

US EPA ARCHIVE DOCUMENT

OCT 15 1996



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FILE

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT  
AND RECOMMENDATIONS FOR THE REREGISTRATION  
ELIGIBILITY DECISION DOCUMENT FOR CYPERMETHRIN

FROM: Laura E. Morris, Environmental Scientist *Laura E. Morris*  
Occupational and Residential Exposure Branch

TO: Mike Metzger, Acting Chief  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

THRU: Ed Zager, Acting Chief  
Occupational and Residential Exposure Branch  
Health Effects Division (7509C)

*Susan V. Hummel,  
acting for*

Please find the OREB review of cypermethrin.

DP Barcode: D226116

Pesticide Chemical Codes: 109702

EPA Reg Nos: Cypermethrin EPA Reg. Nos. (53 labels)  
279-3046; 279-3070; 279-3081; 279-3082; 279-3084; 279-  
3085; 279-3109; 279-3117; 279-3118; 279-3120; 279-3131;  
etc.

EPA MRID No.: None

PHED: Yes, Version 1.1

## OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER

In this document, which is for use in EPA's development of the Cypermethrin Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to cypermethrin. Included is a discussion of the adequacy of the occupational and residential exposure data that have been submitted in support of the reregistration of cypermethrin.

### **(RED SECTION III - TOXICITY, EXPOSURE, AND RISK)**

#### **Summary of Toxicity Concerns Impacting Occupational and Residential Exposures**

##### Acute Toxicology Categories

The toxicological data base for cypermethrin is adequate and will support reregistration. Guideline studies for acute toxicity indicate that the technical grade of cypermethrin is classified as category II for acute oral toxicity, category III for acute dermal toxicity, category III for acute inhalation toxicity, category IV for primary eye irritation, category IV for primary skin irritation, and cypermethrin is classified as a skin sensitizer.

##### Other Endpoints of Concern

The *Toxicity Endpoint Selection Document*, dated 9/16/96, indicates that there are toxicological endpoints of concern for cypermethrin.<sup>3</sup> Endpoints have been identified, for short-term, intermediate-term and chronic dermal exposure. The NOEL for both short-term and intermediate-term exposures is 5 mg/kg/day based on a chronic feeding study for dogs which focused on effects to neurotoxicity.<sup>3</sup> The NOEL for chronic term occupational and/or residential exposure is 5 mg/kg/day. Cypermethrin has a dermal absorption rate of 50 percent.<sup>3</sup> A toxicology endpoint to estimate risk via inhalation exposure has also been identified. Based on a 21-day inhalation toxicity study which focused on decreased body weight, a NOEL of 0.01 mg/L was reported.<sup>3</sup> Using the route-to-route adjustment detailed in the following equation/explanation, a NOEL of 2.67 mg/kg/day was calculated (confirmed in discussion with J. Whalan/HED, 10/96).

Route-to-route extrapolation was used to convert the animal inhalation concentration into an approximate mg/kg dose by the following method:

$$\frac{\text{mg/L/day} \times A \times RV \times D \times AF}{BW} = \text{mg/kg/day}$$

where:

A	=	Absorption - The ratio of inhaled material which is retained and absorbed into systemic circulation, expressed as a decimal; default is 1 (i.e., 100%).
RV	=	Respiratory Volume - Mean liters of air respired per hour (8.46 L/hr).
D	=	Duration - Duration of daily animal or human exposure in hours (e.g., 6 hrs).
AF	=	Activity Factor - Animal AF is 1 (if pulmonary function data are unavailable).
BW	=	Body Weight - Mean animal or human weight in kilograms (e.g., rat = 0.19 kg).

Also included in the *Toxicology Endpoint Selection Document* for cypermethrin are special instructions for combining the risk from dermal and inhalation exposure for cypermethrin. These instructions are applicable for characterizing and analyzing the risks associated with the use of cypermethrin; OREB defers the combining of the risks (using the exposure/risk assessment provided in this chapter) based on the calculation provided in the *Toxicology Endpoint Selection Document* to the Risk Characterization and Analysis Branch.

### **Epidemiological Information**

The following poisoning incident summary data are presented in the memorandum dated July 2, 1996 from V. Dobozy/HED to L. Morris/HED. For more information concerning the incidents involving cypermethrin, see the attached memorandum entitled, "Cypermethrin - Review of Pesticide Poisoning Incident Data".

Poisoning incident summary/conclusions:

#### **Incident Data System**

There were 124 reports in the Incident Data System for cypermethrin. Seventy-six (76) reports of adverse effects involved 129 humans; three additional reports were of offensive odor only. Many of the reports did not contain sufficient details to make a judgment as to whether the illness was caused by exposure to cypermethrin. However, there were reports of 22 cases of skin effects (described as irritation or tingling) and 6 reports of eye irritation (when product splashed in eyes) which are consistent with the known toxic effects of the chemical.

Thirty-nine (39) reports involved the following number and species of animals: dogs (25); cats (10), goats (1), birds (1), gold fish (1), iguana (1) and python (1). The majority of these reports, most of which were submitted by FMC Corporation, were extremely sketchy and did not provide the clinical signs of illness. Therefore, any judgment about causality is not feasible.

An additional 6 reports dealt with environmental or ecological effects.

#### **California Data, 1982-1993**

There were 61 reports in the California data base from 1982 through 1993 involving exposure to cypermethrin alone, cypermethrin plus adjuvant or cypermethrin plus diazinon in which cypermethrin was judged to be responsible for the adverse reaction.

The majority of the people in this data base were exposed to cypermethrin in a non-agricultural work situation but were not assigned to deal with pesticides as a part of their employment. Of the 61 incidents, 47 exposures occurred while working in a structure previously treated with cypermethrin. The remaining activity categories (number of incidents) were exposure to drift (7), mixer/loader (4), applicator (1) and exposure to concentrate (1).

