. Field freezer storage temperatures ranged from -36°C to 18°C (spike when freezer was initially started or during sample addition/removal). These samples were transported to temporary frozen storage at the Bayer Research Farm in Portage La Prairie, Manitoba. Hand wash samples were placed in field coolers with ice substitute shortly after collection and remained under cool conditions until they could be solid phase extracted. Field cooler storage temperatures ranged from -7°C to 18°C. All hand wash samples were extracted within one day of collection. Once extracted, the hand wash samples were placed in temporary frozen storage at the Bayer Research Farm. Temporary frozen storage temperatures ranged from -23°C to -10°C. All samples were shipped on dry ice via Federal Express to the analytical laboratory. Samples were stored for a maximum 56 days for inner dosimeters, 40 days for hand wash samples, 34 days for face/neck wipes, and 25 days for OVS tubes prior to analysis.

8. Analytical Methodology:

Extraction method(s): Inner Dosimeters – The dosimeter samples and aluminum foil, in which they were wrapped, were transferred to a one-gallon glass jar. Approximately 2 L of methanol was added to the jar along with an aliquot of imidacloprid-^{13}C-D_3IS (Internal Standard), and the jar was gently shaken on a shaker table for about 15 minutes. Using a vacuum SPE manifold and vacuum pump, a 5-mL aliquot was adsorbed onto a C18 SPE cartridge pre-conditioned with methanol. The eluate was collected and the solvent was evaporated by TurboVap. The concentrate was reconstituted in methanol and diluted with 0.1% aqueous formic acid (1:4) for analysis.

Face and Neck Wipes - Face/neck wipe samples and the aluminum foil, in which they were wrapped, were transferred to a sample glass jar. Approximately 100 mL of methanol was added to the jar along with an aliquot of imidacloprid-^{13}C-D_3IS (Internal Standard), and the jar was gently shaken on a shaker table for about 15 minutes. Using a vacuum SPE manifold and vacuum pump, a cartridge volume of extract was adsorbed onto a C18 SPE cartridge pre-conditioned with methanol. The eluate was collected and diluted with 0.1% aqueous formic acid (1:4) for analysis.

Hand Washes – The hand wash samples were fortified with an internal standard (imidacloprid ^{13}C-D3) in the field. Using a vacuum SPE manifold and vacuum pump, aliquots were adsorbed onto three C18 solid

phase extraction (SPE) cartridges that had been pre-conditioned with methanol and water. The eluate and the remaining hand wash sample were discarded. The SPE cartridges were washed with a cartridge volume of water (eluate again discarded) and allowed to dry under vacuum for about 5 minutes. The SPE cartridges were labelled, capped, and placed in temporary frozen storage as soon as possible for transport to the analytical facility.

At the analytical laboratory, the SPE cartridge containing the adsorbed sample was eluted with methanol using a vacuum SPE manifold and vacuum pump. The eluate was collected and the solvent evaporated by TurboVap. The concentrate was reconstituted in methanol and diluted with 0.1% aqueous formic acid (1:4) for analysis.

OVS Tubes – The contents of each XAD-2 OVS cartridge used for air sampling were divided into two sections. The back foam plug and the 140 mg XAD-2 sampling section were placed in a vial with 15 mL of methanol (bottom sample). The middle foam plug, the 270 mg XAD-2 sampling section, the 13-mm glass fiber filter, a 15-mL methanol rinse of the glass tube, and the retaining ring were emptied into a vial (top sample). An aliquot of imidacloprid-^{13}C-D_3IS (Internal Standard) was added to each of the vials, and the vials were gently shaken on a shaker table for about 30 minutes. An aliquot of the extract was removed and diluted with 0.1% formic acid (1:4) for analysis.

Detection method(s): All samples were analyzed using high pressure liquid chromatography/triple stage quadruple mass spectrometry (LC/MS/MS). Quantitation of the imidacloprid analyte was based on daughter ion transitions of the analyte and its respective internal standard analog.

High Performance Liquid Chromatography (HPLC) separation was performed using a Waters XTerra MS C18, 50 mm x 2.1 mm column, with 0.1% aqueous formic acid and methanol as mobile phases on a ThermoFinnigan Surveyor HPLC. The HPLC was interfaced to a ThermoFinnigan Quantum Ultra tandem mass spectrometer for analyte detection. Additional HPLC conditions were not provided.

Method validation: Imidacloprid residues were determined using the methods, "An Analytical Method for the Determination of Residues of Imidacloprid in Face Wipes, Hand Washes, and Dosimeter Garments" (Bayer CropScience Method No. NT-002-X06-01) and "An Analytical Method for the Determination of Residues of Imidacloprid in OVS-2 Air Monitoring Tubes" (Bayer CropScience Method No. NT-001-N06-01). The study author reported that the methods were validated by analysis of blank untreated control samples fortified in the laboratory. Additionally, the method was verified with the field fortification samples containing residues. These data support a Limit of Quantitation (LOQ) of 1 µg in inner dosimeters, hand washes and face/neck wipes and 0.025 µg in OVS tubes. The calculated Limit of Determination (LOD) for the analyte was 0.04 µg for cloth dosimeters, 0.15 µg for hand washes, 0.05 µg for face/neck wipes, and 0.004 µg for OVS tubes.

