



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF PREVENTION, PESTICIDES AND TOXIC  
SUBSTANCES

July 2, 2008

MEMORANDUM

**SUBJECT:** **d-Phenothrin** (Sumithrin®): Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED)

PC Code: 069005	DP Barcode: 326945
Decision No.: 364968	Registration No.: 1021-1383, 10308-6
Petition No.: 7F7251	Regulatory Action: Reregistration/Registration
Assessment Type: NA	Reregistration Case No.: 0426
TXR No.: None	CAS No.: 026022-80-2
MRID No.: None	40 CFR: NA

**FROM:** Becky Daiss, Biologist *Becky Daiss*  
Reregistration Branch 4  
Health Effect Division (7509C)

**THROUGH:** Susan Hummel, Senior Scientist *Susan Hummel*  
Reregistration Branch 4  
Health Effects Division (7509C)

**TO:** Jennifer Howenstine  
Chemical Review Manager  
Reregistration Branch 3  
Special Review and Registration Division (7508C)  
and  
Ann Sibold  
Review Manager  
Insecticide Branch  
Registration Division (7505C)

This document provides an assessment of occupational and residential exposure and risk for d-Phenothrin. The document has been revised to address public comments submitted on the d-phenothrin risk assessment dated February 6, 2008.

## **1.0 Executive Summary**

### **1.1 Background and Purpose**

This occupational and residential exposure and risk assessment is being conducted as part of EPA's human health risk assessment for the d-Phenothrin Reregistration Eligibility Decision (RED) Document. This document addresses the exposures and risks associated with exposure to d-Phenothrin (phenothrin) based on label prescribed uses.

### **1.2 Use Patterns and Formulations**

Based on data from the Office of Pesticide Programs Information Network (OPPIN), there are currently 198 actively registered labels for phenothrin. Phenothrin is a broad spectrum insecticide effective against a wide range of flying and crawling insects. It is used for control of insects on ornamental plants, pets and their dwellings, and in outdoor and indoor areas of residential, recreational, commercial and industrial sites. It is available primarily as ready-to-use, pressurized liquid, and emulsifiable concentrate formulation. It is applied by commercial and residential applicators with application methods and equipment typically used for liquid formulations.

### **1.3 Hazard Identification**

Phenothrin has a low acute toxicity by oral (category III), dermal (category III), and inhalation (category IV) routes of exposure. It is a mild eye irritant (Category III) but is not a skin irritant or a skin sensitizer.

The effects on the liver are the most systemically sensitive endpoint following repeated oral exposure. These effects include increased liver weight, hepatocellular vacuolization and hypertrophy and, at higher doses, increased liver serum enzymes. The most sensitive effects from repeated inhalation exposure are portal of entry effects (histopathological changes in the nasal turbinates in both sexes) based on an inhalation study. The inhalation study also indicated histological effects on the liver, thyroid and adrenal which are of borderline toxicological significance alone, but which are supported in part by the increased organ weights and histological findings of similar occurrence in some oral studies. Phenothrin was not associated with any systemic toxicity up to the limit dose of 1000 mg/kg/day in a 3-week dermal toxicity study in rats. Currently, phenothrin is lacking acute, subchronic, and developmental neurotoxicity studies. The only available, but unacceptable/non-guideline, neurotoxicity study in rats is negative for neurotoxicity (observations based on clinical signs, but lacking other currently required parameters) when administered at 5000 mg/kg for 5 consecutive days. The most prominent evidence for phenothrin neurotoxicity is the presence of spina bifida in 1 fetus at 100 mg/kg/day, microphthalmia in 1 fetus at 300 mg/kg/day and hydrocephaly in four rabbit fetuses (within 3 litters) at the highest dose tested of 500 mg/kg/day in a rabbit developmental study. The carcinogenic potential of phenothrin has been classified by the HED Cancer Assessment Review Committee as "not likely to be carcinogenic to humans."

Toxicological endpoints were selected for the inhalation exposure pathway for workers and residential handlers/occupants. An incidental oral endpoint was selected for residential exposure via the hand to mouth exposure pathway. Toxicological endpoints for dermal exposure were not required for this assessment because dermal effects were not observed at the limit dose in animal studies. Short and intermediate-term exposures are expected based primarily on the use pattern. The level of concern (LOC) or margin of exposure (MOE) for occupational and residential exposure is 1000 (10x for intraspecies variation, 10x for interspecies extrapolation, 10x for data base uncertainty).

## **1.4 Occupational and Residential Exposure and Risk**

Based on toxicological criteria, use patterns, and potential for exposure, HED has conducted inhalation and incidental oral exposure assessments for a variety of occupational and residential scenarios. Occupational and residential exposure via inhalation can occur during mixing, loading, and application activities. Inhalation and incidental oral exposures can occur during residential post-application activities.

### **1.4.1 Occupational Exposure Assessment**

Risk assessments were conducted for occupational and residential exposure pathways based on registered uses. Occupational and residential handler exposure and risk estimates were conducted using HED standard deterministic modeling methodology and default assumptions for most exposure scenarios. Occupational exposure and risk estimates indicate MOEs of concern (MOEs < 1000) at the maximum use rate for only one of the worker scenarios assessed: mixing, loading and applying liquids with high pressure hand wand for non-food greenhouse. MOEs for this greenhouse use are not of concern at maximum application rates with use of a PF5 respirator. All other occupational exposure scenarios do not present risks of concern (i.e., MOEs  $\geq$  1000).

### **1.4.2 Residential Exposure Assessment**

Risk assessments were conducted for residential exposure pathways based on registered uses. Residential post-application exposure and risk to phenothrin was assessed using both deterministic and probabilistic modeling approaches. The results of the deterministic residential post-application exposure assessment indicate risks of concern (i.e., MOEs  $\leq$  1000) for the following residential scenarios; incidental ingestion risks to toddlers playing on vinyl floor and carpet after treatment with fogger formulation, post-application incidental ingestion risks to toddlers playing on carpet after treatment with carpet powder, incidental ingestion of residues on pets via hand-to-mouth after pet treatment. All other residential handler and post-application exposure scenario assessments conducted using deterministic modeling result in MOEs that are not of concern (MOEs  $\geq$  1000).

HED conducted a probabilistic assessment using the Cumulative and Aggregate Risk Evaluation System (CARES<sup>®</sup> Version 3.0; <http://cares.ilsi.org/>), a publicly available software program, for those residential post-application exposure scenarios that presented risks of concern

based on the deterministic assessment. Probabilistic exposure assessment is recognized as a refinement over deterministic assessment because it incorporates the full range of exposures and their associated probabilities. Therefore, HED's conclusions regarding potential risks of concern for residential indoor post-application incidental oral exposures to phenothrin are based on the results of the probabilistic assessment. Based on the probabilistic assessment, MOEs were below 1000 at the 99.9<sup>th</sup> and 99.5<sup>th</sup> percentiles for the pet care spot-on and indoor carpet powder scenarios. Label requirements for the carpet powder use direct the user to keep children and pets out of the room for 2 hours and then vacuum. When use of a vacuum with a removal efficiency of 30% is assumed, MOEs greater than 1000 are seen at the 99.9<sup>th</sup> percentile. All other post-application exposure scenario assessments conducted using probabilistic modeling result in MOEs that are not of concern (MOEs  $\geq$  1000).

Aggregate risk is the estimated risk associated with combined risks from average food and drinking water exposures and short-term residential incidental oral and inhalation exposures. However, exposures from these pathways have not been aggregated for phenothrin because the toxicity endpoints for these exposure routes are not based on common specific target organ toxicity effects.

## 2.0 Hazard Identification

### 2.1 Acute Toxicology Categories

Table 1 presents the acute toxicity categories.

<b>Table 1. Summary of Acute Toxicity Endpoints</b>				
<b>GLN No.</b>	<b>Study Type</b>	<b>MRID</b>	<b>Results</b>	<b>Toxicity Category</b>
870.1100	Acute oral [Rat]	40908302	LD <sub>50</sub> > 5000 mg/kg (no deaths)	IV
870.1200	Acute dermal [Rat]	40908303	LD <sub>50</sub> >2000 mg/kg (no deaths)	III
870.1300	Acute inhalation [Rat]	43889301	LC <sub>50</sub> > 2.1 mg/L (no deaths)	IV
870.2400	Acute eye irritation [Rabbit]	40908304	Mild irritant	III
870.2500	Acute dermal irritation [Rabbit]	40908304	Non-irritating	IV
870.2600	Skin sensitization [Guinea pig]	40908305	Not a sensitizer	

### 2.2 Toxicological Endpoints

Endpoints and LOCs used to complete this assessment are summarized below in Tables 2 and 3.

