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JCR

Attached please find the EAB review of...

Reg./File No.: 50534-8

Chemical: Chlorothalonil

Type Product: Fungicide

Product Name: Bravo

Company Name: SDS Biotech

Submission Purpose: Exposure Assessment

ZBB Code: other

ACTION CODE: 400 & 335

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 Ecological Effects Branch

Action Code 335 is a duplicate of 400.

 Residue Chemistry Branch

 X Toxicology Branch

Chlorothalonil - Aerial and Ground Application Exposure Assessment

Introduction

Chlorothalonil is a widely used fungicide for application on numerous vegetables, fruits, nuts, and field crops. Both aerial and ground applications are used. Recommended application rates vary from 1 1/2 to 4 1/4 pints per acre. However, for purposes of this applicator exposure study, the maximum application rate - 4 1/4 pints 1 acre and the most frequently employed - 2 3/4 pints/acre are considered.

Materials and Methods

Potential dermal exposure was assessed by the use of eleven patches at seven different body locations. Pads were located on the individuals at the following locations:

- one on top of the cap
- one on each shoulder
- one on the chest
- one on the back of each palm
- one on the back
- one on the front of each upper thigh
- one just below each knee

The two patches on the shoulders, hands, thighs, and knees were analyzed together as one sample. Standard procedures were employed for construction, design, storage and fixation of the patches. Respiratory exposure was monitored by continuous sampling of the air in the vicinity of the applicators nose. This was accomplished with a personal pump powered sampler unit drawing air at a nominal rate of 2.0 liters/min.

For each application method (ground boom and aerial) application rates of 2 3/4 and 4 1/4 pints/acre were studied. For aerial application, the pilot, mixer, and flagman were separately monitored for both inhalation and dermal exposure. The exposure period for the mixer consisted of carrying the 2-gallon Bravo 500 containers to the mixing tank and preparing approximately 320 gallons of the mix containing about 27 1/2 gallons of the Bravo 500. The exposure period for the pilot consisted of boarding the previously loaded airplane (160 gallons of mix), spraying a predetermined field until the tank, was empty, landing, reloading (160 gallon mix) and repeating the spraying cycle and finally landing and stepping off the airplane and thus completing his exposure period. The exposure period for the flagman consisted of standing at the edge of the field facing the field and when the airplane reached about halfway up the length of the field, walking to his next position down the width of the field and ending when the airplane was out of sight. Each spraying run was about 15 to 30 minutes in duration.

For ground application spraying was conducted with an open-cab tractor equipped with a 500 gallon tank and a spray boom with nozzles. Again, application rates of 2 3/4 and 4 1/4 pints/acre were used. In the ground boom operation, the mixer and applicators were the same individual and was outfitted as described earlier with the air sampling unit and dermal patches. The exposure period for this individual consisted of preparing three to five tank loads consisting of 2 3/4 gallons of Bravo 500 into the tank while water was being pumped into it. At the end of approximately 2 3/4 hours (the time to spray one tank load) the work was interrupted to change dermal patches and filter cassette. These operations were carried out at both referenced application rates for celery and tomato fields.

In order to validate the selected analytical methods for accuracy and precision, a duplicate analysis and a reproducibility test were performed. For the duplicate analysis, duplicate sets of patches and filters were certified at various levels with chlorothalonil. A second reproducibility study was undertaken to confirm the validity of the analytical method. Storage stability studies were also performed at intervals up to 14 days to determine the stability of the patches and filters.

Results

The dermal exposure values were obtained by converting to a per unit area (square inch) basis and considering the patch area exposed. The results were then standardized to per unit exposure hour by applying the sampling time of each sample. (Thus the exposure values are expressed as ug/in²/hr). For respiratory exposure, the exposure values obtained at sampling at 2.0 liters of air per minute were scaled up to reflect the respiration rate of the workers estimated at 20 liters per minute. The results were again standardized to per unit exposure hour by applying the sampling time of each sample.

The following summary tables taken directly from the Diamond Shamrock Corporation submittal provides summaries for each of the eleven applicators involved in the three phases of the study for two common application rates.