There were four reports involving 40 people exposed when offices were treated by a structural pest control operator. The majority of those affected had symptoms of systemic illness, including chest pain/tightness, coughing, sneezing, headache, nausea, vomiting and diarrhea. Watery/burning eyes and tingling skin were also reported.

#### **NPTN**

Cypermethrin was number 16 on the top 200 active ingredients for which NPTN received calls from 1982-1991. There were 2905 calls reporting 310 incidents; 206 were in humans, 50 in animals and 54 others.

#### **Adverse Effects Reported in the Literature**

There have been very few systemic poisonings of humans by pyrethroids. However, chemicals containing a cyano group, including cypermethrin, are known to cause a paresthesia reaction when the liquid or volatilized substance comes in contact with the skin. The face seems to be the most commonly affected; sweating and exposure to sun, heat or water may enhance the sensation. The effect is usually noted within minutes of the exposure and rarely persists more than 24 hours. It is thought to result from pyrethroid contact with sensory nerve endings.

#### **Recommendations based on incident evaluation**

Based on the review of incident data from California, there is evidence that groups of people may experience systemic illness when exposed to cypermethrin residue after premise treatments by structural pest control operators. Mitigation measures should be aimed at reducing this exposure. Product labels should have clear instructions that an area should be vacated prior to treatment and well-ventilated after treatment to reduce cypermethrin exposure. In addition, based on the known toxic effects of pyrethroids, dermal exposure to cypermethrin should be minimized.

## **(EXPOSURE)**

### **Occupational and Residential**

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. Cypermethrin meets these criteria.

### **Use Summary**

#### **Use Patterns**

Cypermethrin [cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl, cyano (3-phenoxyphenyl)methyl ester] is an insecticide/acaricide.<sup>1,2</sup> Cypermethrin is formulated as an emulsifiable concentrate (13.1 to 43.2 percent active ingredient), an impregnated collar/tag (7.0 to 10.0 percent active ingredient), a ready-to-use liquid (0.15 percent active ingredient), a pressurized liquid (0.05 to 0.15 percent active ingredient), a soluble concentrate/liquid (0.6 to 30.6 percent active ingredient), a wettable powder (35.6 to 50 percent active ingredient), a bait/solid (20 percent active ingredient), and as a technical grade active ingredient (88.8 percent active ingredient).<sup>1,2</sup>

Cypermethrin is an acaricide, insecticide, and a repellent/feeding depressant registered for use on the following sites: terrestrial food/feed crop (cabbage, cotton, garlic, lettuce, onion, pecan, etc.), terrestrial non-food crop (i.e., animal kennels and sleeping quarters, etc.), terrestrial non-food outdoor (i.e., ornamental lawns and turf, food processing plant, animal treatment (ear tag, spray), indoor (i.e., food processing plant premises, household/domestic dwellings, commercial transportation facilities, hospitals, food/grocery storage/distribution, warehouses, etc.), greenhouses, terrestrial outdoor residential (i.e., ornamental and/or shade trees), wood protection treatment to buildings indoors and outdoors, patios, horses, ornamental woody shrubs and vines, ornamental sod farm, refuse/solid wastes sites, etc. The target pests for this chemical include insects and related organisms, mollusks, fouling organisms, and miscellaneous invertebrates.<sup>1,2</sup>

The following equipment is used to apply cypermethrin: aerosol can, aerosol/fog generator, aircraft, band sprayer, brush, by hand using cloth, drencher or sponge, groundboom sprayer, hand held sprayer, high pressure sprayer, high volume ground sprayer, injection equipment (for termiticide use), low pressure ground sprayer, low volume ground sprayer, pliers (for ear tags), power sprayer, rod, sprinkler can, and sprinkler irrigation.<sup>1,2</sup>

### **Occupational-use products and homeowner use products**

At this time products containing cypermethrin are intended primarily for both occupational uses and homeowner uses.

### Handler Exposures & Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with cypermethrin. Based on the use patterns, 17 major exposure scenarios were identified for cypermethrin: (1a) mixing/loading liquids for aerial/chemigation application; (1b) mixing/loading liquids for groundboom application; (2) applying liquids with fixed-wing aircraft; (3) applying liquids with a helicopter; (4) broadcast application of liquids using a groundboom sprayer; (5) Applying liquid to rights-of-way; (6) applying liquids with a handgun (turf grass application); (7) applying with an aerosol can; (8) applying ear tags to cattle; (9) applying liquids using a brush; (10) mixing/loading/applying with an aerosol generator/fogger; (11) mixing/loading/applying by hand (cloth, drencher, sponge); (12) mixing/loading/applying liquid with a high pressure sprayer; (13) mixing/loading/applying liquid with a termiticide injection; (14) mixing/loading/applying liquid with a low pressure handwand; (15) mixing/loading/applying liquid with a backpack sprayer; (16) mixing/loading/applying liquids with a sprinkler can; and, (17) flagging aerial liquid application.

#### Assumptions/Issues to Note:

- To represent the brush application scenario, PHED Version 1.1 surrogate data from the paint brush application were used.
- Surrogate data are not available for aircraft with open cockpit; therefore, the surrogate data used to assess the aerial scenarios are for aircraft with enclosed cockpits (considered an engineering control).
- Surrogate data are not available of the hand gun application without chemical resistant gloves. therefore, the exposure/risk values for this exposure scenario represent workers wearing single layer clothing and chemical resistant gloves.
- The following tables do not mention homeowner exposure/risk for the applicable scenarios (low pressure hand wands, high pressure handwands and backpack sprayers). Because it is expected that the homeowners will cover less area during treatment than occupational workers (1,000 sq. ft. for homeowners compared to 0.5 acres for occupational workers), the homeowner scenarios are not specifically stated in the table. Since the MOEs were greater than 100 for occupational workers, it is presumed that the MOEs should also be greater than 100 for homeowners; consequently, a homeowner assessment was not conducted.