Instrument performance and calibration: Calibration curves were prepared using at least 4 concentrations. The relative response of the LC/MS/MS to imidacloprid in solvent was linear over the range of 0.01 µg to 6.25 mg. The correlation coefficients of the linearity curves were all >0.99.

Quantification: The response of the analyte and the corresponding internal standard from the LC/MS-MS analysis was measured in the test samples and the standards and a relative response was calculated. The relative response of the analyte in the test samples was then compared to the relative response of the analyte in the standard solutions.

9. Quality Control:

Lab Recovery: Laboratory fortification samples were not analyzed concurrently with each analytical set. In lieu of laboratory fortification samples, each field sample was spiked with a known aliquot of imidacloprid [^{13}C-D_3] internal standard. The response of the analyte and the corresponding internal standard during LC/MS/MS analysis were measured and a relative response was calculated. The relative response of the analyte in the samples was then compared to the relative response of the analyte in the standard solutions. The ratio determined the amount of imidacloprid residues in the test samples.

Field blanks: Field blank samples were exposed to the environment in the field to correct for any contamination which may have occurred in the field, in transport, or in handling. Many of the untreated control samples had reported imidacloprid residues >LOD. They include the following: eleven (out of 12) dosimeter samples had reported imidacloprid residues of 0.52 µg, 0.11 µg, 0.57 µg, 0.24 µg, 0.19 µg, 0.27 µg, 0.05 µg (two samples), 1.20 µg, 0.56 µg and 0.76 µg; two face/neck wipe samples had reported imidacloprid residues of 0.08 µg and 0.05 µg; eleven (out of 24) OVS-2 tube samples had reported imidacloprid residues of 0.028 µg (two samples), 0.029 µg, 0.027 µg, 0.031 µg, 0.024 µg, 0.006 µg, 0.007 µg, 0.022 µg (two samples), and 0.018 µg. The remaining samples were all <LOD. The registrant corrected the fortification samples for the residues detected in the field blanks by subtracting out the average of the detected residues in each sample set (including values <LOD). Versar did not correct for the untreated control values.

Field recovery: Field fortification was performed at four of the field trial locations in Manitoba (Glenboro – Trial NT021, Portage La Prairie – Trial NT025, Winkler – Trial NT029, and Rosetown – Trial NT033). Triplicate samples from three concentrations levels (low-, mid- and high-level) were prepared for each matrix, with the exception of the OVS tube fortifications where six 1.00 µg samples were collected at the Glenboro test site and only two 1.00 µg samples were collected at the Portage La Prairie and Winkler sites. Samples were spiked and maintained in an area free from possible contamination from the test substance, but under similar conditions as the field samples.

Cloth dosimeters and hand wash solutions were fortified at 5.00 µg/sample, 100 µg/sample, and 5000 µg/sample; gauze face/neck wipe samples were fortified at 5.00 µg/sample, 100 µg/sample, and 2500 µg/sample; and OVS air sampling tubes were fortified at 0.050 µg/sample, 1.00 µg/sample, and 50.0 µg/sample.

The overall average field fortification recoveries per matrix ranged from 98.2 ± 3.4% (face/neck wipes) to 100.5 ± 2.1% (hand washes) at the Glenboro field site (Trial NT021); ranged from 93.6 ± 3.2% (cloth dosimeters) to 120.2 ± 27.3% (OVS tubes) at the Portage La Prairie field site (Trial NT025); ranged from 91.5 ± 4.5% (OVS tubes) to 96.8 ± 1.1% (hand washes) at the Winkler field site (Trial NT029); and ranged from 96.3 ± 4.2% (cloth dosimeters) to 120.0 ± 29.0% (OVS tubes) at the Rosetown field site (Trial NT033). Table 3 provides a brief summary of the field fortification recoveries.

