5-16-88

Shaughnessy No: 103301

Date Out of EAB: 5/16/88

To: M. Mautz
Product Manager #3
Registration Division (TS-767C)

From: Michael P. Firestone, Chief
Special Review Section #2
Exposure Assessment Branch/HED (TS-769C)

Thru: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Attached, please find the EAB review of:

Reg./File # : 239-2471

Chemical Name : Acephate

Type Product : Insecticide

Product Name : Orthene Systemic Insect Control

Company Name : Chevron

Purpose : Homeowner Exposure Study

Date Received : 3/17/88 Action Code: 660

Date Completed: 5/5/88 EAB #(s): 80536

Monitoring study requested: X Total Reviewing Time: 3 days

Monitoring study volunteered: _____

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1/9

CHEMICAL NAME: Acephate

SHAUGNESSY NO. 214636

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BELOW)	Accession Number	(HED/BUD/TSS Complete) Study found to be Acceptable (A)/ Unacceptable(U) for review or reviewer comment
239-2471	660	28	216903	Applicator Exposure - Home use	2	40504827	
EAB	Route to	M. Firestone					

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER: W.H. Miller (16)

PM/RM TEAM MEMBER AND NUMBER: M. Maitz (3)

DATE RECEIVED (EPA): 2/3/88

RD BRANCH CHIEF INITIALS: JPK

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406)
- ☐ Suspect Data (415,416)
- ☐ IBT Data (485,486)
- ☐ Product Specific Data (Reregistration) (655,656)
- ☒ Generic Data (Reregistration) (660,661) As per agreement with EAB
- ☐ Special Review Data (870,871)

NUMBER OF INDIVIDUAL STUDIES SUBMITTED: 1

HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) If yes, please identify the study(ies):

RELATED ACTIONS: Refer to record # 215345

INSTRUCTIONS: EAB already has data. This is transmittal of Data sheet only.

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 3-17-88

PRIORITY NUMBER: 83

PROJECTED RETURN DATE: 6/30/88

DATE RETURNED TO RD (HED/BUD/TSS PROVIDE):

REVIEWS SENT TO:

HED: ☐ SIS ☐ TB ☐ RCB ☒ EAB ☐ EEB RD: ☐ TSS BUD: ☐ EAB ☐ SSB

	TYPE OF REVIEW	NUMBER OF ACTIONS: Reregistration	Special Review	Other
TO:	Toxicology			
	Ecological Effects			
	Residue Chemistry			
X	Exposure Assessment	✓		
	Product Chemistry			
	Efficacy			
	Precautionary Labeling/Acute Tox.			
	Science Support			
	Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD: Review Submission Criteria

Policy Note #31

1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria

2 = data of particular concern

3 = data necessary to determine tiered testing requirements

NOTE TO TSS: Return 1 Copy To RSERB

INCLUDE AN ORIGINAL AND FOUR (4) COPIES OF THIS COMPLETED FORM FOR EACH BRANCH CHECKED FOR REVIEW.

DATA EVALUATION RECORD

I. Study Type: Exposure Study - Homeowner

II. Citation: Potential Exposure to Acephate During Home Use of Orthene Systemic Insect Control, Merricks, D.L., Chevron Chemical Company, November 4, 1986
Accession No. 40504827

III. Reviewer: Curt Lunchick, Chemist
Special Review Section
Exposure Assessment Branch/HED (TS-769C)

IV. Approval: Michael P. Firestone, Chief
Special Review Section
Exposure Assessment Branch/HED (TS-769C)

V. Conclusions:

Based on the data submitted, the exposure to homeowners applying liquid formulations of acephate to bushes and shrubs by hose-end sprayer will average 480 mg/lb ai when wearing shorts and short-sleeved shirts. The use of long pants and short-sleeved shirts would reduce exposure to 460 mg/lb ai and long pants and long-sleeved shirts to 450 mg/lb ai. The hands account for over 90 % of the total exposure and inhalation was insignificant at not more than 0.15 mg/lb ai.

VI. Methods:

The study was conducted to determine dermal and respiratory exposure to homeowners applying acephate outdoors by hose-end sprayers. Orthene Systemic Insect Control, a liquid formulation containing 9.4 % acephate or approximately 0.75 lb ai per gallon, was applied by hose-end sprayer. The sprayer was an Ortho Spray-ette 4 which is capable of spraying 4 gallons of finished spray. The spray was mixed at the label maximum rate of 2 fl oz Orthene/gallon. Eight gallons of spray contained 16 fl oz Orthene or 0.094 lbs of acephate. A total of five homeowners were monitored as they mixed, sprayed, remixed, sprayed a second time, and cleaned out the sprayer by back flushing. The homeowners sprayed shrubbery in their neighborhood.