PHASE I -- AERIAL AND GROUND APPLICATION ON CELERY AT 2 3/4 PINTS/ACRE

	-----CHLOROTHALONIL LEVEL-----			
	<u>Aerial Application</u>			<u>Ground Application</u>
	<u>Pilot</u>	<u>Mixer</u>	<u>Flagman</u>	<u>Sprayer/Mixer</u>
<u>Dermal Exposure:</u> (ug/sq inch/hour)				
Head	>0.79	>2.00	22.56	3.16
Shoulders	>0.56	>19.47	22.56	3.30
Chest	>0.84	>40.57	7.93	6.85
Back	(c)	>39.04	47.81	2.03
Hands	>0.60	>111.60	>12.35	1,688.64
Thighs	>0.62	>26.34	>7.42	142.06
Shins	>0.65	>27.92	>6.27	313.54
<u>Respiratory</u>				
<u>Exposure</u> (ug/hour)	14.95	69.42	19.13	57.56

PHASE II -- AERIAL AND GROUND APPLICATION ON CELERY AT 4 1/4 PINTS/ACRE

	-----CHLOROTHALONIL LEVEL-----			
	<u>Aerial Application</u>			<u>Ground Application</u>
	<u>Pilot</u>	<u>Mixer</u>	<u>Flagman</u>	<u>Sprayer/Mixer</u>
<u>Dermal Exposure</u> (ug/sq inch/hour)				
Head	5.06	7.59	584.52	1.29
Shoulders	3.93	26.09	281.93	1.62
Chest	3.25	246.40	60.80	2.26
Back	(c)	8.50	101.51	4.37
Hands	4.91	430.84	39.78	140.15
Thighs	5.23	278.65	15.69	3.12
Shins	5.48	3,421.35	14.40	4.39
<u>Respiratory</u>				
<u>Exposure</u> (ug/hour)	29.40	170.48	558.23	31.36

PHASE III -- AERIAL AND GROUND APPLICATION ON TOMATOES AT 4 1/4 PINTS/ACRE
-----CHLOROTHALONIL LEVEL-----

	Aerial Application		Ground Application
	<u>Pilot/Mixer</u>	<u>Flagman</u>	<u>Sprayer/Mixer</u>
<u>Dermal Exposure</u> (ug/sq inch/hour)			
Head	3.95	12.25	0.72
Shoulders	1.01	12.52	1.09
Chest	1.70	12.46	1.10
Back	(c)	10.84	1.02
Hands	8.10	18.94	58.86
Thighs	1.17	14.29	4.20
Shins	2.14	14.50	46.11
<u>Respiratory</u> <u>Exposure</u> (ug/hour)			
	8.13	200.43	16.98

Review of the Bravo 500 (Chlorothalonil) label found no specific provisions for protective clothing. Thus I will assume that the exposed person will wear long pants, a short sleeved open neck shirt, shoes and socks but no gloves or hat and that his clothing will provide complete protection of the areas covered. Thus the parts of the body subject to potential exposure will be the head, (including face), back of the neck, front of neck and V of chest, forearms, and hands.

The following table illustrates the patch locations of the Diamond Shamrock study which I will use to compute the dermal exposure values for the unprotected body areas.

<u>Diamond Shamrock</u> <u>Patch Location</u>	<u>Exposed Body</u> <u>Area Represented</u>	<u>Body Surface</u> <u>Area (cm²)</u>
Head	Face	650
Shoulders	Back of the Neck	110
Chest	Front of neck & V of Chest	150
Chest	Forearms	1210
Hands	Hands	820

Thus taking the dermal exposure values previously presented from the Diamond Shamrock submittal and converting from ug/in/hr to ug/cm²/hr and from ug/hr to mg/hr, the following tables summarize dermal exposure for the three phases of the study.

Phase 1 - Aerial and Ground Application on Celery at 2 3/4 Pints/Acre

Exposed Body Area	Dermal Exposure (ug/cm ² /hr)				Body Surface Area (cm ²)	Total Dermal Exposure (mg/hr)			
	Aerial Application		Ground Application			Aerial Application		Ground Application	
	Pilot	Mixer	Flagman	Sprayer/Mixer		Pilot	Mixer	Flagman	Sprayer/Mixer
Face	0.12	0.30	3.50	0.48	650	0.078	0.20	2.20	0.31
Back of the neck	0.09	3.02	3.50	0.51	110	0.01	0.33	0.38	0.06
Front of neck and V of chest	0.12	6.30	1.20	1.00	150	0.02	0.94	0.18	0.16
Forearms	0.12	6.30	1.20	1.00	1200	0.14	7.60	1.50	1.30
Hands	0.09	17.00	1.90	260.00	820	0.07	15.0	1.60	210.00
<u>Total</u>						0.32	24.0	5.840	220.00