Table 3. Field Fortification Recovery Results for Each Matrix

Location	Fort. Level (µg)	Glenboro Field Site (Trial NT021)			Portage La Prairie Field Site (Trial NT025)			Winkler Field Site (Trial NT029)			Rosetown Field Site (Trial NT033)		
		Average Percent Recovery (by Fort. Level)	Overall Average Percent Recovery	Std. Dev.	Average Percent Recovery (by Fort. Level)	Overall Average Percent Recovery	Std. Dev.	Average Percent Recovery (by Fort. Level)	Overall Average Percent Recovery	Std. Dev.	Average Percent Recovery (by Fort. Level)	Overall Average Percent Recovery	Std. Dev.
Cloth Dosimeters n = 9 (per trial site)	5.00	105.0	98.4	6.1	94.4	93.6	3.2	96.1	94.1	2.3	100.7	96.3	4.2
	100	94.4			95.6			94.1			96.1		
	5000	95.7			90.7			92.1			92.3		
Hand Washes n = 9 (per trial site)	5.00	99.1	100.5	2.1	100.3	100.3	2.5	96.1	96.8	1.1	98.2	97.8	2.2
	100	99.3			99.1			96.9			97.5		
	5000	103.1			101.5			97.5			97.7		
Face/Neck Wipes n = 9 (per trial site)	5.00	94.5	98.2	3.4	97.9	98.9	1.3	83.0	93.7	16.5	97.8	97.3	1.1
	100	98.6			98.4			98.5			97.3		
	2500	101.7			100.3			99.6			96.7		
OVS Tubes n = 8 (NT025 & NT029 n = 9 (NT021 & NT033)	0.05	158.0	118.6	29.6	152.0	120.2	27.3	86.7	91.5	4.5	154.7	120.2	29.0
	1.00	98.9			98.4			93.1			100.2		
	50	NA			103.1			95.3			105.6		

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Formulation: ADMIRE 240F contains a nominal 21.4% of the active ingredient, imidacloprid. Analysis of Batch No. E160150-JF074 on April 11, 2006 resulted in a concentration of 21.45% imidacloprid (w/w).

Tank mix: Solutions were mixed by open pouring the ADMIRE 240F into the Potato Seed Piece Applicator (PSPA). Analysis of the tank mix was not conducted.

Travel Recovery: Travel recoveries were not discussed.

Storage Stability: The registrant verified storage stability using the field fortification samples. These samples were conducted concurrently with sample sets from initial generation through field storage, transport, storage at the analytical facility, and through the period of time between sample extraction and analysis. The maximum storage interval was 56 days for inner dosimeters, 40 days for hand wash samples, 34 days for face/neck wipes, and 25 days for OVS tubes prior to analysis.

10. Relevancy of Study to Proposed Use:

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

II. RESULTS AND CALCULATIONS:

The Registrant provided dermal and inhalation exposure values expressed as µg/sample. The Registrant corrected the raw field data based on field fortification recoveries analyzed concurrently with each sample set. The Registrant also corrected method validation samples and field fortification samples with residues detected in untreated control samples. The residues from the untreated controls were subtracted from the fortification sample before calculating percent recovery. The Registrant adjusted the flow rate of each worker by an average breathing rate of 0.0167 m^3/min. for light activities when calculating the inhalation exposure. The inhalation exposure values of treaters were calculated separately from the cutter/sorter replicates.

Versar estimated dermal and inhalation exposure values for treaters as µg/lb ai handled. Average field fortification recoveries, calculated by fortification level and matrix from each of four locations were used to adjust the field residues if the recoveries were less than 90%. Ranges for the recovery adjustment factor were derived by taking the midpoint between adjacent fortification levels for each matrix type. The midpoint between adjacent spike levels was selected as the breakpoint for applying the recovery adjustment factor. To calculate the inhalation exposures, Versar adjusted the flow rate of each treater by an average breathing rate of 0.0167 m^3/min. for light activities. The inhalation exposures for the cutter/sorter replicates were expressed as daily exposure (µg/day), since cutter/sorters were not handling active ingredient directly and no correlation could be made with pounds active ingredient handled.

Total Dermal Exposures

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, face/neck wipes, and hand washes. Table 4 provides the Versar-calculated dermal exposures for the treaters. Total dermal exposures of treaters ranged from 19.6 µg/lb ai handled (Replicate NT024) to 296.2 µg/lb ai handled (Replicate NT036). The overall geometric mean for total dermal exposure was 99.0 µg/lb ai handled.

Hand Exposures

Hand exposures were calculated based on hand wash solutions collected for each of the worker replicates. Table 5 provides the Versar-calculated hand exposures. Hand exposures of treaters ranged from 3.18 µg/lb ai handled (Replicate NT027) to 165.46 µg/lb ai handled (Replicate NT029). The overall geometric mean for hand exposures was 33.75 µg/lb ai handled. Note: handwashes were performed on bare hands only. The gloved hands were not rinsed. Therefore, the unit exposure values for hands in this study represent exposure that would be expected if chemical-resistant gloves are worn during seed piece treatment.

Face/Neck Exposures

Face/neck exposures were based on wipes collected from each of the worker replicates. Table 6 provides the Versar-calculated face/neck exposures. Face/neck exposures of treaters ranged from 0.58 µg/lb ai handled (Replicate NT032) to 10.31 µg/lb ai handled (Replicate NT026). The overall geometric mean for face/neck exposures was 2.27 µg/lb ai handled.

Inhalation Exposures

Inhalation exposures for treaters were calculated by both the Registrant and Versar from the breathing-zone air concentrations determined from the amount of imidacloprid found in the OVS tubes. The personal monitoring pumps were set at an airflow of 2.0 L/min. Both the Registrant and Versar used the NAFTA recommended inhalation rate of 0.0167 m^3/min for light activities when calculating the inhalation exposure.