Inhalation exposure was monitored by placing a personal air sampler in the breathing zone of the study participants. The sampler contained two polyurethane foam plugs through which air was drawn at the rate of 2.0 l/min. Dermal exposure was

monitored using dosimeters placed outside the clothing worn by the study participants. Two types of dosimeters were used. The first type consisted of a 10 x 10 cm foil-backed alpha-cellulose patch that was loosely covered by shirt material on the upper body dosimeters and denim on the lower body dosimeters. The residues on the alpha-cellulose portion of the dosimeter represented residues to skin covered by clothing. The unprotected dosimeters were placed on the shoulders, chest, back, head (hat), forearms, upper arms, thighs, and shins. The protected dosimeters were placed adjacent to the unprotected dosimeters with the exception of the hand which had only an unprotected dosimeter. Hand exposure was monitored using white cotton gloves. The dosimeters were placed on the study participants just prior to mixing the Orthene and were removed after cleanup of the sprayer that followed the two sprayings.

Quality assurance sampling was done in the field during the study. For each collection matrix, a blank sample was exposed to the environmental conditions. In addition, two replicates of each matrix was spiked at 10, 100, and 1000 ug acephate. Triplicate samples of each of the ten spray solutions were taken to compare actual spray concentrations to nominal values. Laboratory fortification of six dosimeters and three gloves was done at 2.0 ug and at 1.0 ug for the foam filter plugs. Storage stability over 41 days was measured by spiking the matrices with 100 ug acephate.

Acephate in the matrices was extracted using Chevron analytical methods. The extracts were quantified for acephate by using Shimadzu GC-9A that used a thermionic detector. Standards for each matrix were analyzed on each day that samples were analyzed. The detection limits were 1.0 ug/foam plug, 0.01 ug/cm^2 on the patches, and 2.0 ug per pair of gloves.

VII. Results

Acephate was determined to be stable on all matrices after 41 days of storage. The average recoveries of the field-spiked matrices were 82%, 77%, and 88% for the patches, gloves, and foam filter plugs, respectively. The average concentration of acephate in the spray mixer was 87% of nominal with a range of 78 to 100% of nominal. The Orthene Systemic Insect Control was determined to contain 88.6% of nominal concentration of 9.4% acephate. The laboratory-spiked patches fortified at 2 ug were determined to have a recovery of 91% (range 75-98%), the cotton gloves fortified at 2 ug had an average recovery of 79% (range 73-85%), and the polyurethane foam filters fortified at 1 ug had an average recovery of 81% (range 80-82%).

Dermal exposure was calculated by the Exposure Assessment Branch (EAB) for three clothing scenarios. The scenarios assumed the homeowners wore shorts and a short-sleeved shirt, wore long pants and a short-sleeved shirt, and wore long pants and a long-sleeved shirt. None of the scenarios assumed the use of protective gloves. The total dermal exposure was calculated by multiplying the residues of acephate (ug/cm^2) presented in Table 8 by the respective body surface area as given in Subdivision U of the Pesticide Assessment Guidelines. When the dosimeter contained less than the detection limit, EAB used 50% of the detection limit to calculate exposure. Tables 1 - 3 present the exposure for the five applicators for each of the three clothing scenarios. The geometric mean dermal exposure for the five replicates was 480 mg/lb ai when the applicators wore shorts and short-sleeved shirts; 460 mg/lb ai when the applicators wore long pants and short-sleeved shirts; and 450 mg/lb ai when the applicators wore long pants and long-sleeved shirts. The range of exposure was over one order of magnitude. The hands accounted for over 90% of the total exposure with unprotected forearms and shins account for most of the remaining dermal exposure.

None of the five replicates had detectable levels of acephate in their polyurethane foam filters. Based on the approximately 30-minute monitoring period, an air flow rate of 2 l/min, and a detection level of 1.0 ug/plug, the air concentration of acephate wa less than 0.017 ug/l. Assuming a ventilation rate of 29 l/min, the inhalation exposure did not exceed 14.5 ug over a 30-minute monitoring period. The inhalation exposure was, therefore, less than 0.15 mg/lb ai which is about 0.03% of the dermal exposure.

VIII. Discussion

The study provided insight into the exposure expected for homeowners treating their grounds with acephate by hose-end sprayer. The number of replicates (5) was minimal, but still sufficient to demonstrate an exposure range of 120 to 1,500 mg/lb ai. This range is not unexpected as personal habits and wind conditions are expected to have great impact on homeowner exposure. Replicates 1 and 3 had relatively large hand exposures compared with replicates 2, 4, and 5. Replicate 3 also had greater exposure to other body areas as compared to replicates 2, 4, and 5. Having observed this particular study, one was able to observe the effect of positioning, in relation to wind direction, on exposure. The hose-end sprayer produced enough mist that would blow back on individuals spraying toward the wind. One participant dropped the sprayer while spraying; therefore, the range observed in this study supports the belief that homeowner exposure will vary greatly, depending on personal work habits and weather conditions.