<b>Table 2. Summary of Toxicological Doses and Endpoints for d-Phenothrin for Use in Dietary and Non-Occupational Human Health Risk Assessments</b>				
<b>Exposure/ Scenario</b>	<b>Point of Departure</b>	<b>Uncertainty/FQPA Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 50 mg/kg/day	UF <sub>A</sub> = 10 x UF <sub>H</sub> = 10 x FQPA SF= 10 x UF <sub>DB</sub>	Residential LOC for MOE = 1000	2-generation rat reproduction study LOAEL = 150 mg/kg/day based decreased body weight (4-6%) and increased liver weight in F0 and F1 parental animals, and an increase in absolute and relative spleen weight, and decreased absolute
Dermal All Durations	Dermal toxicity systemic LOAEL = not established 21/28 Dermal toxicity study in rats dermal toxicity systemic LOAEL not established up to 1000 mg/kg/day (HDT)			
Inhalation Short- Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 0.104 mg/L (26.6 mg/kg/day)	UF <sub>A</sub> = 10 x UF <sub>H</sub> = 10 x FQPA SF= 10 x UF <sub>DB</sub>	Residential LOC for MOE = 1000	90 Day inhalation toxicity study LOAEL = 0.291 mg/L (74.4 mg/kg/day) based on histopathological changes in the nasal turbinates.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

<b>Table 3. Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Occupational Human Health Risk Assessments</b>				
<b>Exposure/ Scenario</b>	<b>Point of Departure</b>	<b>Uncertainty Factors</b>	<b>LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Dermal All Durations	Dermal toxicity systemic LOAEL = not established 21/28 Dermal toxicity study in rats dermal toxicity systemic LOAEL not established up to 1000 mg/kg/day (HDT)			
Inhalation Short- Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 0.104 mg/L (26.6 mg/kg/day)	UF <sub>A</sub> = 10 x UF <sub>H</sub> = 10 x UF <sub>DB</sub> = 10 x	Occupational LOC for MOE = 1000	90 Day inhalation toxicity study LOAEL = 0.291 mg/L (74.4 mg/kg/day) based on histopathological changes in the nasal turbinates.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

## 2.3 Levels of Concern for Risk Assessment

A summary of target LOCs/MOEs for risk assessment is provided in Table 4.

<b>Table 4. Target Levels of Concern/Margin of Exposure for Phenothrin</b>			
<b>Route/Duration</b>	<b>Short-Term (1-30 Days)</b>	<b>Intermediate-Term (1 - 6 Months)</b>	<b>Long-Term (&gt; 6 Months)</b>
<b>Occupational (Worker) Exposure</b>			
Dermal	N/A	N/A	N/A
Inhalation	1000	1000	N/A
<b>Residential (Non-Dietary) Exposure</b>			
Oral	1000	1000	N/A
Dermal	N/A	N/A	N/A
Inhalation	1000	1000	N/A

The occupational and residential LOCs are based on the conventional uncertainty factor of 100X (10X for intraspecies extrapolation and 10X for interspecies variation) plus the factor of 10x for the database uncertainty due to the absence of the rat developmental study and the acute, subchronic, and developmental neurotoxicity studies.

## 3.0 Summary of Use Patterns and Formulations

### 3.1 Target Pests

Phenothrin-containing insecticides are used to control vast numbers and types of pests. Currently, based on EPA's OPPIN data base, phenothrin is used to control the following types of pests: ants, aphids, bed bugs, bees, beetles, billbugs, box elder, borer, cockroach, cadelle, caterpillars, centipedes, crickets, daubers, earwigs, fleas, flies, gnats, hornets, crawling insects, flying insects, grain insects, lace bugs, leafhoppers, leafminers, lice, moths, mites, mealybugs, midges, millipedes, mosquitoes, roaches, rust, scab, scales, scorpion, silverfish, spiders, sowbugs, thrips, ticks, wasps, waterbugs, weevil, worms, and yellowjackets. General applications for which phenothrin is currently registered are as follows.

- Outdoor Non-food Plants (domestic and commercial): ornamentals, lawns, groundcover, greenhouse non-food plants
- Commercial/Industrial/Agricultural Indoor and Outdoor Structures, Premises, and Equipment (does not include eating establishments, food processing plants and equipment, or grain storage facilities)
- Indoor Domestic Dwellings
- Outdoor Domestic Buildings and Premises
- Pets: cats, dogs, and all other domestic animals

### 3.2 Formulations

Based on EPA's pesticide registration database phenothrin is available as a technical manufacturing product, formulation intermediate, emulsifiable concentrate (EC), ready-to-use

(RTU) liquids and powders, and pressurized liquids (PrL). Percent a.i. in end use (commercially available) products ranges from 0.03 to 85.7%.

### 3.3 Registered Use Sites and Application Rates

Maximum application rates for various application categories are provided in Table 5. Maximum rates are based primarily on information provided in the LUIS data base, a review of active labels, and information provided by the registrants.

<b>Table 5. Summary of phenothrin Commercial and Residential Uses</b>			
<b>Site Category</b>	<b>Max % AI*</b>	<b>Maximum AR**</b>	<b>Reg No.</b>
<b>Occupational Uses</b>			
Non-food Crops – Greenhouses	1	0.08 lb ai/gal	499-291
Indoor Commercial and Domestic Structures Premises and Equipment: Surface and Crack and Crevice Application	3	0.25 lb ai/1000 sq ft	499-321
Indoor Commercial and Domestic Structures Premises and Equipment: Space Application	3	0.25 lb ai/1000 sq ft	499-321
Outdoor Commercial, Recreational and Domestic Outdoor Sites, Agricultural/Farm Structures, Premises and Equipment	1	0.08 lb ai/gal	499-371
Mosquito Abatement/Adulticide - Commercial, Recreational and Domestic Outdoor Sites	2	0.0036 lb ai/Acre	1021-1687
Direct Application to Pets	0.3	0.0015 lb ai/ application	4822-404
Airplane Cargo Holds ***	10	0.8 g ai/1000 cu ft	10308-21
<b>Residential Uses</b>			
Indoor Household Sprays – Space Spray	3	10 sec spray 1.5 g/sec (0.002 lb ai/application)	44446-66
Indoor Household Sprays – Surface/Crack and Crevice Spray	3	1 16 oz can (0.03 lb ai/16 oz can)	44446-66
Indoor Household Carpet Powder	0.5	1 lb/108 sq ft (0.000046 lb ai/sq ft)	2596-132
Total Release Fogger	2	1 5 oz can/8000 cu ft (0.0008 lb ai cu ft)	68543-2
Out Door House and Garden Sprays	0.2	3 sec/cu yd; 1.5 g/sec	1021-1588
Direct Application to Pets	0.3	½ 16 oz can per animal (680 mg ai/animal)	4822-404
Direct Application to Pets - Spot-on	85.7	0.09 fl oz per 6000 cm <sup>2</sup> (2230 mg ai/animal)	2596-151

\* Maximum % active ingredient in applied formulation

\*\* Maximum Application Rate

\*\*\* Phenothrin is applied to by or under the direction of Federal/State Personnel to airplane cargo holds in planes originating outside the US in accordance with U.S. Plant Protection and Quarantine Series, GS-0436 Guidance.

### 3.4 Application Methods and Equipment

Phenothrin is applied with the following types of equipment; aerosol can, non-aerosol pump sprayer, total release aerosol, aerial, truck-mounted ultra low volume (ULV) equipment,

cold aerosol generators, conventional mechanical compressed air equipment and conventional hydraulic sprayers (e.g., high and/or low pressure wand, backpack sprayer), and thermal fogging equipment.

#### **4.0 Incident Report**

The following data bases were consulted for poisoning incident data on the active ingredient phenothrin: OPP Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), and the National Institute of Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risks (SENSOR).

The IDS review showed 39 incidents reported since 1992. Reports submitted to the IDS typically represent anecdotal reports or allegations only; therefore no conclusions can be drawn implicating the pesticide as a cause of any the reported health effects unless supported by results from other data sources or the individual incidents are well documented. A total of 2342 occupational and non-occupational exposure cases were reported to PCC for the period from 1993-2005; 309 of the cases were seen in a health care facility. No trend in total exposure, symptomatic cases, or cases seen in a health care facility is apparent for the 13 year-span of data collected on phenothrin. The data indicate a steady average of about 180 exposures per year, 46 symptomatic cases per year, and 23 cases per year seen in a health care facility. The health symptoms observed in PCC reported exposure cases included gastro intestinal effects (nausea, throat irritation, and vomiting), dermal effects (skin irritation/pain, pruritis, rash, and erythema) neurological effects (headache, and dizziness/vertigo) and ocular effects (eye irritation). Detailed descriptions of 44 cases submitted to the CDPR California Pesticide Illness Surveillance Program (1998-2004) were reviewed. In five of these cases, phenothrin was used alone or was judged to be responsible for the health effects. Based on the NIOSH SENSOR data for 1998 to 2003, there were only four occupationally related cases involving phenothrin. Three cases were reported in Washington State and one in Florida. All reported cases produced mild symptoms including, allergic rhinitis exacerbation, asthmatic response to insecticide, and pruritis.

#### **5.0 Occupational Exposure and Risk**

Based on data provided by the registrant and review of active labels, twelve primary occupational exposure scenarios have been assessed for this RED. Only inhalation exposures have been assessed for each of the occupational scenarios based on toxicity data. Only short and intermediate-term exposures are expected/assessed for occupational exposure scenarios based on use and expected exposure patterns.

##### **5.1 Occupational Exposure Scenarios**

Only occupational handler scenarios were assessed for the phenothrin RED. The term "handler" applies to individuals who mix, load, and apply the pesticide product. Occupational

post-application scenarios were not assessed because there is no dermal endpoint and post-application inhalation exposures are not expected for non-volatile compounds such as phenothrin. Based primarily on active label uses, HED assessed the following worker exposure scenarios for the phenothrin RED.

### **5.1.1 Pesticide Control Operator Handler Scenarios**

- 1) Mixing, loading and applying liquids with high pressure hand wand for non-food green house.
- 2) Mixing, loading and applying liquids with low pressure hand wand for non-food green house.
- 3) Mixing, loading and applying liquids with low pressure hand for outdoor (e.g., recreational) sites.
- 5) Mixing, loading and applying liquids with low pressure hand wand indoors to domestic residences for surface and crack and crevice treatment.
- 6) Mixing, loading and applying liquids with low pressure hand wand to commercial non-food handling/processing/eating establishments and warehouses for surface and crack and crevice treatment.
- 7) Applying ready to use aerosol to airplane cargo holds (for use on imported products in accordance with the Plant Protection and Quarantine Manual)

### **5.1.2 Mosquito Abatement Scenarios**

- 1) Mixing, loading liquids for aerial application.
- 2) Mixing, loading liquids for ULV truck mounted spray application.
- 3) Applying liquids with truck mounted ULV ground spray (airblast sprayer unit exposure used as surrogate).
- 4) Mixing, loading, applying liquids with backpack sprayer/low pressure handwand.