Tables 7 and 8 provide the Versar-calculated potential inhalation exposures. Inhalation exposures ranged from 0.80 µg/lb ai handled (Replicate NT028) to 20.90 µg/lb ai handled (Replicate NT031) for treaters. The overall geometric means for inhalation exposures

were 3.87 µg/lb ai handled for treaters. The inhalation exposures for cutter/sorters were expressed as daily exposure (µg/day), since cutter/sorters were not handling active ingredient directly and no correlation could be made with pounds active ingredient handled. Inhalation exposures ranged from 4.87 µg/day (Replicate NT029) to 447.22 µg/day (Replicate NT032) for cutters/sorters. The overall geometric means for inhalation exposures were 47.40 µg/day for cutters/sorters.

III DISCUSSION:

A. LIMITATIONS OF THE STUDY:

The major issues of concern when reviewing this study for compliance with the Group A, 875.1100 (dermal exposure) and 875.1300 (inhalation exposure) Guidelines are:

1) The tests were conducted with many variables, including equipment type and location and personal protective equipment. It is not clear how all of these variables may have affected the exposure values of each individual worker. Versar has presented the dermal and inhalation exposure data for treaters and the inhalation exposure data for sorter/cutters by combining the replicates and calculating the mean, geomean, standard deviation, and coefficient of variability. The results we obtained from combining all of the replicates are of a concern, since standard deviation values are quite high, demonstrating the variability in the results. In addition, Versar has presented separate tables (Tables 9-11) where some of the variables have been analyzed to assist HED in determining whether the variable significantly affects the exposure levels.

Major Variables include:

- **Treater Type:** Of the sixteen replicates, half were conducted using a cannon style treater and half were conducted with a barrel style treater.
- **Nozzle Shields:** The shields on the cannon treater were open to the air, side-shielded, or side-shielded and covered. The shields on the barrel style treaters were exposed to the environment, shielded, or unshielded similar to the cannon-style treater.
- **Number of Nozzles:** The number of nozzles on the treater equipment varied.
- **Flow Rate**: The nozzle flow rates of the treater equipment varied.
- **Treatment Location:** Twelve of the treater replicates were conducted indoors and four were conducted outdoors. (Note: All the sorter/cutters replicates were indoors.)
- **Indoor Ventilation:** The ventilation at the indoor sites varied.
- **Personal Protective Equipment:** Seven treaters also wore cutter, leather or heavy nitrile gloves in addition to the study-supplied chemical-resistant gloves. Six treaters wore dust masks and three treaters apparently wore two layers over the inner dosimeter - a t-shirt plus a sweater, a sweatshirt, or a hoodie.
- **Distance between Treatment Site and Cutter/Sorters:** The cutter/sorters worked 2 to 40 feet from the treaters.

2) During trial NT024, the treater wore two layers of clothing over their inner dosimeter (t-shirt and hooded sweatshirt). This worker's inner dermal dosimeter values were the lowest of all the treater replicates, which may be due to the additional layer of clothing worn over the dosimeter. Two other replicates (NT026 and NT028 apparently also wore additional layers of clothing (t-shirt and sweatshirt); however, these replicates were not listed as study deviations.

3) The hand washes were not immersed in Aerosol OT solution for 30 seconds at Trial NT028. The hand exposures were one of the lowest recorded at this site;

4) Field fortification samples were only collected at four of the eleven sites.

5) For the field fortification samples, only three samples from three concentrations levels were prepared for each matrix, with the exception of the OVS tube fortifications where six 1.00 µg samples were collected at the Glenboro test site and only two 1.00 µg samples were collected at the Portage La Prairie and Winkler sites;

6) The study author corrected the method validation and field fortification samples for residues detected in untreated control samples. The residues from the untreated controls were subtracted from the fortification sample before calculating percent recovery;

7) The full analytical method was not included in the study report. Raw data and an analytical method summary were provided; however, details of the LC/MS/MS equipment and conditions were not provided and could not be verified;

8) It is uncertain if breakthrough and trapping efficiency studies were conducted;

9) A separate storage stability study was not conducted; however, the registrant verified storage stability using the field fortification samples. These samples were conducted concurrently with sample sets from initial generation through field storage, transport, storage at the analytical facility, and through the period of time between sample extraction and analysis; and

10) In lieu of laboratory fortification samples, a new method was utilized, spiking each field sample with a known aliquot of the imidacloprid [^{13}C-D_3] internal standard. The response of the analyte and the corresponding internal standard during LC/MS/MS analysis were measured and a relative response was calculated. The relative response of the analyte in the samples was then compared to the relative response of the analyte in the standard solutions. The ratio determined the amount of imidacloprid residues in the test samples. Since the test substance and radio-labeled standard are identical, 100% recovery is assumed with the standard and if there is any procedural loss, it will be proportional to both the field sample and the internal standard.