The distribution of the exposure and the magnitude of the hand exposure supports the Agency's concern that homeowners must wear long pants, long-sleeved shirts, and protective gloves. Because hands accounted for over 90% of the total exposure and if one assumes protective gloves reduce hand exposure 90%, the simple act of wearing protective gloves could reduce total exposure 80% or five-fold on the average. As an example, replicate 1 had an exposure of 1,5000 mg/lb ai based on the use of shorts, short-sleeved shirt, and no gloves. The exposure based on the use of long pants, long-sleeved shirt, and protective gloves would have been 150 mg/lb ai. The guidance document for acephate reregistration requires homeowner product labels to state that users must wear long pants, long-sleeved shirt, and protective gloves. This study demonstrates that this label change could have substantial potential impact on homeowner exposure.

IX. CBI Information Addendum

The registrant, Chevron, made no claim of confidentiality for any information submitted as defined in FIFRA Section 10 (d)(1). The information provided in the study may not be used to support the registration of another company's pesticide without data compensation, as defined in FIFRA Section 3.

Table 1. DERMAL EXPOSURE TO ACEPHATE FOR HOMEOWNERS WEARING SHORTS AND SHORT-SLEEVED SHIRTS

	DERMAL EXPOSURE (MG)				
BODY AREA	Rep. 1	Rep. 2	Rep. 3	Rep. 4	Rep. 5
Face	0.23	0.003	0.22	0.003	0.013
Front of Neck	0.042	0.003	0.090	0.003	0.003
Back of Neck	0.004	(a)	0.011	0.001	0.001
Chest	(a)	0.018	0.67	0.018	0.018
Back	0.018	0.018	0.25	0.018	0.018
Upper Arms	0.015	0.015	0.23	0.015	0.015
Forearms	2.2	0.061	1.5	0.13	0.40
Thighs	0.27	0.019	0.019	0.019	0.019
Shins	5.2	0.24	3.2	0.64	3.9
Hands	134.0	11.0	96.0	31.0	31.0
Total	142.0	11.0	102.0	32.0	35.0
Lbs ai handled	0.094	0.094	0.094	0.094	0.094
Exposure (mg/lb ai)	1,500	120	1,100	340	370
log Exposure	3.18	2.08	3.04	2.53	2.57
Geometric mean exposure			480 mg/lb ai		
Arithmetic mean exposure			690 mg/lb ai		

(a) Sample lost

Table 2. DERMAL EXPOSURE TO ACEPHATE FOR HOMEOWNERS WEARING LONG PANTS AND SHORT-SLEEVED SHIRTS

	DERMAL EXPOSURE (MG)				
BODY AREA	Rep. 1	Rep. 2	Rep. 3	Rep. 4	Rep. 5
Face	0.23	0.003	0.22	0.003	0.013
Front of Neck	0.042	0.003	0.090	0.003	0.003
Back of Neck	0.004	(a)	0.011	0.001	0.001
Chest	(a)	0.018	0.67	0.018	0.018
Back	0.018	0.018	0.25	0.018	0.018
Upper Arms	0.015	0.015	0.23	0.015	0.015
Forearms	2.2	0.061	1.5	0.13	0.40
Thighs	0.27	0.019	0.019	0.019	0.019
Shins	0.048	0.012	0.12	0.012	0.048
Hands	134.0	11.0	96.0	31.0	31.0
Total	137.0	11.0	99.0	31.0	32.0
Lbs ai handled	0.094	0.094	0.094	0.094	0.094
Exposure (mg/lb ai)	1,500	120	1,050	330	340
log Exposure	3.18	2.08	3.02	2.52	2.53
Geometric mean exposure			460 mg/lb ai		
Arithmetic mean exposure			670 mg/lb ai		

(a) Sample lost

Table 3. DERMAL EXPOSURE TO ACEPHATE FOR HOMEOWNERS WEARING LONG PANTS AND LONG-SLEEVED SHIRTS

	DERMAL EXPOSURE (MG)				
BODY AREA	Rep. 1	Rep. 2	Rep. 3	Rep. 4	Rep. 5
Face	0.23	0.003	0.22	0.003	0.013
Front of Neck	0.042	0.003	0.090	0.003	0.003
Back of Neck	0.004	(a)	0.011	0.001	0.001
Chest	(a)	0.018	0.67	0.018	0.018
Back	0.018	0.018	0.25	0.018	0.018
Upper Arms	0.015	0.015	0.23	0.015	0.015
Forearms	0.036	0.006	0.11	0.21	0.25
Thighs	0.27	0.019	0.019	0.019	0.019
Shins	0.048	0.012	0.12	0.012	0.048
Hands	134.0	11.0	96.0	31.0	31.0
Total	135.0	0.094	0.094	0.094	0.094
Lbs ai handled	0.094	0.094	0.094	0.094	0.094
Exposure (mg/lb ai)	1,400	120	1,040	330	330
log Exposure	3.15	2.08	3.02	2.52	2.52
Geometric mean exposure			450 mg/lb ai		
Arithmetic mean exposure			640 mg/lb ai		

(a) Sample lost