### **5.1.3 Direct Application to Pets**

- Spray application by veterinarians and/or groomers.  
note: phenothrin is not registered for and may not be used on animals that may be used for human consumption.

## **5.2 Occupational Exposure Data and Assumptions**

### **5.2.1 Exposure Data**

#### **5.2.1.1 Application Parameters**

Maximum application rates for all of the exposure scenarios assessed are based on information provided in the active phenothrin labels and/or information provided by the registrant. Application methods and equipment are based on labels, information provided by the registrant (MRID 47119801), and OPP data bases.

#### **5.2.1.2 Occupational Handler Exposure Data**

##### HED Occupational Exposure SOPs

It is HED's policy to use data from the Pesticide Handlers Exposure Database (PHED) or Outdoor Residential Exposure Task Force (ORETF) data to assess handler exposures for regulatory actions when chemical-specific monitoring data or other handler-specific data are not available. PHED was designed by a task force of representatives from the US. EPA, Health Canada, the California Department of Pesticide Regulation, and members of the American Crop Protection Association. PHED is a software system consisting of two parts; 1) a database of measured exposures for workers involved in the handling of pesticides under actual field conditions, and 2) a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). The ORETF completed four studies which were designed to provide representative, or "generic" surrogate exposure data for residential risk assessment. The studies were designed by the Task Force, which included input from representatives of the crop protection field, regulatory agencies, and commercial applicators. The studies monitored professionals applying granular formulation by push spreader and various formulations by pressurized hose-end "handgun" or spray gun; and volunteers representing non-professional consumers applying granular formulation by push spreader and liquid formulations by garden hose-end sprays. Overall, the four ORETF studies were well-conducted and the data for all scenarios are considered of better quality and quantity than what is currently contained in PHED. Default application assumptions regarding areas treated or amounts applied for greenhouse and mosquito abatement handler exposure scenarios are documented in the HED Science Advisory Committee on Exposure's (ExpoSAC's) SOP 9, "Standard Values for Daily Acres Treated in Agriculture" (7/5/2000).

##### National Pest Management Association Survey

Information on pest control operator's use of pesticide products was obtained from a survey conducted by the National Pest Management Association (NPMA). NPMA sponsored a "Pest Control Operators (PCO) Product Use and Usage Information Survey". Using a retrospective telephone survey method, the enumerator (Dr. Richard Patterson of the University of Florida) contacted 148 PCO firms and was able to complete 67 surveys. The survey was

national in scope and included 12-23 responses from each of four regions. The survey collected information on where PCOs apply their products, product brands that are used for wood destroying insects and general pest control, and the amount of time PCOs spend on application, travel, equipment set up, mixing/loading products, administrative and other activities.

OPP's Biological and Economic Analysis Division (BEAD) conducted a review of the NPMA survey. BEAD drew the following conclusions regarding the robustness and validity of the survey data. Given that there are approximately 19,000 PCO firms in the U.S., it is highly unlikely that a sample size of 67 represents a statistically valid sample. The use of a retrospective survey methodology may have introduced errors in the data. Pesticide survey firms like Doane use a prospective survey instrument sent to growers in advance thus allowing them to keep detailed accounts of their pesticide usage in real time throughout the year. Despite its small size and retrospective methodology, however, the information collected is far more robust than BEAD typically gets when asking questions of this nature. BEAD typically contacts 1-5 PCO's and asks chemical specific questions which may bias the responses if PCO's value the chemical under review. BEAD believes that the NPMA Survey is a useful tool for conducting ORE assessments on upcoming RED chemicals (D. Brassard, D305276, 7/19/04).

## **5.2.2 Exposure Assumptions**

Assumptions used in estimating risks to occupational handlers from exposure to phenothrin are provided in the following sections.

### **5.2.2.1 Standard Exposure Assumptions**

- Average body weight of an adult handler is 70 kg.
- Exposure duration is short-term and intermediate-term for all workers assessed.
- Maximum application rates as determined by label review and/or registrant information were used for all types and methods of application.
- SOP daily volumes handled and/or area treated used for the scenarios assessed are as follows:
  - 7500 acres treated per day for aerial mosquito control application.
  - 3000 acres treated per day for mosquito control ULV truck mounted sprayer.
  - 5 gallons of spray solution used per day for mosquito control low pressure handwand or backpack sprayer applications (based on maximum application rate of 2 mph).
  - 1000 gallons of spray solution used per day for greenhouse high pressure handwand application
  - 40 gallons of spray solution used per day for greenhouse low pressure handwand application
  - 40 gallons of spray solution used per day for outdoor (recreational area) low pressure handwand application

### 5.2.2.2 Non-Standard Exposure Assumptions

Non-SOP daily volumes handled and/or area treated used for the scenarios assessed are as follows:

- Assumptions used for veterinary applications are not included in the Occupational Exposure SOPs but represent values that have been used by the Agency in previous assessments (e.g., carbaryl, cyfluthrin).
  - 8 pets are treated per day by pet groomers/veterinarians.
  - one half of a 16 oz spray container used to treat each animal.
- Assumptions used for daily area treated for food handling establishments and warehouses are based on best professional judgment.
- Assumptions used for general pest control applicators are based on data from the NPMA survey. Based on BEAD's review of the NPMA survey, PCOs conducting general pest control activities would treat an average of between 6 and 7 buildings per day, assuming an 8-hour work day. According to the EPA Exposure Factors Handbook, a central tendency estimate of the average residential house is 369 m<sup>3</sup> (12800 ft<sup>3</sup>). Given a typical ceiling height of 8 feet, the typical house has about 1,600 ft<sup>2</sup> of surface area. Given that NPMA survey data indicate that PCOs spend approximately the same amount of time applying general pest control formulations to residential and commercial buildings (68 minutes for residential buildings, 70 minutes for day care buildings, and 79 minutes for commercial/institutional buildings), it is assumed that approximately the same area is treated for residential and commercial structures.
  - 5 non-food handling establishment/non-food storage warehouses treated per day, area treated per establishment is 10,000 square feet; low pressure hand wand application
  - 7 commercial offices or residential homes treated per day; average area treated per building is 1600 square feet; low pressure hand wand application
- Airblast application unit exposure data was used to assess exposure resulting from truck mounted ULV application of mosquito adulticide. In the absence of more equipment specific data, airblast unit exposure data is thought to provide reasonable surrogate exposure information based on the similarity of the two application methods and has been used for this purpose in previous HED occupational exposure assessments (e.g., carbaryl).
- Assumptions for aerosol spray of airplane cargo holds: maximum size of cargo hold is 27,000 cubic ft. (<http://www.ups.com/aircargo/using/services/services/domestic/svc-aircraft.html>, <http://www.inamarmarine.com/pdf/LossControl/Air%20Cargo.pdf>), 10 planes treated per day.

### 5.3 Occupational Exposure and Risk Estimates

A target LOC or MOE of 1000 is considered adequate for short and intermediate-term inhalation occupational exposure and risk. All worker exposures are assessed as short-and intermediate-term based on label prescribed uses and expected exposure durations. Exposure and risk estimates indicate MOEs of concern (MOEs < 1000) at the maximum use rate for only one of the occupational exposure scenarios assessed: mixing, loading and applying liquids with

high pressure hand wand for non-food green house. MOEs for this greenhouse use are not of concern with use of a PF5 respirator. All other occupational exposure scenarios do not present risks of concern (i.e., MOEs  $\geq$  1000). A summary of occupational exposure and risk calculations, critical assumptions, and results is provided in Table 6.