- There are wettable powder formulations of cypermethrin; however, there are no mixer/loader scenarios on cypermethrin labels for wettable powders. Based on the labels received, there are no agricultural uses for the wettable powders. All of the wettable powder labels received and reviewed were for mixer/loader/applicator uses, and are represented in the mixer/loader/applicator assessments.

- According to the LUIS report, there is a bait/solid formulation. However, the labels received did not indicate a bait/solid formulation; therefore, an assessment was not performed for this use. In the event that such a product does exist, then an assessment will be conducted providing the bait is a granular dispersed by hand. If the bait is not a granular dispersed by hand, an assessment can not be conducted since surrogate data are not available in PHED Version 1.1 for other bait/solid uses. OREB defers the verification of this use/formulation to SRRD and/or BEAD.

- Daily acres treated values are from EPA OREB estimates of acreage that could be treated in a single day for each exposure scenario of concern.

Short-term and intermediate-term dermal and inhalation exposure assessments using PHED Version 1.1 surrogate data and baseline risk calculations are presented in Table 1. *No chemical-specific data were submitted.* It should be noted that even though a chronic endpoint of 5 mg/kg/day has been identified, it is not expected that the use patterns associated with cypermethrin would result in chronic exposure. Even though the timing and type of application is varied (i.e., applied pre-emergent, applied when needed, applied as a crack and crevice treatment, as a spot treatment, etc.), it is not expected that a worker would be using cypermethrin consistently throughout the year (5 days/week). Therefore, a chronic risk assessment is not required. Table 2 presents the mitigated risk assessment for the short-term and intermediate-term dermal and inhalation exposures. Table 3 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

Potential daily exposure is calculated using the following formula:

$$\text{Daily Exposure} \left( \frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left( \frac{\text{mg ai}}{\text{lb ai}} \right) \times \text{Max. Appl. Rate} \left( \frac{\text{lb ai}}{\text{acre}} \right) \times \text{Max. Area Treated} \left( \frac{\text{acres}}{\text{day}} \right)$$

These calculations of daily exposure to cypermethrin by handlers are used to calculate the daily dose to those handlers.

Table 1. Baseline Short-Term and Intermediate-Term Exposure and Risk Estimates for Cypermethrin

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)*	Baseline Inhalation Unit Exposure (mg/lb ai)*	Maximum Application Rate (lb ai/acre)*	Daily Acres Treated*	Daily Dermal Exposure (mg/day)*	Daily Inhalation Exposure (mg/day)*	Daily Absorbed Dermal Dose (mg/kg/day)*	Daily Inhalation Dose (mg/kg/day)*	Dermal MOE <sup>1</sup>	Inhalation MOE <sup>2</sup>
<b>Mixer/Loader Exposure</b>										
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	2.9	0.0012	0.1	350	101.5	0.042	0.725	0.0006	7	4,450
Mixing/Loading Liquids for Groundboom Application (1b)			0.1	80	23.2	0.0096	0.166	0.0001	30	26,700
<b>Applicator Exposure</b>										
Fixed-wing Aircraft (Sprays) (2)	See Engineering Controls	See Engineering Controls	0.1	350	Because there are no surrogate data available for open cockpit (which would be considered baseline), unit dermal and inhalation values are not presented in this table. There are data available for enclosed cockpit and the exposure/risk values for this scenario are presented under "Engineering Controls" in the following risk mitigation table. These values are presented in the risk mitigation table because an enclosed cockpit is considered an engineering control, whereas, the other values presented in this table are baseline values without additional risk mitigation added.					
Helicopter (Sprays) (3)	See Engineering Controls	See Engineering Controls	0.1	350	See explanation above for fixed-wing aircraft					
Groundboom Application (Broadcast and Band Treatment) (4)	0.015	0.0007	0.1	80	0.12	0.0056	0.00086	0.00008	5,814	33,375
Rights-of-Way (5)	1.17	.0039	0.1	10	1.17	0.0039	0.008	0.00006	625	44,500
Handgun - Turf Grass Application (6)	See PPE	0.00019	0.019	1	See PPE	3.7E-6	See PPE	5.3E-8	See PPE	5.0E+7
Aerosol Can (7)	186.6	1.27	0.0012 lbs ai/can	1 can	0.22	0.0015	0.0016	0.00002	3,125	133,500
Ear Tags (Animal Treatment) (8)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Brush (9)**	182	0.284	0.017 lbs ai/gal.	1 gallon	3.09	0.005	0.022	0.00007	227	38,143
<b>Mixer/Loader/Applicator Exposure</b>										
Aerosol Generator/Fogger (10)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
Application by Hand (Cloth, Drencher, Sponge) (11)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
High Pressure Sprayer (12)	3.4	0.117	0.1	0.5	0.17	0.006	0.0012	0.00009	4,167	29,667
Termiticide Injection (13)	1.26	0.0022	0.05	56 gallons	3.5	0.006	0.025	0.00009	200	29,667
Low Pressure Handwand (14)	103.8	0.0312	0.1	0.5	5.2	0.002	0.037	0.00003	135	89,000
Backpack Sprayer (15)	2.6	30.2	0.1	0.5	0.13	0.002	0.0009	0.00003	5,556	89,000
Sprinkler Can (16)	No data	No data	No data	No data	No data	No data	No data	No data	No data	No data
<b>Flagger Exposure</b>										
Flagging (Sprays) (17)	0.01	0.00028	0.1	350	0.35	0.0098	0.0025	0.0001	2,000	26,700

a Baseline dermal unit exposure represents long pants, long sleeve shirt, no gloves, open mixing/loading, open cab tractor.

b Baseline inhalation exposure represents no respirator.

c Application rate comes from maximum values found in the cypermethrin labels:

Termiticide injection = EPA Reg. No. 279-3118;