B. CONCLUSIONS:

The objective of this study was to determine the dermal and inhalation exposure of experienced agricultural workers performing on-farm liquid seed piece treatment to potatoes and the inhalation exposure of agricultural workers who were sorting and cutting the potato seed pieces near the treatment site. The tests were conducted with many variables, including equipment type and location and personal protective equipment. It is not clear how all of these variables may have affected the exposure values of each individual worker. However, the results we obtained from combining all of the replicates are of a concern, since standard deviation values are quite high, demonstrating the variability in the results. Therefore, Versar has also presented the data where some of the variables have been analyzed to assist HED in determining whether the variable significantly affects the exposure levels.

It should be noted that in lieu of laboratory fortification samples, a new method was utilized, spiking each field sample with a known aliquot of the imidacloprid [^{13}C-D_3] internal standard. The response of the analyte and the corresponding internal standard during LC/MS/MS analysis were measured and a relative response was calculated. The relative response of the analyte in the samples was then compared to the relative response of the analyte in the standard solutions. The ratio determined the amount of imidacloprid residues in the test samples. Since the test substance and radio-labeled standard are identical, 100% recovery is assumed with the standard and if there is any procedural loss, it will be proportional to both the field sample and the internal standard.

Table 4. Total Dermal Exposure for Treaters (μg/lb ai handled)

Replicate	Total Inner Dermal Dos. (μg/sample)	Face/Neck Wipes (μg/sample)[a]	Total Hand Washes (μg/sample)	Total Potential Dermal Residue (μg/sample)[b]	lbs ai handled	Total Potential Dermal Exposure (μg/lb ai handled)[c]
NT021	852.7	18.2	349.7	1220.6	18.0	67.6
NT022	1323.0	17.6	710.8	2051.4	12.0	170.5
NT023	904.9	14.2	248.1	1167.2	12.6	92.4
NT024	121.7[d]	14.0	140.0	275.7	14.0	19.6
NT025	1402.4	63.1	396.3	1861.8	8.0	232.1
NT026	154.9	103.4	569.7	828.0	10.0	82.6
NT027	338.2	15.7	38.3	392.1	12.0	32.6
NT028	299.6	14.6[e]	179.0	493.2	12.0	41.0
NT029	954.5	71.8	1990.8	3017.1	12.0	250.8
NT030	1188.9	27.6	2996.6	4213.1	28.1	150.1
NT031	570.4	86.9	1571.4	2228.7	18.0	123.5
NT032	729.3	15.1	767.4	1511.8	26.1	58.0
NT033	2305.1	29.1	1188.8	3523.0	24.1	146.4
NT034	2443.2	85.0	800.4	3328.6	16.0	207.5
NT035	658.6	81.1	319.0	1058.7	16.0	66.0
NT036	3492.3	63.3	602.0	4157.6	14.0	296.2
Overall Average						**127.3**
Overall Geometric Mean						**99.0**
Overall Standard Deviation						**84.6**
CV (%)						**66%**

a Samples were corrected for field fortification recoveries <90%.
b Total Potential Dermal Residue = inner dosimeter residues + face/neck wipe residues + hand wash residues
c Total Potential Dermal Exposure (μg/lb ai handled) = Total Dermal Residue (μg) /lb ai handled
d The treater at site NT024 wore two layers of clothing over their inner dosimeter (t-shirt and hooded sweatshirt).
e The hand washes were not immersed in Aerosol OT solution for 30 seconds at Trial NT028.

Table 5. Hand Exposures For Treaters (μg/lb ai handled) Based on Hand Washes

Replicate	Hand Residues Detected (μg)	Gallons of ADMIRE handled	lbs ai handled	Hand exposure (μg/lb ai handled)[a]
NT021	349.7	9	18.0	19.38
NT022	710.8	6	12.0	59.08
NT023	248.1	6.3	12.6	19.64
NT024	140.0	7	14.0	9.97
NT025	396.3	4	8.0	49.41
NT026	569.7	5	10.0	56.82
NT027	38.3	6	12.0	3.18
NT028[b]	179.0	6	12.0	14.88
NT029	1990.8	6	12.0	165.46
NT030	2996.6	14	28.1	106.74
NT031	1571.4	9	18.0	87.07
NT032	767.4	13	26.1	29.44
NT033	1188.8	12	24.1	49.40
NT034	800.4	8	16.0	49.89
NT035	319.0	8	16.0	19.88
NT036	602.0	7	14.0	42.89
Arithmetic Mean				**48.95**
Geometric Mean				**33.75**
Std. Dev.				**41.88**
C.V.				**86%**

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

b The hand washes were not immersed in Aerosol OT solution for 30 seconds at Trial NT028.