<b>Table 6. Estimated Phenothrin Exposure &amp; MOEs for Pesticide Control Operator &amp; Mosquito Abatement Activities - Short and Intermediate Term LOC/MOE = 1000</b>						
Exp Scenario <sup>1</sup>	Inhalation Unit Exposure ( $\mu\text{g}/\text{lb ai}$ )	Use <sup>2</sup>	Application Rate <sup>3</sup> (APR)	Daily Area Treated <sup>4</sup>	Inhalation Dose (mg/kg/day) <sup>5</sup>	Inhalation MOE <sup>6</sup>
<b>Green House - Non Food Mix/Load/Apply Liquid Formulation</b>						
High Pressure Handwand <b>Maximum APR</b>	120	Greenhouse	0.08 lb/ai gal	1000 gal/day	0.1371	<b>194</b>
High Pressure Handwand <b>Maximum APR PF5 Respirator</b>	24				0.0274	970
High Pressure Handwand <b>Typical APR</b>	120				0.0137	1940
Low Pressure Handwand	30	Greenhouse	0.08 lb/ai gal	40 gal/day	0.0014	19400
Max AR = 0.01 x 8.35 lb ai/gal = 0.08 lb ai/gal (1% ai); Typical AR = 0.001 x 8.35 lb ai/gal = 0.08 lb ai/gal (0.1%)						
<b>Out Door Sites Mix/Load/Apply Liquid Formulation</b>						
Low Pressure Handwand	30	Recreational Areas	0.08 lb/ai gal	40 gal/day	0.0014	19400
AR = 0.01 x 8.35 lb ai/gal = 0.08 lb ai/gal (1% ai)						
<b>Indoor Homes/Buildings Mix/Load/Apply Liquid Formulation</b>						
Low Pressure Handwand	30	Contact Spray/Crack & Crevice	0.25 lbs/1000 ft <sup>2</sup>	7 buildings per day 1600 ft <sup>2</sup> per building	0.0012	22200
AR = 0.03 x 8.35 lb ai/gal = 0.25 lb ai/gal x 1 gal per 1000 ft <sup>2</sup> = 0.25 lbs ai/1000 ft <sup>2</sup> (3% ai)						
<b>Indoor Non-Food Handling/Processing/Eating Establishments/Non-Food Warehouses Mix/Load/Apply Liquid Formulation</b>						
Low Pressure Handwand	30	Contact Spray/Crack & Crevice	0.25 lbs/1000 ft <sup>2</sup>	5 facilities per day 10000 ft <sup>2</sup> per facility	0.0054	5000
AR = 0.03 x 8.35 lb ai/gal = 0.25 lb ai/gal x 1 gal per 1000 ft <sup>2</sup> = 0.25 lbs ai/1000 ft <sup>2</sup> (3% ai)						
<b>Cargo Containers</b>						
Aerosol Baseline PPE	1300	Cargo Containers	0.048 lb ai/cargo hold	10 planes/day	0.0089	3000
AR = 0.1 (10% ai) x 8 g/1000 ft <sup>3</sup> x 1lb/454 g x 27,000 ft <sup>3</sup> /airplane cargo hold x max 10 planes treated/day						
<b>Mosquito Abatement Mix/Load Liquid Formulation</b>						
ULV Truck Mounted Spray	1.2	Adulticide	0.0036 lb ai/acre	3000 acre/day	0.0002	144000
ULV Aerial	1.2	Adulticide	0.0036 lb ai/acre	7500 acre/day	0.0005	58000
<b>Mosquito Abatement Apply Liquid Formulation</b>						
ULV Truck Mounted Spray (Open Cab)	4.5	Adulticide	0.0036 lb ai/acre	3000 acre/day	0.0007	38000
<b>Mosquito Abatement Mix/Load/Apply Liquid Formulation</b>						
Backpack	30	Adulticide	0.17 lb ai/gal	5 gal/day	0.0004	73000
AR = 0.02 x 8.35 lb ai/gal = 0.17 lb ai/gal						
<b>Pet Groomer and Veterinarian Apply Aerosol</b>						
Aerosol	1300	Pet Spray	0.003 lb ai per 16 oz can	8 pets treated per day ½ can of spray per pet	0.0002	119000

<sup>1</sup> Baseline PPE inhalation unit exposures represent no respirator. Values are reported in the PHED Surrogate Exposure Guide dated August 1998 or are from data submitted by the Outdoor Residential Exposure Task Force dated May 2000.

<sup>2</sup> Use patterns are from the active labels

<sup>3</sup> Application rates are based on maximum values based on label review and/or information provided by registrants. Most application rates upon which the analysis is based are presented as lb ai/A. In some cases, the application rate is based on applying a solution at concentrations specified by the label (i.e., presented as lb ai/gallon).

<sup>4</sup> Amount treated is based on the area or gallons that can be reasonably applied in a single day for each exposure scenario of concern based on the application method and formulation/packaging type. (Standard EPA/OPP/HED values). 5 gal per day application rate for backpack spray mosquito application based on label specified application rate of 2 mph.

<sup>5</sup> Inhalation dose (mg/kg/day) = [unit exposure (ug/lb ai) \* 0.001 mg/ g unit conversion \* Inhalation absorption (100%) \* Application rate (lb ai/acre or lb ai/gallon) \* Daily area treated/amount handled (acres or gallons)] / Body weight (70 kg).

<sup>6</sup> Inhalation MOE = short-term and intermediate-term endpoint for inhalation; (inhalation NOAEL 26.6 mkd)/ Daily Inhalation Dose.

## 6.0 Residential Exposure and Risk

Based on a review of active labels and proposed new uses, twelve residential exposure scenarios have been assessed for this RED. Inhalation and incidental ingestion exposure assessments have been conducted for the residential scenarios. Short and intermediate-term exposures are expected and assessed for residential handler and post-application exposure scenarios based on use and expected exposure patterns.

Residential handler exposure and risk estimates were conducted using HED standard deterministic modeling methodology and default assumptions for most exposure scenarios. Residential post-application exposures and risks to phenothrin for several incidental oral exposure scenarios were assessed using both deterministic and probabilistic modeling approaches.

Historically, HED has used deterministic techniques (i.e., point estimates) for its exposure assessments due to the difficulty in generating and characterizing the various requisite inputs in the form of probability distributions. However, HED has recently begun to address these issues and is moving toward developing probabilistic approaches to estimating residential exposures. For example, the 2006 organophosphate cumulative risk assessment (OPCRA) and the 2007 N-methyl carbamate cumulative risk assessment (NMCCRA) both used probabilistic approaches to evaluate residential exposures and risks. HED is also currently developing a set of revised Standard Operating Procedures (SOPs) for residential exposure assessment which will incorporate probabilistic approaches. Probabilistic exposure assessment is recognized as a refinement over deterministic assessment because it better informs the risk manager with respect to the full range of exposures and their associated probabilities. More specifically, instead of producing a single (potentially high-end) estimate of exposure as is done in deterministic approaches, probabilistic approaches estimate a distribution of exposures from which exposure at any given percentile can be estimated.

The phenothrin registrants submitted a probabilistic residential exposure and risk assessment using the Cumulative and Aggregate Risk Evaluation System (CARES<sup>®</sup> Version 3.0; <http://cares.ilsi.org/>), a publicly available software program. HED conducted a separate probabilistic assessment using the CARES software program for the post-application, incidental oral exposure scenarios for pet care, indoor fogger, and carpet powder products.

## **6.1 Deterministic Residential Handler and Post-Application Exposure and Risk Assessment**

### **6.1.1 Residential Handler and Post Application Exposure Scenarios**

The residential exposure assessment includes two handler and ten post-application residential exposure scenarios. The term “handler” applies to individuals who mix, load, and apply the pesticide product. The term “post-application” describes individuals who are exposed to pesticides after entering areas previously treated with pesticides. Based on a review of active labels and information provided by the registrant, HED assessed the following residential exposure scenarios for the phenothrin RED. Phenothrin products for outdoor residential use are almost exclusively available as aerosol sprays. There are a small number of outdoor fogger products containing phenothrin (at least one). However, due to the absence of scenario specific exposure data for outdoor foggers, the fact that there are very few fogger products for residential outdoor use, and the fact that assessment of aerosol sprays and mosquito ULV applications are likely to address risks from foggers, residential use of outdoor foggers was not assessed separately for this analysis. The following scenarios are assessed.

- 1) Inhalation exposure by applicator to aerosol spray during indoor surface spray/crack and crevice treatment.
- 2) Inhalation exposure by applicator to aerosol spray during outdoor house and garden application.
- 3) Inhalation exposure by applicator to aerosol spray during and after space spray application; post-application inhalation exposure to aerosol spray by child.
- 4) Inhalation exposure from application of mosquito adulticide from fixed wing aircraft and/or helicopter.
- 5) Inhalation exposure from application of mosquito adulticide from ULV truck mounted sprayer.
- 6) Toddler incidental ingestion of residue from exposed turf grass via hand-to-mouth activities.
- 7) Toddler incidental ingestion of residue via object-to-mouth activity while on exposed turf grass.
- 8) Toddler incidental ingestion of soil from treated area.
- 9) Toddler incidental ingestion of residues deposited on carpet via hand-to-mouth activities after use of total release foggers.
- 10) Toddler incidental ingestion of residues deposited on vinyl flooring via hand-to-mouth activities after use of total release foggers.
- 11) Toddler incidental ingestion of residues on pets via hand-to-mouth after pet treatment.
- 12) Toddler incidental ingestion of residues deposited on carpet via hand-to-mouth activities after use of carpet powder.

## **6.1.2 Residential Exposure Data and Assumptions**

### **6.1.2.1 Handler and Post-application Exposure Data**

#### HED Residential Exposure SOPs

The default factors used for the assessment are taken from the ExpoSAC SOP 12. SOP 12 provides values to assess post application inhalation and non-dietary ingestion exposure to lawn care pesticides, and indoor broadcast and crack and crevice treatments.

#### Non-Dietary Exposure Task Force Exposure Data

Primary assumptions for assessing post-application exposure to use of foggers and aerosols in indoor residential settings were based on data provided by the Non-Dietary Exposure Task Force (NDETF). The NDETF was formed in 1996 by members of the Pyrethrin Joint Venture (PJV) and Piperonyl Butoxide Task Force II (PBOTFII), Task Forces set up in the 1980s by producers, formulators, and marketers of the AIs to respond to reregistration needs. NDETF includes; Bayer CropSciences, Botanical Resources Australia, Endura S.p.A, McLaughlin Gormley King Company, Pyrethrum Board of Kenya Prentiss Inc., S.C. Johnson and Son, Inc., Valent BioSciences Corporation, Takasago International Corp, and Whitmire Micro-gen. NDETF's purpose is to produce scientifically sound data on non-dietary exposures to pyrethrin, the pyrethroids, piperonyl butoxide, and MGK-264.

