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Init: SM

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JCR

Attached please find the EAB review of...

Reg./File No.: _____

Chemical: Fosetyl-Al

Type Product: Fungicide

Product Name: Aliette

Company Name: Rhone-Poulenc

Submission Purpose: Applicator Exposure Study - Greenhouse

ACTION CODE: 320

Date In: 07/15/85

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5

Deferrals To:

 Ecological Effects Branch

 Residue Chemistry Branch

 Toxicology Branch

 X Benefits and Use Division

1.0 INTRODUCTION

Rhone-Poulenc, Inc. has submitted an exposure study in support of a proposed registration of their fungicide Aliette for use on greenhouse ornamentals. Aliette is formulated as a wettable powder containing 80 percent Aluminum tris (O-ethyl phosphonate) (Fosetyl Al) as the active ingredient. The spray is to be applied to the foliage at up to monthly intervals using pressurized hand sprayers. The finished spray concentration is 2.5-5.0 pounds of formulation (2.0-4.0 lbs active ingredient) per 100 gallons.

2.0 METHODS

Exposure of workers was measured during application of Aliette to greenhouse ornamentals at Rhone-Poulenc's Research Farm in Columbus, New Jersey. Mixer/loader and applicator exposures were measured separately for 4 different workers. The tasks were changed so that no worker performed the same one twice, yielding a total of 4 replicates each for the mixing/loading and application functions. All workers wore the label required long sleeved shirts, long trousers, and impermeable gloves. Workers also wore baseball hats and respirators which are not required by the label. Each replicate consisted of either mixing/loading or application of 12 tanks of spray mixture. The tanks contained 57 grams of formulated material (45.6 grams of active ingredient) in 2.5 gallons of water. This concentration matches the maximum application rate of 5 pounds of formulation per 100 gallons. The mixer/loader weighed the material from a bag of bulk material on a top loading balance and transferred the required amount into the tank. The tank was then filled with 2.5 gallons of water, capped, pressurized with carbon dioxide, and shaken to mix the contents. Each mixer/loader handled a total of 684 grams of formulation (547 grams or 1.2 pounds of active ingredient) during each replicate. The applicator then sprayed the diluted material to the foliage until runoff. Power for the spray was provided by a carbon dioxide cylinder strapped to the worker's back. Application took 53-65 minutes, with an average time of 58 minutes.

Respiratory exposure was measured by drawing air at a known rate through a cassette containing a fiberglass filter. The cassette was attached to the worker's collar in the breathing zone. Pump flow rates were determined before and after the sampling interval.

Dermal exposure was measured using gauze pads attached to the hat, shoulders, chest, upper arms, forearms, thighs, and lower legs. In order to estimate the effectiveness of protective clothing, duplicate sets of pads (except hat pad) were used, one located on the outside of the clothing and the other inside of the garments. The pads consisted of a 3 inch square gauze in an aluminum lined paper envelope. A 25 cm² circular area

was exposed to the environment. Exposure of the hands was measured by hand wash with 10 percent isopropyl alcohol. The hands were washed 3 times before and after exposure. The washes for each hand were pooled prior to analysis.

Samples were stored frozen prior to analysis. A 10 percent aliquot of the hand wash was mixed with an equal volume of methanol and 5 ml of methoxyethanol. The water was evaporated under vacuum using a rotary evaporator. The residue was then methylated with diazomethane, reduced in volume, and brought to a final of 5 ml with methoxyethanol /acetonitrile (50:50). Gauze pads and fiberglass filters were extracted twice with methanol/deionized water (50:50), followed by evaporation and methylation. The methylated derivatives were quantified by gas chromatography using a phosphorous specific flame photometric detector. The limit of detection for the dosimeters was 0.2 ug and 2.0 ug for hand washes. The recoveries of spiked samples are presented in Appendix A.

