5-5-88

Shaughnessy No: 103301

Date Out of EAB: 5/5/88

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 # : 215,345

Chemical Name : Acephate

Type Product : Insecticide

Product Name : Orthene PCO Spray Concentrate

Company Name : Chevron

Purpose : Exposure Study for Registration Standard

Date Received : 3/1/88 Action Code: 660

Date Completed: 5/4/88 EAB #(s): 80477

Monitoring study requested: X Total Reviewing Time: 4 days

Monitoring study volunteered: ____

Deferrals to: ____ Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

1/9

Confidential Business Information
Does Not Contain National Security Info. (E.O. 12065).

8047

CHEMICAL NAME: Acephate 44883 Hed

(RD PROVIDE) SHAUGHNESSY 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
239-247	660	20	[redacted]	Applicator Exposure	2	40504823	
			215345	Studies		A24 A25 A26	

Reg. Std. Review Submission Criteria (SEE BELOW): 3/3/88

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

PM/RM TEAM MEMBER AND NUMBER: M. Hutt (23)

DATE RECEIVED (EPA): 2/3/88

RD BRANCH CHIEF INITIALS: HHV

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)
- ☐ Special Review Data (870,871)

NUMBER OF INDIVIDUAL STUDIES SUBMITTED: 5

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:

INSTRUCTIONS: These data were identified in the Standard as data to be reviewed when rec'd. Refer to attached copy of Data Table from Acephate RS Standard

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 3-1-88

PRIORITY NUMBER: 50

PROJECTED RETURN DATE: ~~4/30/88~~ 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: Worker Exposure Study - PCO

II. Citation: Potential Exposure to Acephate During and After Application of Orthene PCO Spray Concentrate by Commercial Pest Control Operators.
Merricks, D.L., March 27, 1988
Project No. 2201 EPA Accession No. 40504823

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, a Pest Control Operator (PCO) mixing/loading a wettable powder and applying the spray by hand-held sprayer around baseboards and cabinets received a dermal exposure of 160 mg/lb ai at residential sites and 170 mg/lb ai at commercial sites. The two site categories produced similar exposures. Inhalation exposure was nondetectable in 17 of 18 replicates and was 2.8 mg/lb ai for the 18th replicate. The PCOs wore long-sleeved shirts, long pants, and no gloves. Post-application air levels of acephate in treated rooms were below detection levels with the exception of one sample taken on Day 0 which was 0.015 ug/l. Post-application dermal exposure from contact with walls in treated areas does not appear to be measurable; however, contact with the floor could produce post-application exposure based on residue levels up to 0.12 ug/cm^2.

VI. Methods:

Inhalation and dermal exposure was monitored on PCOs mixing/loading and hand spraying Orthene PCO Spray Concentrate. Orthene PCO Spray Concentrate is a wettable powder in a package that contains 1.4 oz or 39.7 g of acephate, the active ingredient (ai). In addition to PCO exposure, the post-application residues of acephate were monitored for four days.

A total of nine PCO replicates were monitored in which acephate was spot treated around baseboards, under counters, and behind equipment in commercial establishments. An additional

nine replicates were conducted for PCOs treating residential establishments. Each PCO mixed one gallon of finished spray by tearing open one package of Orthene (1.4 oz ai) and adding the acephate to one gallon of water in a two-gallon compressed air hand sprayer. Each PCO sprayed one quart of finished spray (0.35 oz ai). The remaining three quarts of spray were removed by individuals other than the PCO. After spraying, the PCO added a second package of Orthene PCO Spray Concentrate, but did not spray. Based on this routine, each PCO mixed 2.8 oz ai and sprayed 0.35 oz ai.

Respiratory exposure was monitored using personal air samplers. Air was drawn through a sampling tube containing two polyurethane plugs at a rate of 1.0 l/min. The air samples were placed in the breathing zone of the study participants. Dermal exposure was monitored using single- and multi-layered dosimeters. Both dosimeters consisted of an inner layer of 100 cm^2 alpha-cellulose pad backed by aluminum foil. The outer layer of the multi-layered dosimeter was a shirt material on upper body dosimeters and denim for lower body dosimeters. The dosimeters were placed on the shoulders, chest, back, forearms, upper arms, thighs, ankles, and on a baseball cap. The baseball cap dosimeter consisted only of the alphacellulose layer. Hand exposure was monitored using white cotton gloves. Residues of acephate on the inner layer of the multi-layer dosimeters represented exposure to body areas covered by clothing. Unprotected body area exposure is calculated from residues on the single-layer dosimeters.