Table 6. Face/Neck Exposures For Treaters (μg/lb ai handled) Based on Face/Neck Wipes

Replicate	Residues Detected (ug)	Gallons of ADMIRE Handled	lbs ai handled	Face/neck Exposure (μg/lb ai handled)[b]
NT021	18.2	9	18.0	1.01
NT022	17.6	6	12.0	1.46
NT023	14.2	6.3	12.6	1.12
NT024	14.0	7	14.0	1.00
NT025	63.1	4	8.0	7.87
NT026	103.4	5	10.0	10.31
NT027	15.7[a]	6	12.0	1.30
NT028	14.6[a]	6	12.0	1.21
NT029	71.8	6	12.0	5.97
NT030	27.6[a]	14	28.1	0.98
NT031	86.9	9	18.0	4.82
NT032	15.1	13	26.1	0.58
NT033	29.1	12	24.1	1.21
NT034	85.0	8	16.0	5.30
NT035	81.1	8	16.0	5.06
NT036	63.3	7	14.0	4.51
Arithmetic Mean				**3.36**
Geometric Mean				**2.27**
Std. Dev.				**2.97**
C.V.				**88%**

a Samples were corrected for field fortification recoveries <90%.

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

Table 7. Potential Inhalation Exposure For Treaters Based on Residue Levels Found in OVS Tubes

Replicate	Residues (µg)	Total Residues (µg)	Duration (min)	Flow Rate (L/min)	Conc. (µg/m³)[a]	Gallons of ADMIRE handled	lbs ai handled	Vent. Rate L/min *0.001 for m³/min[b]	Inhalation Exposure (µg/lb ai handled)[c]
NT021 - Top	9.28	9.29	546	2.0	8.69	9	18.0	0.0167	4.39
NT021 - Bottom	0.007								
NT022 - Top	1.55	1.55	539	2.0	1.46	6	12.0	0.0167	1.09
NT022 - Bottom	<LOD								
NT023 - Top	5.22	5.22	530	2.0	4.90	6.3	12.6	0.0167	3.43
NT023 - Bottom	<LOD								
NT024 - Top	10.53	10.54	453	2.0	11.63	7	14.0	0.0167	6.27
NT024 - Bottom	0.005								
NT025 - Top	12.78	12.79	405	2.0	15.56	4	8.0	0.0167	13.12
NT025 - Bottom	0.009								
NT026 - Top	2.13	2.13	495	2.0	2.15	5	10.0	0.0167	1.78
NT026 - Bottom	<LOD								
NT027 - Top	1.51	1.51	567	2.0	1.31	6	12.0	0.0167	1.03
NT027 - Bottom	<LOD								
NT028 - Top	1.16	1.16	472	2.0	1.21	6	12.0	0.0167	0.80
NT028 - Bottom	<LOD								
NT029 - Top	6.66	6.66	612	2.1	5.15	6	12.0	0.0167	4.37
NT029 - Bottom	<LOD								
NT030 - Top	7.87	7.87	490	2.0	8.00	14	28.1	0.0167	2.33
NT030 - Bottom	<LOD								
NT031 - Top	45.98	45.98	558	2.0	40.49	9	18.0	0.0167	20.90
NT031 - Bottom	0.004								
NT032 - Top	7.14	7.14	514	2.0	7.03	13	26.1	0.0167	2.31
NT032 - Bottom	0.004								
NT033 - Top	11.20	11.20	528	2.0	10.48	12	24.1	0.0167	3.84
NT033 - Bottom	0.004								
NT034 – Top[d]	5.24	5.26	559	2.2	4.35	8	16.0	0.0167	2.53
NT034 - Bottom[d]	0.016								
NT035 - Top	37.47	37.48	558	2.0	33.42	8	16.0	0.0167	19.42
NT035 - Bottom	0.009								
NT036 - Top	23.49	23.49	469	2.0	25.04	7	14.0	0.0167	13.97
NT036 - Bottom	<LOD								
Arithmetic Mean									**6.35**
Geometric Mean									**3.87**
Std. Dev.									**6.65**
C.V.									**105%**

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

b NAFTA recommended inhalation rate for light activities.

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

d At trial NT034, the OVS air sampling cartridge worn by the treater clogged with particulates approximately 1 hour and 10 minutes prior to the completion of the work day. Inhalation monitoring was terminated for the duration of the work day for this worker. Inhalation exposure was normalized to the actual amount of imidacloprid active ingredient handled prior to the termination of the inhalation monitoring.

Table 8. Potential Inhalation Exposure For Cutters/Sorters Based on Residue Levels Found in OVS Tubes