Agriculture = EPA Reg. No. 279-3084;

Aerosol Can = EPA Reg. No. 4822-389;

Residential Lawns = EPA Reg. No. 279-3117.

d Daily acres treated values are from EPA OREB estimates of acreage that could be treated in a single day for each exposure scenario of concern.

e Daily dermal exposure (mg/day) = Exposure (mg/lb ai) \* Appl. rate (lb ai/A) \* Acres Treated

f Daily inhalation exposure (mg/day) = Exposure (mg/lb ai) \* Appl. Rate (lb ai/A) \* Acres Treated

g Daily Absorbed Dermal Dose (mg/kg/day) = Exposure (mg/kg/day) \* [0.5 dermal absorption]

h Daily Inhalation Dose (mg/kg/day) = Daily inhalation exposure (mg/day)/70 kg.

i Dermal MOE values calculated using the following equation: MOE = NOEL (mg/kg/day)/dermal absorbed dose (mg/kg/day); where dermal NOEL = 5 mg/kg/day.

j Inhalation MOE values calculated using the following equation: MOE = NOEL (mg/kg/day)/inhalation dose (mg/kg/day); where inhalation NOEL = 0.01 mg/L or 2.67 mg/kg/day.

\*\* Surrogate data used for this scenario is the paint brush data.

Table 2. Summary Risk Mitigation Measures for Cypermethrin

Risk Mitigation Measures										
Exposure Scenario (Scen. #)	Additional PPE <sup>c</sup>					Engineering Controls <sup>p</sup>				
	Unit Exposures Dermal = (mg/lb ai)	Daily Absorbed Dermal Dose <sup>d</sup> (mg/kg/day)	Daily Inhalation Dose (mg/kg/day)	Dermal MOE <sup>a</sup>	Unit Exposure Dermal = (mg/lb ai) Inh. = (mg lb ai)	Daily Absorbed Dermal Dose <sup>d</sup> (mg/kg/day)	Daily inhalation Dose (mg/kg/day)	Dermal MOE <sup>a</sup>	Inhalation MOE <sup>b</sup>	
	Mixer/Loader Exposure and Dose Levels									
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	Dermal = 0.043	0.01	N/A	500	N/A	N/A	N/A	N/A	N/A	
Mixing/Loading Liquids for Groundboom Application (1b)		0.002	N/A	2,500		N/A	N/A	N/A	N/A	
Applicator Exposure and Dose Levels										
Fixed-wing Aircraft (Sprays) (2)	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	Dermal = 0.005 Inh. = 0.000068	0.001	0.00003	5,000	89,000	
Helicopter (Sprays) (3)	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	Dermal = 0.0021 Inh. = 0.000002	0.0005	1.0E-6	10,000	2.7E+06	
Handgun - Turf Grass Application (6)	Dermal = 0.338	0.00005	N/A	100,000	N/A	N/A	N/A	N/A	N/A	

A Dermal MOE values calculated using the following equation:  $MOE = NOEL \text{ (mg/kg/day)} / \text{dermal absorbed dose (mg/kg/day)}$ ; where dermal NOEL = 5 mg/kg/day.

B Inhalation MOE values calculated using the following equation:  $MOE = NOEL \text{ (mg/kg/day)} / \text{inhalation dose (mg/kg/day)}$ ; where inhalation NOEL = 0.01 mg/L or 2.67 mg/kg/day.

C PPE = single layer clothing and chemical resistant gloves.

D Engineering Controls = single layer clothing, no gloves, and enclosed cockpit (open cockpit data are not available).

E Daily Dermal Exposure (mg/day) = Exposure (mg/lb ai) \* Max. Appl. Rate (lb ai/acre) \* Max. Treated.

F Daily Absorbed Dermal Dose (mg/kg/day) = [Daily Exposure (mg/day)/Body Weight] \* [0.5 Dermal Absorption].

Those scenarios for which there are no data (i.e., ear tags, aerosol generator/fogger, and hand applications) are not included in Table 2 above, since mitigation measures can not be proposed at this time. In addition, for the scenarios for which the dermal and inhalation MOEs were greater than 100 without the use of additional mitigation techniques (i.e., groundboom application, rights-of-way, aerosol can, brush, high pressure sprayer, termiticide injection, low pressure handwand, backpack sprayer, sprinkler can and flagger) are not indicated in the table above, since mitigation of the risks were not necessary.

Table 3. Exposure Scenario Descriptions for Cypermethrin

Exposure Scenario (Scen. #)	Data Source	Standard Assumptions <sup>a</sup>	Comments <sup>b</sup>
<b>Mixer/Loader</b>			
Open Mixing All Liquids Applications (1a, b)	PHED V1.1	350 acres for aerial and 80 acres for groundboom.	<p>Baseline: "Best Available" grades: Dermal, hands, and inhalation acceptable grades. Dermal = 25 to 122 replicates; Hands = 53 replicates; Inhalation = 85 replicates. High confidence in dermal and inhalation data. No protection factors (PFs) were necessary.</p> <p>PPE: "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates. High confidence in dermal data.</p> <p>No Protection Factors (PFs) were necessary.</p>
<b>Applicator</b>			
Fixed-wing Aircraft (Sprays) (2)	PHED V1.1	350 acres	<p>Engineering Controls (enclosed cockpit): "Best Available" grades: Dermal and hands acceptable grades; inhalation A,B,C grades. Dermal = 24 to 48 replicates; hands = 34 replicates, inhalation = 23 replicates. Medium confidence in dermal and inhalation data.</p> <p>No PFs were necessary.</p>
Helicopter (Sprays) (3)	PHED V1.1	350 acres	<p>Engineering Controls (enclosed cockpit): "Best Available" grades: Dermal and hands A,B,C grades; inhalation acceptable grades. Dermal = 3 replicates; hands = 2 replicates, inhalation = 3 replicates. Low confidence in dermal and inhalation data.</p> <p>No PFs were necessary.</p>
Groundboom Application (Broadcast and Band Treatment) (4)	PHED V1.1	80 acres	<p>Baseline: "Best Available" grades: Dermal, hands, and inhalation acceptable grades. Dermal = 32 to 42 replicates; Hands = 29 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data.</p> <p>No PFs were necessary.</p>
Rights-of-Way (5)	PHED V1.1	10 acres	<p>Baseline: "Best Available" grades: Dermal, hands, and inhalation acceptable grades. Dermal = 0 to 16 replicates; Hands = 16 replicates; Inhalation = 16 replicates. Low confidence in dermal data; high confidence in inhalation data.</p> <p>No PFs were necessary.</p>