Quality control analytical chemistry was conducted on all sampling matrices. Four replicates of each matrix were spiked with 100 ug acephate prior to study initiation. One replicate was immediately analyzed and a second replicate analyzed at the time the field samples were analyzed. The second replicate served as a storage stability replicate. The remaining two replicates were held as backups. On each day of testing, four replicates of each matrix were spiked in the field at 0, 10, 100, and 1000 ug. One replicate was immediately frozen and a second exposed to field conditions. Triplicate samples of each spray solution were also collected for analysis. The alphacellulose patches and polyurethane plugs were analyzed by thermionic N/P gas chromatography and the gloves were analyzed using a flame photometric detector. The limits of detection were 2 ug for the polyurethane plugs, 0.01 ug/cm^2 for the patches, and 100 ug for the cotton gloves.

VII. Results

The storage stability analysis showed no breakdown of acephate on samples kept frozen over a 46-day period. The field-spiked alphacellulose patches had recovery values between 80 and 99 percent at the three fortification levels. The glove samples were similar and ranged from 79 to 104 percent recovery with the exception of the gloves fortified at 10 ug and left exposed. The two replicates had recoveries of 64 and 115 percent. Problems also existed in the polyurethane foam plugs fortified at 10 ug and left exposed. Recovery values for these two samples were 34 and 49 percent. The frozen plugs fortified at 10 ug had recovery values of 71 and 73 percent. The range of recoveries for the frozen and exposed plugs fortified at 100 and 1000 ug was 88 to 104 percent, with the exception of a 63 percent recovery on an exposed plug fortified at 1000 ug. The actual concentration of acephate in the actual spray solutions were between 92 and 110 percent of nominal concentrations with the exception of commercial replicates 3 and 8 which were 79 and 75 percent of nominal.

Dermal exposure to the PCOs was calculated assuming the individual wore long pants, a long-sleeved shirt, and no gloves. The exposures were calculated by multiplying the residues in ug/cm^2 for a given dosimeter by the representative body part surface area, as given in Subdivision U of the Pesticide Assessment Guidelines. When a matrix had residues below the detection limit, an arbitrary residue level of 50 percent of the detection limit was used to calculate exposure.

The dermal exposures for residential and commercial PCOs are presented in Tables 1 and 2, respectively. No differences in the total dermal exposure was observed between the individuals treating residences and treating commercial establishments. The overwhelming majority of the dermal exposure occurred to the hands, with the remaining exposure occurring primarily to the legs. Because the study monitored individuals during mixing/loading of the powder and spraying without differentiating between the two functions, it is not possible to determine if the mixing/loading or spraying contributed the greatest amount to the hand exposure. The Exposure Assessment Branch (EAB) calculated the dermal exposure in mg/lb ai, based on the 0.35 oz ai sprayed. A total of 2.8 oz ai were handled during mixing/loading, but because the exposures received during each job function were not differentiated, it is not possible to determine what the exposure was during mixing/loading and use 2.8 oz as the quantity of active ingredient handled. The geometric mean dermal exposure for PCOs mixing/loading and hand spraying acephate as a wettable

powder was 160 mg/lb ai for residential use and 170 mg/lb ai for commercial use. Respiratory exposure was insignificant compared to the dermal exposure. All but one of the 18 replicates has acephate levels in the polyurethane plugs below the detection limit of 2.0 ug/plug. The sixth commercial-site replicate had 2.1 ug acephate in the plug. Based on an airflow of 1.0 l/min and a 20-minute sampling time, the air concentration of acephate in the worker's breathing zone was 0.105 ug/l (2.1 ug/20 l). Assuming a ventilation rate of 29 l/min and the 20-minute exposure period, the PCO inhaled 580 l of air during the 20-minute monitoring period. At a concentration of 0.105 ug/l, the PCO would inhale 61 ug or 2.8 mg/lb ai.

Acephate levels on the walls, floors, and in the air of the treated sites were monitored for four days post application at three residential and three commercial sites. The alpha-cellulose cards placed on the walls contained acephate levels at or below the detection limit of 0.01 ug/cm^2. On study Day 0, all floor alpha-cellulose cards in the three residential sites contained detectable levels of acephate. The levels were 0.12, 0.11, and 0.02 ug/cm^2. The levels of acephate on the cards collected on Days 1, 2, and 4 were 0.01 ug/cm^2. All alpha-cellulose cards placed on the floor of the commercial sites contained 0.01 ug/cm^2 or less of acephate, with the exception of the Day 4 sample at one commercial site. This sample contained 0.04 ug/cm^2. The post-application air sampling was done on Days 0, 1, 2, and 4 over four-hour periods. The treated rooms remained closed during sampling. The total residues of acephate on the polyurethane foam plugs were below the detection limit of 2.0 ug, with the exception of 3.5 ug at Day 0 in one of the commercial sites. Based on a pump rate of 1 l/m and a four-hour sample time, a total of 240 l were drawn through the plugs. The residue level of 3.5 ug is equivalent to an air concentration of 0.015 ug/l.