Replicate	Residues (µg)[a]	Total Residues (µg)	Duration (min)	Flow Rate (L/min)	Conc. (µg/m^3)[b]	Vent. Rate L/min *0.001 for m^3/min[c]	Inhalation Exposure (µg/day)[d]
NT021 - Top	5.48	5.48	551	2.0	5.01	0.0167	40.14
NT021 - Bottom	<LOD						
NT022 - Top	2.47	2.47	527	2.0	2.37	0.0167	19.02
NT022 - Bottom	<LOD						
NT023 - Top	1.50	1.50	531	2.0	1.39	0.0167	11.14
NT023 - Bottom	<LOD						
NT024 - Top	5.67	5.68	362	2.0	7.81	0.0167	62.59
NT024 - Bottom	0.006						
NT025 - Top	28.58	28.58	346	2.1	39.43	0.0167	316.05
NT025 - Bottom	<LOD						
NT026 - Top	22.54	22.55	527	2.0	21.23	0.0167	170.20
NT026 - Bottom	0.007						
NT027 - Top	1.36	1.36	607	2.0	1.11	0.0167	8.92
NT027 - Bottom	<LOD						
NT028 - Top	NA[e]	0.004	447	2.0	0.00	0.0167	NA[f]
NT028 - Bottom	0.004						
NT029 - Top	0.78	0.78	600	2.1	0.61	0.0167	4.87
NT029 - Bottom	<LOD						
NT030 - Top	0.82	0.82	481	1.9	0.88	0.0167	7.05
NT030 - Bottom	<LOD						
NT031 - Top	30.34	30.35	569	2.0	27.04	0.0167	216.76
NT031 - Bottom	0.009						
NT032 - Top	55.82	55.83	506	2.0	55.79	0.0167	447.22
NT032 - Bottom	0.005						
NT033 - Top	28.34	28.35	478	2.0	29.00	0.0167	232.50
NT033 - Bottom	0.005						
NT034 – Top	0.69	0.70	450	2.1	0.73	0.0167	5.84
NT034 – Bottom[f]	0.006						
NT035 – Top[f]	14.34	14.36	530	2.0	13.30	0.0167	106.58
NT035 - Bottom	0.015						
NT036 - Top	12.73	12.75	469	2.0	13.86	0.0167	111.12
NT036 - Bottom	0.016						
Arithmetic Mean							**117.33**
Geometric Mean							**47.40**
Std. Dev.							**134.51**
C.V.							**115%**

a There was only one set of field fortification samples with <90% recovery that needed correction. The applicable field samples associated with these fortification samples were all the bottom portion of the air sampling tubes and were <LOD. Therefore, these samples were not corrected.

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

c NAFTA recommended inhalation rate for light activities.

d Inhalation Exposure (μg/day) = [(Concentration (μg/m^3) x Respiration rate (m^3/min) x work day (hours/day) x conversion factor (minutes/hour)]

e For Replicate NT028 (cutters/sorters), the top portion of the sample was destroyed during analysis. This replicate was not included in the total exposure calculations.

f At trial NT034, the OVS air sampling cartridge worn by cutter/sorter clogged approximately 3 hours and 50 minutes prior to the completion of the work day. Inhalation monitoring was terminated for the duration of the work day for this worker. Inhalation exposure was normalized to the actual amount of imidacloprid active ingredient handled prior to the termination of the inhalation monitoring.

Table 9. Summary of Hander Dermal Exposures during Seed Piece Treatment					
Exposure Scenario	**Number of Replicates**	**Mean Exposure (µg/lb ai)**	**Geomean Exposure (µg/lb ai)**	**Standard Deviation**	**Coefficient of Variability (percent)**
All Handler Replicates					
All Handler Replicates	16	127.3	99.0	84.6	66%
Equipment Type					
Barrel Treater	8	134.0	113.0	87.5	65%
Cannon Treater	8	120.6	86.8	86.9	72%
Treatment Location					
Indoors	12	112.2	84.5	85.5	76%
Outdoors	4	172.7	159.4	72.9	42%
Nozzle Shields					
Completely Shielded	6	124.9	96.6	96.9	78%
Partially Shielded	9	129.3	98.3	86.8	67%
Unshielded	1	123.5	123.5	NA	NA
Gloves (hand data)					
Chemical-Resistant Gloves only	9	60.7	42.8	50.9	84%
Double Gloves	7	33.8	24.9	21.5	64%
Dust Mask (face/neck data)					
No Dust Mask	9	1.5	1.3	1.3	83%
Dust Mask	7	5.7	4.8	2.9	51%

Table 10. Summary of Hander Inhalation Exposures during Seed Piece Treatment					
Exposure Scenario	**Number of Replicates**	**Mean Exposure (µg/lb ai)**	**Geomean Exposure (µg/lb ai)**	**Standard Deviation**	**Coefficient of Variability (percent)**
All Handler Replicates					
All Handler Replicates	16	6.4	3.9	6.7	105%
Equipment Type					
Barrel Treater	8	10.0	6.9	7.8	79%
Cannon Treater	8	2.7	2.2	1.9	70%
Treatment Location					
Indoors	12	7.5	4.4	7.3	97%
Outdoors	4	2.8	2.6	1.1	41%
Nozzle Shields					
Completely Shielded	6	7.1	4.2	7.6	107%
Partially Shielded	9	4.2	3.0	3.8	90%
Unshielded	1	20.9	20.9	NA	NA