Table 3. Exposure Scenario Descriptions for Cypermethrin

Exposure Scenario (Scen. #)	Data Source	Standard Assumptions <sup>a</sup>	Comments <sup>b</sup>
Handgun - Turf Grass Application (6)	PHED V1.1	1 acre	PPE: "Best Available" grades: Dermal and hands = all grades; inhalation = acceptable grades. Dermal = 0 to 14 replicates; Hands = 14 replicates; Inhalation = 14 replicates. Low confidence in dermal data; Low to medium confidence in inhalation data. No PFs were necessary.
Aerosol Can (7)	PHED V1.1	1 can	Baseline: "Best Available" grades: Dermal, hands, and inhalation acceptable grades. Dermal = 15 replicates; Hands = 15 replicates; Inhalation = 15 replicates. High confidence in dermal and inhalation data. No PFs were necessary.
Ear Tags (8)	No data	No data	No data
Paint Brush (9)	PHED V1.1	1 gallon	Baseline: "Best Available" grades: Dermal and hands = A,B,C grades; inhalation = grade C. Dermal = 15 replicates; Hands = 15 replicates; Inhalation = 15 replicates. Medium confidence in dermal and inhalation data. No PFs were necessary.
Mixer/Loader/Applicator			
Aerosol Generator (10)	No data	No data	No data
Application by Hand (Cloth, Drencher, Sponge) (11)	No data	No data	No data
High Pressure Sprayer (12)	PHED V1.1	0.5 acres	Baseline: "Best Available" grades: Dermal = all grades; hands = A,B,C grades; inhalation = acceptable grades. Dermal = 7 to 13 replicates; Hands = 13 replicates; Inhalation = 117 replicates. Low confidence in dermal and inhalation data. Since the only hand data available in PHED was for gloves, a 90 percent PF was removed from the PPE scenario and the baseline hand exposure was back calculated.
Termiticide Injection (13)	PHED V1.1	56 gallons as per label instructions for a 30 ft x 40 ft house.	Baseline: "Best Available" grades: Dermal, hands and inhalation = acceptable grades. Dermal = 17 replicates; Hands = 17 replicates; Inhalation = 17 replicates. High confidence in dermal and inhalation data. Since the only hand data available in PHED was for gloves, a 90 percent PF was removed from the PPE scenario and the baseline hand exposure was back calculated.

Table 3. Exposure Scenario Descriptions for Cypermethrin

Exposure Scenario (Scen. #)	Data Source	Standard Assumptions <sup>a</sup>	Comments <sup>b</sup>
Low Pressure Handwand (14)	PHED V1.1	0.5 acres	Baseline: "Best Available" grades: Dermal, hands and inhalation = All grades. Dermal = 25 to 96 replicates; Hands = 70 replicates; Inhalation = 96 replicates. Low confidence in dermal and inhalation data. No PFs were necessary.
Backpack Sprayer (15)	PHED V1.1	0.5 acres	Baseline: "Best Available" grades: Dermal and hands = A,B,C grades; inhalation = Acceptable grades. Dermal = 9 to 11 replicates; Hands = 11 replicates; Inhalation = 11 replicates. Low confidence in dermal and inhalation data. Since the only hand data available in PHED was for gloves, a 90 percent PF was removed from the PPE scenario and the baseline hand exposure was back calculated.
Sprinkler Can (16)	No data	No data	No data
Flagger Exposure and Dose Levels			
Flagger (Sprays) (17)	PHED V1.1	350 acres	Baseline: "Best Available" grades: Dermal, hands, and inhalation acceptable grades. Dermal = 16 to 18 replicates; Hands = 16 replicates; Inhalation = 18 replicates. High confidence in dermal and inhalation data. No PFs were necessary.

<sup>a</sup> Standard Assumptions based on the Registrant's risk mitigation response.

<sup>b</sup> "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part  
 Medium = grades A, B, and C and 15 or more replicates per body part  
 Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

## Post Application Exposure & Assumptions

The potential for post-application exposure exists. For example, a person reentering a food handling establishment which has been treated with cypermethrin may come in contact with a treated surface or may inhale remaining residues. There are no chemical specific data available for which to perform a quantitative exposure assessment. However, when qualitatively assessing post-application exposure, in the case of cypermethrin, it is not expected that reentry workers/persons would be exposed to more material than the mixer/loader/applicator. It should be noted however, that based on the incident review provided, specific label instructions have been provided in the labeling section to reduce the potential post-application exposures.

### (RISK)

#### Occupational and Residential

The daily dose is calculated using the following formula:

$$\text{Daily Dose} \left( \frac{\text{mg ai}}{\text{kg/day}} \right) = \text{Daily Exposure} \left( \frac{\text{mg ai}}{\text{day}} \right) \times \left( \frac{1}{\text{body weight (kg)}} \right)$$

These calculations of daily dose of cypermethrin received by handlers are used to assess the dermal risk to those handlers. The short-term and intermediate-term MOEs were calculated using the following formula:

$$\text{MOE} = \frac{\text{NOEL} \left( \frac{\text{mg}}{\text{kg/day}} \right)}{\text{Daily Dose} \left( \frac{\text{mg}}{\text{kg/day}} \right)}$$

These calculations of daily dose of cypermethrin by handlers are used to assess the risk to those handlers. For the short-term and intermediate-term risk assessment, a NOEL of 5 mg/kg/day was used along with a 70 kg body weight. For the inhalation risk assessment, a NOEL of 2.67 mg/kg/day was used along with a 70 kg body weight.