Phase 2 - Aerial and Ground Application on Celery at 4 1/4 Pints/Acre

Exposed Body Area	Dermal Exposure (ug/cm ² /hr)				Body Surface Area (cm ²)	Total Dermal Exposure (mg/hr)			
	Aerial Application		Ground Application			Aerial Application		Ground Application	
	Pilot	Mixer	Flagman	Sprayer/Mixer		Pilot	Mixer	Flagman	Sprayer/Mixer
Face	0.78	1.20	91.6	0.20	650	0.50	0.77	59.0	0.13
Back of the neck	0.61	4.0	44	0.25	110	0.07	0.44	4.80	0.03
Front of neck and V of chest	0.50	38.20	9.4	0.35	150	0.07	5.8	1.4	0.05
Forearms	0.50	38.20	9.40	0.35	1210	0.06	46.0	11.0	4.21
Hands	0.76	67.0	6.270	21.0	820	0.62	55.0	5.1	12.0
<u>Total</u>						1.30	110.0	82.0	22.0

Phase III - Aerial and Ground Application on Tomatoes at 4 1/4 Pints/Acre

Exposed Body Area	Dermal Exposure (ug/cm ² /hr)			Body Surface Area (cm ²)	Total Dermal Exposure (mg/hr)		
	Aerial Application		Ground Application		Aerial Application		Ground Application
	Pilot	Mixer	Flagman		Sprayer/Mixer	Pilot/Mixer	Flagman
Face	0.61	1.90	0.11	650	0.40	1.21	0.07
Back of the neck	0.16	1.9	0.17	110	0.01	0.21	0.02
Front of neck and V of chest	0.26	1.9	0.17	150	0.04	0.30	0.02
Forearms	0.26	1.9	0.17	1210	0.31	2.31	0.20
Hands	1.3	2.9	9.1	820	1.0	2.4	7.5
<u>Total</u>					1.79	6.5	7.8

Discussion and Conclusions

This three phased study measure both dermal and respiratory exposure for ground and aerial application of chlorothalonil. For ground application sprayer and mixer exposure was combined while for aerial pilot, mixer, and flagman exposure were measured separately. A better approach would have been to measure the mixer/loader and the applicator exposure separately for the tractor drawn sprayer application technique. Separate measurements would have provided a rationale for protective clothing recommendations and also provided a more realistic field situation. All dermal patches utilized in this study were outside patches and thus no attempt was made to deduce protective clothing effectiveness or consider the reduction in exposure protective clothing would afford.

Two deficiencies existed in the placement of the dermal patches for the three phases. First, there were no patches placed in the forearm area of the individuals used in the study. This is a potentially significant area of exposure and also represents a large surface area (1210 cm²) when an individual with no protective clothing is considered. Secondly, measuring hand exposure with dermal patches placed in the palms of the hand is at best a questionable technique. More appropriate methods would have been to utilize a hand wash technique or a cotton glove method.

Dermal exposure measured in this study ranged from 0.32 to 1.80 mg/hr for the pilot, 24.0 to 110 mg/hr for the mixer, and 5.8 to 81.9 for the flagman for the aerial application. For the ground application dermal exposure ranged from 7.8 to 220 mg/hr for the sprayer/mixer. However, one of the six replicates performed in Phase I of the study for the sprayer/mixer in the ground application reported extremely high dermal exposure. This was more than likely due to a direct spill or splash on the dermal patch measured (i.e., hands). If this value is neglected the range for the sprayer/mixer is 8.0 to 22.0 mg/hr for the ground application.

Respiratory exposure measured in this study ranged from 8.0 to 15.0 ug/hr for the pilot, 69.0 to 200.0 ug/hr for the mixer, and 19.0 to 558.0 ug/hr for the flagman for the aerial application. For ground application, the sprayer/mixer respirator exposure ranged from 19 to 58 ug/hr. These measured values for respiratory exposure are significantly lower than the dermal exposure values and this can most likely be neglected.

Overall, this Diamond Shamrock study represents a well organized acceptable study. The study was thoroughly conducted with sufficient replicates performed and good laboratory practices were used both for the applicator exposure portion and validation of the analytical methods. The major drawbacks to the study were the combined measurements for the sprayer/mixer in the ground application and the placement of the dermal patches.

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