The NDETF conducted studies to examine the deposition of residues from total release foggers. The studies conducted with formulations of pyrethrin/piperonyl butoxide and permethrin/piperonyl butoxide were submitted to EPA in January 2004. The studies simulated the use of a fogger and aerosol products indoors to provide data on air dispersion and deposition on surfaces (walls, floor). Carpet and vinyl were selected as the flooring surfaces of interest because of their different physical and chemical properties and because they represent a significant amount of the floor coverings used in homes in North America. While the focus of the NDETF efforts was on total release foggers, a study was also conducted to determine both dispersion (air levels) and deposition (on flooring) of pyrethrin/piperonyl butoxide resulting from the use of a hand held aerosol spray can. Potential direct exposure of the aerosol spray applicator was also measured; air sampling from the breathing zone was performed. A more detailed evaluation of the NDETF study data used for the phenothrin residential exposure assessment is provided in a separate review (D302120, B. Daiss, 5/11/04).

#### Mosquito Abatement Air Concentration and Deposition Modeling

The Environment Fate and Effects Division (EFED) used the AGRicultural DISPersal model (AGDISP v. 8.15.0.4 10/31/06), to calculate airborne and ground concentrations of phenothrin from aerial mosquito abatement spray applications (J. Melendez, D342403, *date*). AGDISP provides estimates of the 1-hour average concentration and the downwind deposition of spray material released from the aircraft equipment. AGDISP predicts the motion spray material

released, including the mean position of the material and the position variance about the mean as a result of turbulent fluctuations, providing a prediction of spray drift.

Results of the Spray Drift Task Force (SDTF) field studies were used to validate the model results under agricultural conditions. Since adulticides are more efficacious if they come into contact with insects in flight and less effective if applied directly to water, they are applied as mists that remain in the air for longer periods than traditional agricultural sprays. Despite the differences between agricultural and mosquito adulticide applications, reports from several researchers also suggest that AGDISP is an appropriate prediction tool for mosquito adulticide applications.

For the AGDISP model, label recommendations were followed, but conservative assumptions were made. Results of the AGDISP model are provided in Tables 7 and 8. Data from the AGDISP model were used to assess inhalation exposure resulting from aerial application of phenothrin as a mosquito adulticide. Deposition data from the AGDISP model were not used to assess post-application incidental oral exposure to phenothrin, however, because residential application of phenothrin products outdoors to patios and lawn areas results in higher deposition. Therefore, post-application incidental oral exposures were assessed using estimated deposition from homeowner application of outdoor house and garden spray products.

<b>Speed\Type of Application</b>	<b>Aerial</b>
1 mph	1.2
3 mph	0.7
7 mph	~0.25

<b>Speed\Distance</b>	<b>0 ft</b>	<b>1000 ft</b>	<b>2000 ft</b>
1 mph	0.0032	$5.29 \times 10^{-5}$	$3.07 \times 10^{-8}$
3 mph	0.0025	0.0008	0.0002
5 mph	0.0012	0.0013	0.0006

Air concentrations from truck-mounted ULV spray applications are estimated based on the SOP for residential exposure assessment for inhalation exposure from use of an outdoor space spray for pest control. The approach was modified to assume that 1% of the highest application rate for a truck mounted ULV sprayer is available in the breathing zone of the resident. It is assumed that the full application rates for a truck-mounted ULV sprayer (with a one percent dilution factor) is available in the breathing zone of the residential bystander, i.e., an application rate expressed as lbs. ai/ft<sup>2</sup> is converted into a concentration expressed in a per cubic foot (ft<sup>3</sup>) basis.

### 6.1.2.2 Exposure Assumptions

#### Standard Exposure Assumptions

The following assumptions were used in estimating risks from residential exposure to phenothrin:

- Average body weight of an adult is 70 kg.
- Average body weight of a toddler is 15 kg.
- Exposure is assessed on day of application (i.e., day zero).
- Exposure duration is short- and intermediate-term.
- Maximum application rates as determined by the label review and/or information provided by the registrants were used for all types and methods of application.
- Residential Applicator – Aerosol Spray for Indoor/Outdoor Surface Spray
  - 1 can per day for outdoor home and garden patio/yard/ornamental spray.
  - 1 can per day for surface spray and/or crack and crevice treatment.
- Mosquito Abatement Scenario Aerial Application
  - Boom height equal 75 ft. (label specified boom height is 75-300 ft).
  - Droplet sizes of  $D_{v0.5}$  (DVM)  $< 60 \mu\text{m}$  and  $D_{v0.9} < 100 \mu\text{m}$  based on label specifications (DVM =  $60 \mu\text{m}$  means that half of the volume is contained in droplets smaller than  $60 \mu\text{m}$  and half of the volume is contained in droplets larger than  $60 \mu\text{m}$ ).
- Mosquito Abatement Scenario Truck Mounted ULV Application
  - A dilution factor of 0.01 is applied to the airborne concentration at the maximum application rate (i.e., 1% of product released is available for exposure)
- Mosquito Abatement Scenario Standard Assumptions for Aerial Applications
  - Wind speed of 1 mph (label recommends 1-10 mph).
  - Temperature and relative humidity of 85°F and 90%, respectively, to simulate conditions where mosquitoes are likely to grow.
  - Other parameters selected were the default values in AGDISP.
  - Breathing zone airborne concentration is estimated to be approximately 4-6 ft from the ground.
  - Adult breathing rate is 1.0 m<sup>3</sup> per hour; child breathing rate is 0.8 m<sup>3</sup> per hour (NAFTA breathing rates for light activity).
  - Exposure duration is  $\leq 20$  minutes (permethrin assessment)
- Toddler Outdoor (turf) and Indoor Fogger (carpet and vinyl) and Carpet Powder Hand to Mouth Scenario
  - Outdoor turf surface residue is 1.1  $\mu\text{g}/\text{cm}^2$  based on maximum application rate of 3 seconds per cubic yard; 1.5 g/sec; 0.2% ai.
  - Estimated turf transferable residue is assumed to be 5% of the maximum application rate for sprays.
  - Indoor surface residue is 3.2  $\mu\text{g}/\text{cm}^2$  based on NDETF study data and a maximum application rate of 0.0008 lbs ai/1000 ft<sup>3</sup> for indoor foggers (see section 6.2.2.2).
  - Hand transfer efficiency is 13% for carpet; 7% for vinyl based on NDETF data (see section 6.2.2.2).

- Saliva extraction factor is 50 percent.
- Surface portion of hand put in mouth is 20 cm<sup>2</sup>.
- Hand-to-mouth exposure frequency is 20 times per hour.
- For carpet powder scenario, exposures are estimated assuming vacuum cleaner efficiencies of 36% (MRID 47119801) and 80% (Svendsen, E. et al. 2006. Journal of Occupational and Environmental Hygiene, 3: 334-341); Exposures are also estimated assuming no vacuuming after application.
- Exposure duration is 8 hours for indoor and 2 hours for outdoor exposures.
- Toddler Object to Mouth Scenario
  - Object to mouth transfer efficiency is equal to 20% of the application rate.
  - Surface area from mouthing turf or a small object is 25 cm<sup>2</sup>.
- Toddler Incidental Soil Ingestion Scenario
  - Soil ingestion rate is 100 mg/day .
  - Fraction of ai available in uppermost cm of soil (fraction/cm) is 100 percent based on soil incorporation into top 1 cm of soil after application.
- Toddler Pet Treatment Hand to Mouth Scenario
  - One half of a 16 oz spray container is used to treat each animal.
  - Transferable residue from a treated pet is assumed to be 2% of the maximum application rate for sprays (MRID 45485501)
  - Surface area of a treated (30 lb) dog is 6000 cm<sup>2</sup> (EPA 1993 Wildlife Exposure Factors Handbook).
  - Surface portion of hand put in mouth is 20 cm<sup>2</sup>
  - Frequency of hand to mouth events is 20 per hour
  - Exposure duration is 2 hours per day
- Inhalation during and after aerosol space spray application
  - Maximum application rate of 0.002 lbs ai per application (based on a maximum application of 30 grams of product per 2048 ft<sup>3</sup> (10 seconds per 1000 ft<sup>3</sup>; 1.5 grams per sec; 3% ai) (see section 6.2.2.2).
  - Adult breathing rate is 1.0 m<sup>3</sup> per hour; child breathing rate is 0.8 m<sup>3</sup> per hour.
  - Exposure duration is ≤2 hours (the applicator is assumed to leave the premise after application and return after a minimum of 15 minutes; post-application exposure for the non-applicator is assumed to begin at a minimum of 15 minutes and a maximum of 2 hours after application based on label restrictions).

#### Chemical-Specific Exposure Assumptions

Scenario specific data on pyrethrin and/or permethrin from the NDETF study was used to determine deposition of phenothrin on vinyl and carpet flooring following use of a total release indoor fogger. Given the close structural similarity of pyrethrin, permethrin, and phenothrin and the similarity of use patterns for these chemicals, HED believes that the NDETF pyrethrin and/or permethrin data provide appropriate surrogate data for phenothrin. Permethrin data were used preferentially for this assessment if available since permethrin and phenothrin are both synthetic pyrethroids. A more detailed evaluation of the NDETF Study data used for the phenothrin residential exposure assessment is provided in a separate review (D302120, B. Daiss, 5/11/04).

Post-fogger/aerosol floor concentration of phenothrin was assumed to be 3.2 µg/cm<sup>2</sup>. This is based on data from NDETF Study Volume 23, “Post-Application Deposition Measurements for Permethrin & Piperonyl Butoxide Following Use of a Total Release Indoor Fogger.” (MRID 46188602). The measured mean floor concentration of permethrin was 3.6 µg/cm<sup>2</sup> following fogger application at the rate of 0.0009 lb ai per 1000 ft<sup>3</sup>. This value is very close to the theoretical deposition of 3.53 µg/cm<sup>2</sup> for permethrin. The maximum application rate for phenothrin is 0.0008 lb ai per 1000 ft<sup>3</sup> based on application of a 5 oz can containing 2% ai to a 8000 cubic ft space. Therefore, deposition of phenothrin was estimated to be 3.2 µg/cm<sup>2</sup>. [Note: Average field fortification recoveries for the deposition coupons were below 90% (recoveries averaged 75% for permethrin). Corrected residues were calculated by Versar to be 4.8 ± 3 µg/cm<sup>2</sup>.]