## **Risk From Handler Exposures**

### **Short-Term and Intermediate-Term Risk**

#### **Risks via the Dermal Route**

The calculations of risk indicate that the MOEs are more than 100 at **baseline** (i.e., workers wearing long pants, long sleeve shirt, no gloves, open mixing and open cab tractor) for short-term and intermediate-term risk for the following scenarios:

- (4) liquid application with a groundboom sprayer;
- (5) application to rights-of-way;
- (7) aerosol can application;
- (9) applying with a brush;
- (12) mixing/loading/applying liquid with a high pressure sprayer;
- (13) mixing/loading/applying liquids via termiticide injection techniques;
- (14) mixing/loading/applying liquids with a low pressure handwand;
- (15) mixing/loading/applying liquids with a backpack sprayer; and,
- (17) flagging aerial liquid applications.

The calculations of risk indicate that the MOEs are more than 100 with **Additional PPE** (workers wearing single layer clothing and chemical resistant gloves) for short-term and intermediate-term risk for the following scenarios:

- (1a) mixing/loading liquid application for aerial/chemigation application;
- (1b) mixing/loading liquid application for groundboom sprayer application; and,
- (6) applying liquids with a handgun (turf grass application).

The calculations of risk indicate that the MOEs are more than 100 with **Engineering Controls** (workers wearing single layer clothing, no gloves and an enclosed cockpit) for short-term and intermediate-term risk for the following scenarios:

- (2) applying liquids with a fixed wing aircraft; and,
- (3) applying liquids with a helicopter.

In summary, all the scenarios for which there were data resulted in MOEs greater than 100 when maximum mitigation measures were applied. As previously mentioned, a chronic risk assessment was not conducted because the use patterns of cypermethrin are such that chronic exposure is not anticipated.

There were no surrogate or chemical-specific data for the following scenarios:

- (2) baseline and additional PPE data for liquids aerial application with a fixed-

- wing aircraft. There are engineering controls data for this scenario;
- (3) baseline and additional PPE data for liquids aerial application with a helicopter. There are engineering controls data for this scenario;
- (5) baseline data for liquid application with a handgun (for turf grass application);
- (8) application of ear tags;
- (10) mixing/loading/applying with an aerosol generator/fogger;
- (11) mixing/loading/applying liquids by hand (cloth, drencher, sponge); and,
- (16) mixing/loading/applying liquids with a sprinkler can.

#### Risks via the Inhalation Route

The calculations of risk indicate that the MOEs are more than 100 at baseline (i.e., no respirator) for inhalation risk for the following scenario:

- (1a) mixing/loading liquid application for aerial/chemigation application;
- (1b) mixing/loading liquid application for groundboom sprayer application;
- (4) liquid application with a groundboom sprayer;
- (5) application to rights-of-way;
- (6) applying liquids with a handgun (turf grass application)
- (7) aerosol can application;
- (9) applying with a brush;
- (12) mixing/loading/applying liquid with a high pressure sprayer;
- (13) mixing/loading/applying liquids via termiticide injection techniques;
- (14) mixing/loading/applying liquids with a low pressure handwand;
- (15) mixing/loading/applying liquids with a backpack sprayer; and,
- (17) flagging aerial liquid applications.

The calculations of risk indicate that the MOEs are more than 100 with **Engineering Controls** (i.e., enclosed cockpit) for inhalation risk for the following scenarios:

- (2) applying liquids with a fixed wing aircraft; and,
- (3) applying liquids with a helicopter.

In summary, all of the scenarios (except two) for which there were data the inhalation MOEs were greater than 100 without the need for additional PPE or engineering controls. When mitigation measures were considered, inhalation MOEs for all scenarios were greater than 100.

There were no surrogate or chemical-specific data for the following scenarios:

- (2) baseline and additional PPE data for liquids aerial application with a fixed-

- wing aircraft. There are engineering controls data for this scenario;
- (3) baseline and additional PPE data for liquids aerial application with a helicopter. There are engineering controls data for this scenario;
- (8) application of ear tags;
- (10) mixing/loading/applying with an aerosol generator/fogger;
- (11) mixing/loading/applying liquids by hand (cloth, drencher, sponge); and,
- (16) mixing/loading/applying liquids with a sprinkler can.

### **Risk From Post-Application Exposures**

Based on the assessments conducted for the mixer/loader/applicator, for most scenarios risks to applicators should not be of concern, and in the case of cypermethrin, it is anticipated that persons reentering a treated area would not be exposed to more material than the mixer/loader/applicator. Therefore, when qualitatively assessing post-application exposure, it is determined that if the chemical is used in accordance with label instructions risks to persons reentering a treated area should not be of significant concern. It should be noted, however, that based on the incident review provided, specific label instructions have been provided in the labeling section to reduce the potential post-application exposures. The existing REI of 12 hours as imposed by WPS appears to be adequate for minimizing risks.

### **Additional Occupational/Residential Exposure Studies**

#### **Handler Studies**

Despite the fact that there are scenarios for which there are no data or low confidence in the data used, OREB does not anticipate that evaluation of additional data for these scenarios (except as stipulated below) would result in MOEs less than 100. OREB is requesting confirmatory data for the aerosol/fogger generator scenario. The potential for significant exposure exists during this application; therefore, OREB is requesting that data be submitted in support of guideline numbers:

- 875.1100 - estimation of dermal exposure at outdoor sites;
- 875.1300 - estimation of inhalation exposure at outdoor sites;
- 875.1200 - estimation of dermal exposure at indoor sites; and
- 875.1400 - estimation of inhalation exposure at indoor sites.