VIII. Discussion

The study provided useful data to permit assessing the exposure PCOs would receive when treating indoor areas with wettable powder formulations of acephate. The exposure pattern observed in the study appears to be typical of individuals handling wettable powders and then applying the pesticide by hand spray in a downward direction. Almost 100 percent of the dermal exposure occurred to the hands and the legs. The hands accounted for approximately 90 to 95 percent of the total exposure. Because of the distribution of the exposure, chemical-resistant gloves would dramatically reduce exposure, if properly used. Inhalation exposure accounted for less than two percent of the total exposure.

The study monitored dermal and inhalation exposure during the combined mixing/loading and application process. Because the monitoring was not split for each function, the contribution of each function to total exposure can not be ascertained. The study had each participant handle 2.8 oz ai during mixing/loading and 0.35 oz ai during spraying. Since the monitoring did not separate mixing/loading and application, the 0.35 oz ai handled during application was used in calculating exposure on a mg/lb ai basis. This procedure will overestimate the exposure received during mixing/loading when more than 0.35 oz were handled. EAB does not consider the study design to be deficient because the two job functions were not monitored separately, PCOs do not handle large quantities of pesticide, compared to agricultural users, and the likelihood of samples containing nondetectable levels of residue increase as the quantity of pesticide handled decreases. Therefore, it is a trade off between monitoring separate job functions and increasing the quantity of pesticide handled per replicate.

IX. CBI Information

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. RESIDENTIAL PCO DERMAL EXPOSURE

Body Area	DERMAL EXPOSURE (MG) PER REPLICATE								
	1	2	3	4	5	6	7	8	9
Face	0.003	0.003	0.003	0.003	0.007	0.003	0.003	0.003	0.01
Front of Neck	0.001	0.001	0.001	0.001	0.001	0.002	0.001	0.001	0.00
Back of Neck	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.00
Chest	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.01
Back	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.01
Upper Arms	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.01
Forearms	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.00
Thighs	0.019	0.019	0.019	0.230	0.110	0.420	0.920	0.019	0.01
Shins	0.012	0.012	0.012	0.120	0.140	0.071	0.012	0.012	0.01
Hands	4.800	0.260	2.000	2.900	1.700	15.000	15.000	3.200	3.60
Total	4.900	0.350	2.100	3.300	2.000	16.000	16.000	3.300	3.70
Dermal Exposure[a] (mg/lb ai)	224	16	96	151	91	731	731	151	16
log Dermal Exposure	2.35	1.20	1.98	2.18	1.96	2.86	2.86	2.18	2.2

Geometric Mean Dermal Exposure 160 mg/lb ai

Arithmetic Mean Dermal Exposure 260 mg/lb ai

[a] Based on PCO spraying 0.35 oz ai

TABLE 2. COMMERCIAL PCO DERMAL EXPOSURE

Body Area	DERMAL EXPOSURE (MG) PER REPLICATE								
	1	2	3	4	5	6	7	8	9
Face	0.003	0.003	0.003	0.003	0.003	0.007	0.007	0.003	0.003
Front of Neck	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Back of Neck	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Chest	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018
Back	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018	0.018
Upper Arms	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015	0.015
Forearms	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006	0.006
Thighs	0.019	0.019	0.019	0.076	0.110	0.150	0.019	0.019	0.019
Shins	0.012	0.012	0.012	0.095	0.095	0.071	0.012	0.012	0.012
Hands	56.000	0.670	3.800	3.900	0.770	5.800	3.600	2.300	4.000
Total	56.000	0.760	3.900	4.000	1.000	6.100	3.70	2.400	4.000
Dermal Exposure[a] (mg/lb ai)	2,560	35	178	183	46	279	169	110	183
log Dermal Exposure	3.41	1.54	2.25	2.26	1.66	2.45	2.23	2.04	2.26

Geometric Mean Dermal Exposure 170 mg/lb ai

Arithmetic Mean Dermal Exposure 440 mg/lb ai

[a] Based on PCO spraying 0.35 oz ai