3.0 RESULTS

The average exposures of mixer/loaders and applicators are summarized in Tables 1 and 2, respectively. The equations used to obtain these values are presented in Appendix B. Respiratory exposures were much lower than dermal for both mixer/loaders and applicators. Respiratory exposure was approximately 10 percent of the hourly exposure of applicators and 1 percent of that for mixer/loaders. Respiratory exposures to both types of workers dropped to about 1 percent of dermal when considered on the basis of amount of active ingredient handled. Dermal exposure of workers wearing the label required protective clothing averaged 3.9×10^2 ug/hr (3.3×10^2 ug/lb ai) and 5.2×10^2 ug/hr (6.9×10^2 ug/lb ai) for applicators and mixer/loaders, respectively. The use of protective clothing reduced the dermal exposure of applicators by 99 percent and that of mixer/loaders by 85 percent. The difference in the degree of protection reflects the greater exposure of the face and neck of the mixer/loaders. When the uncovered portions of the body are omitted from the calculations, the degrees of protection are 98 for applicators and 92 percent for mixer/loaders. Hand exposures, usually relatively high, contributed only about 7 percent to the total dermal exposure, indicating the effectiveness of the use impermeable gloves in reducing exposure. Mixer/loaders removed their gloves between mixings which may account for the higher hand exposures of these workers. Applicators did not remove their gloves during the mixing procedure

4.0 CONCLUSIONS

The study was carried out using 4 workers for each task. While this is in accordance with the approved protocol, it is a very small number of replicates and only marginally acceptable by

Table 1. Average Exposure of Mixer/loaders to Fosetyl Al during Application of Aliette to Greenhouse Ornamentals.

Body Part	Surface Area (cm ²)	Unprotected (ug)	Protected ¹ (ug)
Face	650	2.7 x 10 ²	2.7 x 10 ²
Front of Neck	150	62	62
Back of Neck	110	3.6	3.6
Chest	3550	6.3 x 10 ²	91
Back	3550	1.2 x 10 ²	18
Left Upper Arm	660	2.6 x 10 ²	22
Right Upper Arm	660	4.3 x 10 ²	25
Left Forearm	610	3.3 x 10 ²	1.1 x 10 ²
Right Forearm	610	3.2 x 10 ²	1.2 x 10 ²
Left Thigh	1125	2.2 x 10 ³	5.8
Right Thigh	1125	8.5 x 10 ²	16
Left Lower Leg	1190	82	8.3
Right Lower Leg	1190	51	4.8
Left Hand	--	21	21
Right Hand	--	35	35
Total Dermal (ug)		5.7 x 10 ³	8.1 x 10 ²
Time (minutes)		89	89
Total Dermal (ug/hr)		3.5 x 10 ³	5.2 x 10 ²
Pounds of ai handled		1.2	1.2
Total Dermal (ug/lb ai)		4.7 x 10 ³	6.7 x 10 ²
Respiratory (ug/hr)		50	50
Respiratory (ug/lb ai)		6.7	6.7

¹ assumes worker is wearing long sleeve shirt, long trousers, and gloves

Table 2. Average Exposure of Applicators to Fosetyl Al during Application of Aliette to Greenhouse Ornamentals.

Body Part	Surface Area (cm ²)	Unprotected (ug)	Protected ¹ (ug)
Face	650	76	76
Front of Neck	150	18	18
Back of Neck	110	17	17
Chest	3550	1.5 x 10 ²	7
Back	3550	1.0 x 10 ³	50
Left Upper Arm	660	1.5 x 10 ²	2.7
Right Upper Arm	660	53	14
Left Forearm	610	1.5 x 10 ²	28
Right Forearm	610	6.0 x 10 ³	1.0 x 10 ²
Left Thigh	1125	1.6 x 10 ³	21
Right Thigh	1125	8.5 x 10 ²	13
Left Lower Leg	1190	1.3 x 10 ³	8.4
Right Lower Leg	1190	3.9 x 10 ³	5.9
Left Hand	--	12	12
Right Hand	--	12	12
Total Dermal (ug)		1.5 x 10 ⁴	3.9 x 10 ²
Time (minutes)		58	58
Total Dermal (ug/hr)		1.5 x 10 ⁴	3.9 x 10 ²
Pounds of ai handled		1.2	1.2
Total Dermal (ug/lb ai)		1.2 x 10 ⁴	1.2 x 10 ⁴
Respiratory (ug/hr)		3.2	3.2
Respiratory (ug/lb ai)		2.7	2.7