Transfer of phenothrin from carpet after the room was treated with a total release fogger was assumed to be 13% of deposition based on data from Volume 29 of the NDETF Study, “Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation to DSS Wetted Hands Following a Single Hand Press” (MRID 46188629). Transfer of phenothrin from fogger treated vinyl flooring was assumed to be 7% of deposition also based on data from Volume 29 of the NDETF Study. Again, given the close structural similarity between permethrin and phenothrin and the similarity of use patterns, HED believes that the NDETF permethrin data provide an appropriate surrogate for phenothrin.

Indoor air concentrations for the period during and after aerosol space spray application was based on data from Volume 18 of the NDETF Study, “Measurement of Air Concentration, Dermal Exposure, and Deposition of Pyrethrin and Piperonyl Butoxide Following the Use of an Aerosol Spray” (MRID 46188618). The indoor aerosol formulation used for this study was an MGK product containing 0.491% pyrethrin. The measured time weighted average air concentration over a two hour period was 0.0038 µg/L following aerosol application of small amount of a 0.5% ai pyrethrin formulation (1/20th of a can or 9.3 grams of a 170 gram container) to a simulated residential room measuring 16 ft x16 ft x8 ft or 2048 ft<sup>3</sup> (equivalent application rate of 0.0001 lb ai per application). Measured air concentrations are provided in Table 9 below. The TWA measured air concentration was adjusted to reflect a likely maximum application rate of 0.002 lbs ai per application (i.e., per 2048 ft<sup>3</sup>) based on a maximum application of 30 grams of product per 2048 ft<sup>3</sup> (10 seconds per 1000 ft<sup>3</sup>; 1.5 grams per sec; 3% ai). The maximum rate is based on a review of active labels and information provided by the registrant (MRID 47119801).

<b>Sampling Interval (minutes)</b>	<b>Air Concentration (µg/L)</b>	<b>Air Concentration (µg/L TWA)</b>
0-5	0.119	0.004958
5-15	0.0324	0.0027
15-30	0.0227	0.002838
30-60	0.0178	0.00445
60-90	0.0168	0.0042

Sampling Interval (minutes)	Air Concentration (µg/L)	Air Concentration (µg/L TWA)
90-120	0.0138	0.00345
2 hour average air concentration	0.0371	<b>0.0038</b>

Inhalation following application of an indoor total release fogger was not modeled separately because the aerosol spray application scenario is likely to provide a more conservative exposure estimate and therefore be protective of exposures following use of a total release fogger. While application rates for total release foggers aerosol sprays are comparable, labels for use of total release foggers require that the room be closed and vacated during release of the fogger and that the room be opened and air for a period of time (e.g. 30 minutes, 1 hour) prior to reentry.

### 6.1.3 Residential Exposure and Risk Estimates

A target LOC or MOE of 1000 is considered adequate for inhalation and incidental oral residential exposure and risk. Exposure and risk estimates indicate that several of the residential scenarios result in exposures of concern (i.e., MOEs ≤ 1000). MOEs for incidental ingestion risks to toddlers playing on vinyl floor and carpet after treatment with fogger formulation are 780 and 200 respectively. MOEs for post-application incidental ingestion risks to toddlers playing on carpet after treatment with carpet powder range from 80 to 390 depending on assumptions regarding vacuum use and efficiency. The MOE for risks to toddlers from incidental ingestion of residues on pets via hand-to-mouth after pet treatment is 150. All other residential exposure scenario assessments result in MOEs that are not of concern (MOEs ≥ 1000). A detailed summary of risk calculations, critical assumptions, and results for each scenario is provided in Tables 10-16.

**Table 10. Estimated Phenothrin Exposure & MOEs for Residential Applicator - LOC/MOE = 1000**

Exposure Scenario	Inhalation Unit Exposure (ug/lb ai)	Use	Maximum Application Rate	Daily Area Treated	Inhalation Dose (mg/kg/day)	Inhalation MOE
RTU Aerosol Spray -	2400	Contact Spray/Crack & Crevice	0.03 lb ai per 16 oz can	1 can per day	0.0010	26000
RTUAerosol Spray	2400	Outdoor House and Garden	0.002 lb ai per 16 oz can	1 can per day	0.00007	390000

Inhalation dose (mg/kg/day) = [unit exposure (ug/lb ai) \* 0.001 mg/ g unit conversion \* Inhalation absorption (100%) \* Application rate (lb ai /16 oz can of aerosol spray) \* Daily area treated / Body weight (70 kg).

Inhalation MOE = short-term and intermediate-term endpoint for inhalation; Inhalation NOAEL (26.6 mkd)/ Daily Inhalation Dose.

**Table 11. Estimated Phenothrin Post-application Inhalation Risks Mosquito Adulticide Application - LOC/MOE = 1000**

Exposed Individual	Maximum Application Rate lb ai/acre	Breathing Zone Concentration (mg/m <sup>3</sup> )	Inhalation Dose (mg/kg/day) <sup>1</sup>	MOE
<b>Aerial Spray (Fixed Wing and Rotary Aircraft)</b>				
Adult	0.0036	0.0012	0.000006	>1000000
Child	0.0036	0.0012	0.00002	>1000000
<b>Truck Mounted ULV Sprayer</b>				
Adult	0.0036	0.0132	0.00006	422000
Child	0.0036	0.0132	0.0002	113000

Inhalation Dose (mg/kg/day) = PDR/ BW

$$PDR(t) \text{ (mg/day)} = (BZC) * BR * ED$$

where:

- PDR = Potential Dose Rate - inhalation dose in breathing zone after spray application (mg/m<sup>3</sup>)
- AR = maximum application rate, lb/ai per acre (0.0036 lb ai/acre)
- BZC = Breathing Zone Concentration (mg/m<sup>3</sup>) - from AgDisp Model based on AR of 0.0036 lb ai/A for aerial spray application (1.2 ng/L = 0.0012 mg/m<sup>3</sup>); 1% of application rate for truck mounted ULV sprayer application
- BR = Breathing rate for adult or child (m<sup>3</sup>/hr) (1.0 m<sup>3</sup>/hr adult, 0.8 m<sup>3</sup>/hr child)
- BW = 70 kg for adult; 15 kg for toddler
- ED = Exposure Duration (20 min/day)
- MOE = Inhalation NOAEL(26.6 mkd)/Inhalation Dose (mg/kg/day) MOEs are reported to two significant figures

**Table 12. Screening Level Estimate - Phenothrin Post-application Incidental Ingestion Risks to Toddlers Reentering Treated Lawns: Hand to Mouth, Object to Mouth, Incidental Soil Ingestion and Aggregate Incidental Ingestion - LOC/MOE = 1000**

Max App Rate (ug/cm <sup>2</sup> )	Hand to Mouth			Object to Mouth			Soil Ingestion			Aggregate
	Hand Transfer (ug/cm <sup>2</sup> )	Daily Oral Dose (mg/kg/day)	MOE	Dislogeable Foliar Residue (ug/cm <sup>2</sup> )	Daily Oral Dose (m/k/d)	MOE	Soil Residue (ug/g)	Daily Oral Dose (m/k/d)	MOE	Aggregate MOE
1.1	0.055	0.0014	34000	0.22	0.0004	136000	0.74	0.000005	>1000000	27200

Max App Rate = 1.1 µg/cm<sup>2</sup> for a 0.2% formulation based on maximum spray duration of 3 seconds per cubic yard at a discharge rate of 1.5 g/sec assuming all spray settles to the turf (MRID 47119801)

$$\text{Daily Oral Dose (mg/kg/day)} = (PDR / BW)$$

BW = 15 kg for toddler

**Hand To Mouth Calculation**

$$PDR(t) \text{ (mg/day)} = (HTE(t) \text{ (}\mu\text{g/cm}^2\text{)} * SEF * SA * \text{Freq} * ED / 1000 \text{ (}\mu\text{g/mg)})$$

where:

- PDR = Potential Dose Rate at time (t) attributable for activity in a previously treated area (mg/day)
- HTE = Hand Transfer Efficiency at time t = 5% of Application Rate (µg/cm<sup>2</sup>) Application rate = 0.2% ai, 3 seconds per cubic yard, 1.5 g/sec, all spray settles to turf (MRID 47119801)
- SEF = Saliva Extraction Factor (50%)
- SA = Surface Area of Two Fingers (20 cm<sup>2</sup>)
- Freq = Frequency of Hand to Mouth Events (20)
- ED = Exposure Duration in hours (2 hr/day)
- t = Postapplication Day on which exposure is being assessed (day 0)
- MOE = ST/IT Oral NOAEL (50 mkd)/Daily Oral Dose (mg/kg/day)

**Object to Mouth Calculation**

$$PDR(t) \text{ (mg/day)} = (DFR(t) \text{ (}\mu\text{g/cm}^2\text{)} * SA / 1000 \text{ (}\mu\text{g/mg)})$$

where:

- PDR = Potential Dose Rate at time (t) attributable for activity in a previously treated area (mg/day)
- DFR(t) = Dislogeable Foliar Residue at time t = 20% of Application Rate (µg/cm<sup>2</sup>) APR = 1.1 µg/cm<sup>2</sup>
- SA = Surface Area of grass or toy mouthed by toddler (25 cm<sup>2</sup> day)
- t = Postapplication day on which exposure is being assessed (day 0)
- MOE = ST/IT Oral NOAEL(50 mkd)/[Daily Oral Dose (mg/kg/day) MOEs are reported to two significant figures

**Soil Ingestion Calculation**

$$PDR(t) \text{ (mg/day)} = (SR_t * IgR * CF1)$$

where:

- PDR = Potential Dose Rate - nondietary ingestion rate from contact with treated surface (mg/day)
- SR<sub>t</sub> = Soil Residue on day "t" (µg/g) = Application Rate (µg/cm<sup>2</sup>) \* 1/cm \* 0.67 cm<sup>3</sup>/g soil [1/cm is fraction of ai available in uppermost cm of soil]
- IgR = Ingestion Rate of soil (mg/day); (100 mg/day)
- CF1 = Weight unit conversion factor (1E-6 g/µg)
- t = Postapplication Day on which exposure is being assessed, assumed to be day zero
- MOE = ST/IT Oral NOAEL (50 mkd)/[Daily Oral Dose (mg/kg/day). MOEs are reported to two significant figures
- AggMOE=1/(1/MOE HTM + 1/MOE OTM + 1/MOE SI)

**Table 13. Estimated Phenothrin Post-application Incidental Ingestion Risks To Toddlers Playing on Vinyl Floor and Carpet after Treatment with Fogger Formulation - MOE/LOC = 1000**

Indoor Surface	Application Rate (lb ai/1000 ft <sup>3</sup> )	Indoor Surface Residue(ug/cm <sup>2</sup> )	Hand Transfer Efficiency (%)	Daily Oral Dose (mg/kg/day)	MOE
Carpet	0.0008	3.2	13	0.044	200
Vinyl	0.0008	3.2	7	0.012	780

$$\text{Application Rate} = 5 \text{ oz}/8000 \text{ ft}^3 \times 1 \text{ lb}/16 \text{ oz} \times 0.02 \text{ (2\% ai)} = 0.0008 \text{ lbs ai}/1000 \text{ ft}^3$$

$$\text{DOD(mg/kg/day)} = \text{Daily Oral Dose} = PDR / BW$$

$$PDR_{(0)} \text{ (mg/day)} = (ISR_{(0)} \text{ (}\mu\text{g/cm}^2\text{)} * HTE * SEF * SA * \text{Freq} * ED / 1000 \text{ (}\mu\text{g/mg)})$$

where:

- PDR = Potential Dose Rate on day of application (mg/day)
- ISR = Indoor Surface Residue ( $\mu\text{g}/\text{cm}^2$ ) at maximum AR of 0.0008 lbs ai/1000  $\text{ft}^3$  – based on NDETF data for total release fogger for permethrin at application rate of 0.0008 lbs ai/1000  $\text{ft}^3$  (AR = 5 oz unit containing 2% ai per 8000  $\text{ft}^3$ )
- HTE = Hand Transfer Efficiency - transfer of (13% for carpet; 7% for vinyl – based on NDETF data for total release fogger)
- SEF = Saliva Extraction Factor (50%)
- SA = Surface Area of Two Fingers (20  $\text{cm}^2$ )
- Freq = Frequency of Hand to Mouth Events (20)
- ED = Exposure Duration in hours = 8 hr/day carpet; 4 hr/day vinyl
- t = Postapplication Day on which exposure is being assessed (day 0)
- BW = 15 kg for toddler
- MOE= ST/IT Oral NOAEL (50 mkd)/Daily Oral Dose (mg/kg/day) MOEs are reported to two significant figures.

**Table 14. Estimated Phenothrin Post-application Incidental Ingestion Risks To Toddlers Playing on Carpet after Treatment with Carpet Powder - LOC/MOE = 1000**

Application Rate (lb ai/ $\text{ft}^2$ )	Indoor Surface Residue( $\mu\text{g}/\text{cm}^2$ )	Vacuum Efficiency(%)*	Hand Transfer Efficiency (%)	Daily Oral Dose (mg/kg/day) <sup>1</sup>	MOE
0.00005	22.6	36	5	0.0771	2100
		80		0.0241	<b>650</b>
		0		0.1205	<b>415</b>

Application Rate = 1 lb/108  $\text{ft}^2$  x 0.005 (0.5% a.i.) = 0.000046 lb ai/  $\text{ft}^2$  (22.6  $\mu\text{g}/\text{cm}^2$ ).

DOD(mg/kg/day) = Daily Oral Dose = PDR/ BW

$\text{PDR}_{(0)}$  (mg/day) =  $(\text{ISR}_{(0)} (\mu\text{g}/\text{cm}^2) * \text{FRV} * \text{HTE} * \text{SEF} * \text{SA} * \text{Freq} * \text{ED}/1000$  ( $\mu\text{g}/\text{mg}$ )

where:

- PDR = Potential Dose Rate on day of application (mg/day)
- ISR = Indoor Surface Residue ( $\mu\text{g}/\text{cm}^2$ ) at maximum AR of 1 lb/108  $\text{ft}^2$  (0.5% a.i.) (22.6  $\mu\text{g}/\text{cm}^2$ ).
- FRV = Fraction Remaining after Vacuuming (64%, 20%, 100%)
- HTE = Hand Transfer Efficiency – 5% SOP
- SEF = Saliva Extraction Factor (50%)
- SA = Surface Area of Two Fingers (20  $\text{cm}^2$ )
- Freq = Frequency of Hand to Mouth Events (20)
- ED = Exposure Duration in hours = 8 hr/day
- t = Postapplication Day on which exposure is being assessed (day 0)
- BW = 15 kg for toddler
- MOE= ST/IT Oral NOAEL (50 mkd)/Daily Oral Dose (mg/kg/day) MOEs are reported to two significant figures.

**Table 15. Estimated Phenothrin Post-application Incidental Ingestion Risks To Toddlers Playing with Pets –LOC/MOE = 1000**

Application Method	AR (mg ai/animal)	Transferable Residue (%)	Daily Oral Dose (mg/kg/day)	MOE
Aerosol Spray	590	2	0.0524	<b>950</b>
Spot-on	2230	2	0.1982	<b>250</b>

$\text{AR}_{\text{AS}} = 16 \text{ oz}/\text{lb} \times 0.5 = 0.5 \text{ lb} \times 0.003 (0.26\% \text{ ai}) 454 \text{ g}/\text{lb} \times 1000 \text{ mg}/\text{g} = 590 \text{ mg ai/ animal}$

$\text{AR}_{\text{SO}} = 0.09 \text{ fl oz} (2.6 \text{ mL})/\text{animal} \times 0.857 (85.7 \% \text{ ai}) \times 1\text{L}/1000\text{mL} \times 1 \text{ gal}/3.8 \text{ L} \times 8.37 \text{ lb ai}/\text{gal} \times 454 \text{ g}/\text{lb} \times 1000 \text{ mg}/\text{g} = 2230 \text{ mg}/\text{animal}$

DOD(mg/kg/day) = Daily Oral Dose = PDR/ BW

$\text{PDR}_{(0)}$  (mg/day) =  $((\text{AR}_{(0)} (\text{mg ai}/\text{animal}) * F)/\text{SA}_{\text{pet}}) * \text{SEF} * \text{SA}_{\text{hands}} * \text{Freq} (\text{events}/\text{hr}) * \text{ED} (\text{hrs}/\text{day})$

where:

- PDR = Potential Dose Rate - non-dietary ingestion dose from contact with treated pets (mg/day)
- AR = Application Rate or amount applied to animal in a single treatment (mg ai/animal) = 1/2 of 16 oz spray container with maximum of 0.3% ai per 6000  $\text{cm}^2/\text{animal}$
- $F_{\text{AR}}$  = Fraction of Application Rate available contact as dislodgeable residue (2%) based on tetrachlorvinphos study
- $\text{SA}_{\text{pet}}$  = Surface Area of a treated dog (6000  $\text{cm}^2/\text{animal}$ )
- t = Time After Application (0 days)
- SEF = Saliva Extraction Factor (50%)
- $\text{SA}_{\text{hands}}$  = Surface Area of the hands (20  $\text{cm}^2$ )
- Freq = Hand-to-Mouth Events (20 events/day)
- ED = Exposure Duration in hours = 2 hr/day
- BW = 15 kg for toddler
- MOE = ST/IT Oral NOAEL (50 mkd)/Daily Oral Dose (mg/kg/day) MOEs are reported to two significant figures.

<b>Table 16. Estimated Phenothrin Inhalation Risks To Adults and Children During and After Indoor Aerosol Space Spray Application -15 minute reentry interval - LOC/MOE = 1000</b>				
<b>Exposed Individual</b>	<b>Application Rate (lb ai/application)</b>	<b>Breathing Zone Concentration (mg/m<sup>3</sup>)</b>	<b>Inhalation Dose (mg/kg/day)</b>	<b>MOE</b>
Adult Application & Post App*	0.002	0.0770	0.0022	11800
Child**	0.002	0.0722	0.0077	3300

Application Rate = 1.5 g/sec x 10 sec/1000 ft<sup>3</sup> x 2048 ft<sup>3</sup>/application x 1 lb/454 g x 0.03 (3%ai) = 0.002 lb ai/application

Inhalation Dose (mg/kg/day) = PDR/ BW

$PDR_{(t)}$  (mg/day) = BZC \* BR \* ED

where:

PDR = Potential Dose Rate - inhalation dose in breathing zone after spray application (mg/m<sup>3</sup>)

AR = Application rate – 3% ai applied to a 16 x 16 x 8 ft room at a rate of 1.5 g/sec; 10 sec/1000 ft<sup>3</sup>; re-entry after 15 minutes per label

BZC = Breathing Zone Concentration (mg/m<sup>3</sup>) - measured time-weighted air concentration from NDETF study adjusted to reflect maximum application rate for phenothrin.