Based on the assessment done for the other scenarios, the results indicated MOEs greater than 100, and it is expected that the data requested would also indicated that the MOEs from this scenario would also be greater than 100. This is rationale for considering these data confirmatory.

OREB is also requesting confirmatory data for mixing/loading/applying liquids by hand

(cloth, drench, sponge). Because this can be a messy application and as previously mentioned, there was low confidence in some of the surrogate data used, OREB is requesting confirmatory data for guideline #s:

875.1200 - estimation of dermal exposure at indoor sites, and  
875.1400 - estimation of inhalation exposure at indoor sites.

### **Post-Application Studies**

Based on the surrogate risk assessment of the current uses of cypermethrin, post-application exposure studies are not required at this time.

## **(SECTION IV - REGULATORY POSITION AND LABELING RATIONALE)**

### **Occupational and Residential Labeling Rationale/Risk Mitigation**

#### **The Worker Protection Standard (WPS)**

##### **Scope of the WPS**

*The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.*

At this time some of the registered uses of cypermethrin are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are *outside* the scope of the WPS include use:

- on pastures or rangelands,
- on livestock or other animals, or in or around animal premises,
- on plants grown for other than commercial or research purposes, which may include plants in habitations, home fruit and vegetable gardens, and home greenhouses,
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms ARE covered by the WPS).
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other

noncrop areas and structural pest control.

### ***Personal Protective Equipment/Engineering Controls for Handlers***

*For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:*

*1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.*

*2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity, systemic effects, or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):*

- *In the RED for that active ingredient, EPA may establish minimum handler PPE or engineering control requirements that pertain to all or most end-use products containing that active ingredient.*
- *These minimum PPE/engineering control requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.*
- *The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.*

*Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.*

### **Occupational-Use Products**

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for certain occupational handlers must be taken for cypermethrin. Since potential handler exposure is similar for WPS and nonWPS uses, there is only one set of active-ingredient-based minimum PPE requirements for both WPS and nonWPS occupational uses of cypermethrin.

The MOEs for dermal exposures were less than 100 at baseline attire for persons mixing and loading the liquid formulations to support aerial, chemigation, and groundboom applications. The addition of chemical-resistant gloves results in dermal MOEs of greater than 100 for these exposure scenarios. Therefore for liquid-concentrate formulations, EPA is requiring mixers and loaders to wear chemical-resistant gloves.

The Pesticide Handlers Exposure Database (ver1.1) does not contain sufficient data to estimate exposure to aerial applicators using aircraft with open cockpits. Therefore, the exposure and risk assessment for aerial applicators was estimated using enclosed cockpits. Although the vast majority of aerial applicators use aircraft with enclosed cockpits, EPA does not have concerns for handlers who may apply cypermethrin using aircraft with open cockpits, since the MOEs for enclosed cockpits are in the thousands.

The Pesticide Handlers Exposure Database (ver1.1) does not contain sufficient data to estimate exposure to applicators using handgun equipment for turfgrass spray applications while wearing baseline attire. Therefore, the exposure and risk assessment for such applicators included the use of chemical-resistant gloves in addition to baseline attire. However, since the MOEs for such applicators are in the thousands and all other applicator and mixer/loader/applicator exposure scenarios are acceptable at baseline attire (no chemical-resistant gloves), EPA will not require applicators using handgun equipment to wear chemical-resistant gloves.

### **Homeowner-Use Products**

EPA is not establishing minimum handler PPE for cypermethrin end-use products that are intended primarily for homeowner use, because the Agency has determined that the frequency, duration, and degree of exposure by such users do not warrant such risk mitigation measures. The MOEs are all greater than 100 at baseline attire for homeowner scenarios.

## **Post-Application/Entry Restrictions**

### **Occupational-Use Products (WPS and NonWPS Uses)**

#### **Entry Restrictions:**

*Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI.*

*In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS. During the reregistration process, EPA considers all relevant product-specific information to determine the appropriate restricted entry interval(s).*

As a result of the reregistration evaluation of the acute and other adverse effects of cypermethrin, the Agency has determined that the risks from post-application dermal exposures to cypermethrin by workers warrant the minimum WPS REI of 12 hours. Furthermore, since EPA has determined that the risks from adverse effects in outdoor areas are minimal, EPA is establishing the minimum WPS early-entry PPE of coveralls, chemical-resistant gloves, shoes and socks. At this time, cypermethrin is not a candidate for a 4-hour REI, since there are toxicological concerns (dermal NOEL and inhalation NOEL) and epidemiological information that indicates groups of people may experience systemic illness when exposed to cypermethrin following applications in enclosed areas.

Post-application exposures associated with non-WPS outdoor uses of cypermethrin generally involve less substantial, and briefer, exposures than those associated with WPS uses. Therefore, the Agency is establishing different requirements for reentry into treated areas following such uses. For nonWPS uses of cypermethrin, the Agency is requiring that reentry be prohibited following liquid applications until sprays have dried and following dry applications until dusts have settled. No PPE for nonWPS uses is specified, since reentry is prohibited until sprays have dried and dusts have settled.

Since epidemiological evidence indicates a possible inhalation concern from post-application exposures to applications in enclosed areas, such as residences, offices, and other enclosed structures, EPA is requiring that the entire application area be vacated during application and remain vacated until the area is thoroughly ventilated.

#### **WPS Notification Statement:**

*Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."*

Cypermethrin is not classified as toxicity category I for select acute dermal toxicity or skin irritation potential and is not classified as a severe skin sensitizer and EPA has no special concerns about cypermethrin for adverse effects where a single exposure can trigger the effect and EPA has not established an unusually long restricted-entry interval. Therefore, at this time, EPA is not requiring a WPS "double" notification statement on the labeling of cypermethrin end-use products.