Table 11. Summary of Cutter/Sorter Inhalation Exposures during Seed Piece Treatment					
Exposure Scenario	**Number of Replicates**	**Mean Exposure (µg/day)**	**Geomean Exposure (µg/day)**	**Standard Deviation**	**Coefficient of Variability (percent)**
All Cutter/Sorter Replicates					
All Replicates	15	117.3	47.4	134.5	115%
Distance to Treatment Site					
30 feet or greater	4	56.2	42.0	42.2	75%
10 to 18 feet	4	31.1	12.1	50.3	162%
6 feet or less	7	201.5	110.9	156.0	77%
Nozzle Shields					
Completely Shielded	6	152.2	65.3	166.6	109%
Partially Shielded	8	78.7	30.8	110.4	140%
Unshielded	1	216.8	216.8	NA	NA
Location of Treatment (Sorters/Cutters are Indoors)					
Treatment Outdoors	4	47.0	13.6	82.1	175%
Treatment Indoors	11	142.9	74.6	143.6	100%

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head,
Occupational Exposure Assessment Section

Date

APPENDIX A

Compliance Checklist for
"*ADMIRE 240F – Determination of Dermal and Inhalation Exposure of Workers During On-Farm Seed Piece Treatment of Potatoes*"

Compliance Checklist

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

Guidelines 875.1100

1. *Investigators should submit protocols for review purposes prior to the inception of the study.* It is uncertain if this criterion was met. It is not known if the protocol was submitted and reviewed by EPA. The Study Report stated that a protocol audit was conducted on February 9, 2006. Additionally, the full analytical method was not included in the study report. Raw data and an analytical method summary were provided; however, details of the LC/MS/MS equipment and conditions were not provided and could not be verified.

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

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

4. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* This criterion was met.

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

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

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

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

9. *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.* This criterion was mostly met. During trial NT024, the treater wore two layers of clothing over their inner dosimeter (t-shirt and hooded sweatshirt). This worker's inner dermal dosimeter values were the lowest of all the treater replicates, which may be due to the additional layer of clothing worn over the dosimeter.

10. *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was met. However, two different types of treatment equipment were utilized across the sixteen replicates and there were slight differences with the equipment or issues that surfaced with each replicate which might have resulted in higher/lower exposure values. It is not clear how all of these variables may have affected the exposure values of each individual worker.

11. *Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require pre-extraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests.* This criterion is not applicable. Whole body dosimetry was used to estimate dermal exposure.

12. *Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would*

interfere with analysis and be pre-extracted if necessary. This criterion is not applicable. Whole body dosimetry was used to estimate dermal exposure.

13. *A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing.* This criterion is not applicable. Whole body dosimetry was used to estimate dermal exposure.

14. *If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion is not applicable. Whole body dosimetry was used to estimate dermal exposure.

15. *Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present.* It is not certain if this criterion was met. Preliminary studies were not discussed.

16. *The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm^2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity).* This criterion was met.

17. *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were only partially met. Laboratory fortification samples were not analyzed concurrently with each analytical set. In lieu of laboratory fortification samples, a new method was utilized, spiking each field sample with a known aliquot of the imidacloprid [^{13}C-D$_3$] internal standard. The response of the analyte and the corresponding internal standard during LC/MS/MS analysis were measured and a relative response was calculated. The relative response of the analyte in the samples was then compared to the relative response of the analyte in the standard solutions. The ratio determined the amount of imidacloprid residues in the test samples. Since the test substance and radio-labeled standard are identical, 100% recovery is assumed with the standard and if there is any procedural loss, it will be proportional to both the field sample and the internal standard. For the field fortification samples, only three samples from three concentrations levels were prepared for each matrix, with the exception of the OVS tube fortifications where six 1.00 µg samples were collected at the Glenboro test site and only two 1.00 µg samples were collected at the Portage La Prairie and Winkler sites. Additionally, field fortification samples were only collected from four of the eleven field sites. Recovery from all samples were >50%.

18. *If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar indoor conditions and for the same time period as those expected during field studies.* This criterion was partially met. Specific storage stability samples were not collected, rather, the field fortification samples were utilized as the storage stability samples. Recoveries from these samples were used to support stability during frozen storage throughout each trial.

19. *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was met. However, the study author also corrected the method validation and field fortification samples for residues detected in untreated control samples. The residues from the untreated controls were subtracted from the fortification sample before calculating percent recovery. Versar did not correct for residues detected in the untreated controls.

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

21. *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was met.

Guidelines 875.1300

1. *When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.* This criterion was met.

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

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

4. *Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field.* It is uncertain whether this criterion was met. A breakthrough test was not discussed in the Study Report.

5. *If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples.* This criterion was partially met. Specific storage stability samples were not collected, rather, the field fortification samples were utilized as the storage stability samples. Recoveries from these samples were used to support stability during frozen storage throughout each trial.

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

7. *Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis.* This criterion was met.

8. *If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* It is not certain if this criterion was met.

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

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

11. *Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same weather conditions.* This criterion was met.

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

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

13544

R183541

Chemical Name: Imidacloprid

PC Code: 129099
HED File Code: 12100 Other Exposure Documents
Memo Date: 6/23/2010
File ID: 00000000
Accession #: 000-00-0135

HED Records Reference Center
6/30/2010