¹ assumes worker is wearing long sleeve shirt, long trousers, and gloves

current EAB standards. The low number of replicates adds to the difficulty in making inferences about the exposure. The study incorporates adequate quality assurance data to support the measured exposure. Unfortunately EAB has no usage data on which to base a daily or annual exposure estimate. If BUD can provide the necessary data a daily and annual exposure estimate can be calculated.

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APPENDIX A. Recovery of Fosetyl Al from Sampling Media

Sampling Medium	Type	Spike Level (ug)	Percent Recovery	
Gauze Pad	Method Dev.	0.50	117	
		5.00	106	
		50.00	130	
	Field ¹	24.0	96	
		240.0	98	
	Laboratory ²		98	
	Storage (6 wk)	0.5	80	
		5.0	120	
		50.0	91	
	Storage (9 wk)	0.5	120	
		5.0	166	
		50.0	110	
Fiberglass filter	Method Dev.	0.50	117	
		2.00	106	
		10.00	119	
	Field ¹	1.0	108	
		10.0	102	
	Laboratory ³		119	
	Storage (6 wk)	1.0	120	
		10.0	70	
	Storage (9 wk)	1.0	70	
		10.0	106	
	Hand Wash	Method Dev.	10	85
			100	88
1000			81	
10000			104	
Field ¹		100	83	
		1000	95	
Laboratory ⁴			85	
Storage (4 wk)		10	130	
		100	86	
		1000	84	
		10000	126	

1 Average of daily spikes.

2 Spikes ranged from 0.5 to 50 ug.

3 Spikes ranged from 1.0 to 10.0 ug.

4 Spikes ranged from 10 to 1000 ug.

APPENDIX B. Calculation of Worker Exposures.

1) Dermal

The exposure of a particular portion of the body was calculated by multiplying the amount found on the dermal monitors, in ug/cm², by the surface area of the appropriate body part. For example, the exposure of the chest of mixer/loader number 1 was:

$$\text{Exposure of chest (ug)} = \frac{0.30 \text{ ug}}{\text{cm}^2} \times 3550 \text{ cm}^2 = 1.1 \times 10^3 \text{ ug}$$

The visor of the baseball hats appeared to reduce the exposure of the hat pad. Therefore, the mean of the exposures of the shoulders and chest were used to estimate the exposure of the face. The hand wash procedure sampled the entire surface area of the hands and no adjustment for surface area was necessary. The total exposure is the sum of the individual exposures of the body parts.

The total dermal exposures were adjusted by the time spent performing the tasks and by the amount of active ingredient handled. The hourly dermal exposure is:

$$\text{Exposure (ug/hr)} = \frac{\text{Exposure (ug)}}{\text{elapsed time (min)}} \times \frac{60 \text{ min}}{\text{hr}}$$

In order to adjust the dermal exposure for the amount of active ingredient handled, the total dermal exposure was divided by 1.2, the number of pounds of active ingredient used in each replicate.

2) Respiratory

The calculation of respiratory exposure was based on the assumption that the respiratory volume of an average worker is 1.2 m³ per hour. The following equation was used to calculate respiratory exposure:

$$\text{Respiratory Exposure (ug/hr)} = \frac{\text{amount on filter (ug)}}{\text{volume collected (m}^3\text{)}} \times \frac{1.2 \text{ m}^3}{\text{hr}}$$

Respiratory exposures were also normalized by the amount of active ingredient by dividing the amount found on the filter by the amount of active ingredient handled (1.2 lbs).