### **Homeowner-Use Products**

Since EPA has concerns about post-application exposures to persons after homeowner applications of cypermethrin, the Agency is requiring that reentry be prohibited following liquid applications until sprays have dried and following dry applications until dusts have settled. In addition, since epidemiological evidence indicates a possible inhalation concern from post-application exposures to applications in enclosed areas, such as residences, offices, and other enclosed structures, EPA is requiring that the entire application area be vacated during application and remain vacated until the area is thoroughly ventilated. For specific requirements, refer to Section V of this document.

### **Other Labeling Requirements**

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing cypermethrin. For the specific labeling statements, refer to Section V of this document.

## **(RED SECTION V - LABELING REQUIREMENTS)**

### **LABELING REQUIREMENTS FOR END-USE PRODUCTS**

#### **PPE/Engineering Control Requirements for Pesticide Handlers**

For sole-active-ingredient end-use products that contain cypermethrin, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain cypermethrin, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

### **Products Intended Primarily for Occupational Use (WPS and nonWPS)**

#### **Minimum PPE/Engineering Control Requirements**

EPA is establishing minimum PPE for some occupational uses of cypermethrin end-use products.

For liquid-concentrate formulations (not liquid ready-to-use formulations):

"Mixers and loaders must wear chemical-resistant gloves."

#### **Determining PPE Requirements for End-use Product Labels**

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

#### **Placement in Labeling**

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

### **Products Intended Primarily for Homeowner Use**

#### **Minimum PPE Requirements**

EPA is not establishing active-ingredient-based minimum handler PPE for cypermethrin end-use products that are intended primarily for homeowner use.

#### **Determining PPE Requirements for End-Use Product Labels**

Any necessary PPE for each cypermethrin end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

#### **Placement in Labeling**

The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

### **Entry Restrictions**

For sole-active-ingredient end-use products that contain cypermethrin the product labeling must be revised to adopt the entry restrictions set forth in this section. Any

conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain cypermethrin the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

### **Products Intended Primarily for Occupational Use**

#### **WPS Uses**

##### **Restricted-entry interval:**

A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all cypermethrin end-use products.

Registrants, add this statement if the end-use product contains directions that would permit application to enclosed areas, such as a greenhouse:

"If application is made to enclosed areas, such as a greenhouse, then one of the WPS ventilation criteria must be met before entry by persons -- other than correctly trained and PPE-equipped handlers -- is permitted."

Registrants, add this statement if the end-use product contains directions for soil-injection or soil-incorporation.

"Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

##### **Early-entry personal protective equipment (PPE):**

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves,
- shoes plus socks.

##### **Placement in labeling:**

The REI and early-entry PPE must be inserted into the standardized REI early-entry PPE statements required by Supplement Three of PR Notice 93-7.

**NonWPS uses****Entry restrictions:**

The Agency is establishing the following entry restrictions for nonWPS occupational uses of cypermethrin end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:

"Do not enter or allow others to enter the treated area until dusts have settled."

For applications in enclosed areas:

"Following applications to enclosed areas, such as residences, office buildings, or other structures, do not allow persons or pets to reenter the treated area until the entire application site has been thoroughly ventilated."

**Placement in labeling:**

**If WPS uses are also on label --** Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

**If no WPS uses are on the label --** Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

**Products Intended Primarily for Homeowner Use****Entry restrictions:**

The Agency is establishing the following entry restrictions for all homeowner uses of cypermethrin end-use products:

For liquid applications:

"Do not allow people or pets to touch treated plants until the sprays have dried."

For dry applications:

"Do not allow people or pets to enter the treated area until dusts have settled."

For applications in enclosed areas:

"Following applications to enclosed areas, such as residences, office buildings, or other structures, do not allow persons or pets to reenter the treated area until the entire application site has been thoroughly ventilated."

**Placement in labeling:** Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

### Other Labeling Requirements

#### **Products Intended Primarily for Occupational Use**

The Agency is requiring the following labeling statements to be located on all end-use products containing cypermethrin that are intended primarily for occupational use.

#### Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

#### Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

#### User Safety Requirements

1. Registrants: add this statement if coveralls are required for pesticide handlers on the end-use product label:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrants: add this statement always:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

#### **User Safety Recommendations**

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

#### **Skin Sensitizer Statement**

"This product may cause skin sensitization reactions in some people."

### **Products Intended Primarily for Home Use**

#### **Application Restrictions**

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application and until the area is thoroughly ventilated."

#### **User Safety Recommendations**

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

#### **Skin Sensitizer Statement**

"This product may cause skin sensitization reactions in some people."

## CONCLUSIONS/RECOMMENDATIONS

Based on the exposure/risk assessments conducted, MOEs for all scenarios resulted in values greater than 100 when additional mitigation measures were considered. Post-application exposures/risks should not be of concern provided the product is used in accordance with the label requirements stated. The label recommendations stipulated should minimize the potential for additional poisoning incidents (for cypermethrin only--doesn't directly influence the impact when combining cypermethrin with other active ingredients or inerts). According to the assessments performed, the risks are being driven by exposures via the dermal route. This should be considered when combining the risks (as recommended in the Toxicology Endpoint Selection Document).

### References

- 1) Cypermethrin labels (53 total labels were reviewed).
- 2) EPA 1996. BEAD Use profile Report for Cypermethrin, dated 4/16/96.
- 3) EPA 1996. Cypermethrin Toxicology Endpoint Selection Document, dated 9/16/96.
- 4) Memorandum entitled, "Cypermethrin - Review of Pesticide Poisoning Incident Data", dated July 2, 1996 from V. Dobozy/HED to L. Morris/HED.

### Attachment

cc: Laura E. Morris/OREB  
Tom Myers/RCAB  
Veronica Dutch/SRRD/7508W  
Chemical File (109702)  
Correspondence File  
Circulation