\*Adult = BZC during and after application (re-entry 15 minutes after application)

\*\*Child = BZC post-application (re-entry 15 minutes after application)

BR = Breathing rate for adult or child (m<sup>3</sup>/hr) (1.0 m<sup>3</sup>/hr adult, 0.8 m<sup>3</sup>/hr child)

BW = 70 kg for adult; 15 kg for toddler

ED = Exposure Duration (2 hr/day)

MOE = Inhalation NOAEL (26.6 mkd)/Inhalation Dose (mg/kg/day) MOEs are reported to two significant figures.

## 6.2 Probabilistic Post-Application Residential Exposure and Risk Assessment

HED conducted a probabilistic assessment using CARES, a publicly available software program for those residential exposure scenarios that resulted in MOEs of concern based on the deterministic exposure assessment.

CARES utilizes a reference population of 100,000 individuals selected from the 1990 U.S. Census. It is considered appropriate for use in exposure analysis due to its similarity with the U.S. Census Public Use Micro Data Sample (PUMS), a statistically representative dataset that contains data for statistical weights from sampled individuals of the general U.S. population, provided by the U.S. Department of Commerce, Bureau of the Census, Economics and Statistics Administration. Key subpopulations relevant to exposure analysis within CARES include different races (e.g., white, black, Hispanic, etc.) and different age groups (e.g., children 1-3 years old, male 20-54 years old, etc.) (Driver et al, 2008). CARES simulates daily (24-hour) exposures over the course of one calendar year for each person in the specified subpopulation based on user-specified routes of exposure (e.g., dietary, dermal, non-dietary ingestion), empirical data, and exposure algorithms. The calculations and algorithms used to estimate exposure for the various scenarios and routes are consistent with standard Agency practice for residential pesticide exposure assessment. The phenothrin exposure scenarios were assessed using standard EPA algorithms for exposure estimation. Distributional inputs were included in the probabilistic assessment where possible. The probabilistic assessment assumes post application exposure occurs on the “day of application.” Five thousand (5000) product uses are assessed for each exposure scenario i.e., percentile distributions for each scenario are generated from 5000 exposure estimates.

### **6.2.1 Exposure Routes and Scenarios**

The calculations and algorithms used to estimate exposure for the various scenarios and routes are consistent with standard Agency practice for residential pesticide exposure assessment. The probabilistic CARES assessment was conducted only for those post application exposure scenarios that presented risks of concern based on a deterministic analysis. Maximum application rates as determined by the label review and/or information provided by the registrants were used for all types and methods of application. The following scenarios were assessed probabilistically using standard EPA algorithms for exposure estimation and with distributional inputs where possible.

- 1) Toddler incidental ingestion of residues deposited on carpet and vinyl flooring via hand-to-mouth activities after use of total release foggers.
- 2) Toddler incidental ingestion of residues on pets via hand-to-mouth after pet treatment.
- 3) Toddler incidental ingestion of residues deposited on carpet via hand-to-mouth activities after use of carpet powder.

The assessment, as is standard practice, assumes post application exposure occurs on the day of application, which is then used in comparison with the appropriate toxicological endpoint. Comparison to continuous-dosing toxicological studies assumes that the day of application exposure occurs every day for the duration of the corresponding toxicity study (e.g., 28 days). Though CARES is applying probabilistic methods, a refinement over standard deterministic practices, the day of application exposure methodology still has conservative assessment characteristics. For example, the assessment assumes that a child is exposed to the same “day zero” phenothrin residue on carpeting for the duration of the corresponding toxicity study without consideration of residue dissipation. The CARES user input files for the HED probabilistic assessment for phenothrin are provided in Attachment 1.

### **6.2.2 Subpopulations**

The phenothrin CARES analysis assesses children (defined as males and females 1-2 years old) since this age group exhibits the highest degree of mouthing behavior – a major route of exposure for this assessment (Tulve et al., 2002). The risk percentages generated by the CARES model correspond only to those individuals who use phenothrin as a pesticide (i.e., the population is “users only”). The assessment does not characterize risk relative to the percentage of the population that does not use phenothrin.

### **6.2.3 Exposure Factor Distributions**

Inputs and distributions considered for the CARES assessment are provided below. Many of the non-phenothrin-specific distributional inputs are based on EPA’s n-methyl Carbamate Revised Cumulative Risk Assessment (NMCCRA), the most recent EPA publication using probabilistic methods and distributional inputs for residential exposure assessment (EPA,

2007). Standard assumptions based on point estimates are the same as those used for the deterministic assessment and are described in Section 7.1.3 above.

### **6.2.3.1 Phenothrin-specific Factors**

#### Residue Characteristics

- Dissipation: standard Agency practice for residential exposure is to assess exposure on the “day of application”. Therefore, use of a 0.00001 day half-life in the CARES submission is consistent with this practice because it is assuming no residue dissipation.
- Residue Transfer – Single-Press, Surface-to-Hand (expressed as a percentage of deposited surface residue)
  - Indoor Fogger and Surface Spray on Carpet and Hard Surfaces: NDETF data in the form of a single lognormal distribution for single-press residue transfer of pyrethroids from hard surfaces or carpeting (Holden, 2005). The parameters of the distribution are as follows:
    - Minimum = 1%
    - Geometric mean (GM) = 3.2%
    - Geometric standard deviation (GSD) = 1.8
    - Maximum = 19%
  - Indoor Carpet Powder – Standard point estimate of 5%
  - Pets: Point estimate of 2% described used in the deterministic assessment.

#### Use Pattern

- Indoor Monthly probability: Equal use for each month of the year. This assumption is acceptable, since these probabilities are irrelevant when assessing “day of application” exposures.
- Day of Week probability: Equal use for each day of the week. This assumption is acceptable, since these probabilities are irrelevant when assessing “day of application” exposures.
- Annual Use: Ten (10) uses per year. This value is irrelevant for “day of application” exposure assessment. [500 CARES individuals are included in a model run a total of 5000 products (500 x 10) are assessed.
- Treatment Interval: Thirty (30) day interval between treatments. This value is irrelevant for “day of application” exposure assessment.
- Co-occurrence Probability: Set to zero. Co-occurrence is irrelevant for “day of application” exposures.

### **6.2.3.2 Non-Phenothrin-specific Factors**

- Body Weight: Correlated to randomly selected individual from the specified subpopulation in the reference population.
- Exposure Duration (expressed as hours per day)

- Indoor Incidental Oral (non-dietary) exposure (children only)  
Carpet and Hard Surfaces: uniform distribution of 1 to 5 hours.  
Pets: triangular distribution (0.03, 0.108, 1.03).
- Outdoor incidental oral (non-dietary) exposure (children only): Uniform distribution of 1 to 2 hours. This is consistent with the standard point estimate of 2 hours for time spent playing on lawns.
- Hand-to-Mouth Exposure Factors (children only)
  - Hand-to-Mouth Events - Indoor/Outdoor Surfaces and Pets: (expressed as contacts per hour) Triangular distribution (1, 13, 26).
  - Hand-to-Mouth Residue Transfer (i.e., saliva extraction factor) (expressed as a percentage of hand residue): Uniform distribution of 20% to 50%.
  - Surface Area of Hand Mouthed (cm<sup>2</sup>): Triangular distribution (1, 7, 20).

#### 6.2.4 Probabilistic Exposure and Risk Estimates

Results of the probabilistic CARES assessment for indoor post-application incidental oral exposure scenarios are presented in Table 17. Risks are presented in the form of MOEs by percentile of exposure. MOEs below 1000 were scenario at the 99.9<sup>th</sup> and 99.5<sup>th</sup> percentiles for the pet care spot-on and indoor carpet powder scenarios. Label requirements for the carpet powder use direct the user to keep children and pets out of the room for 2 hours and then vacuum. When use of a vacuum with a removal efficiency of 30% is assumed, MOEs greater than 1000 are seen at the 99.9<sup>th</sup> percentile.

Percentile	Exposure Scenario and Route				
	Pet Care Spray	Pet Care Spot-on	Indoor Carpet Powder		Indoor Fogger
			No Vacuum	Vacuum 30% Efficiency	
99.9	2489	<b>674</b>	<b>751</b>	1170	5027
99.5	3592	<b>860</b>	<b>914</b>	1492	6527
99	3924	1017	1031	1674	8427

#### 6.2.5 Probabilistic Risk Assessment Characterization

While it is not standard HED policy to use probabilistic methods for residential exposure assessment, recent advances in probabilistic models and the availability of more robust exposure factor data enable HED to utilize such tools. As noted throughout discussion of the probabilistic assessment, the full extent of the probabilistic model was not used. For example, the assessment of “users only” on the “day of application” is not consistent with a fully probabilistic approach. This approach was used due to the still uncertain nature of particular aspects of residential non-dietary risk assessment – including, but not limited to, the proper combination of toxicological endpoints with exposure profiles and the available data meant to refine those concerns (e.g., pesticide use and activity pattern data). Adequate justification (e.g., time-to-effect toxicity, residue dissipation data, application intervals, etc.) would be necessary to depart from this standard practice. HED anticipates that use of standard assumptions about exposure combined with distributional inputs regarding use and dissipation patterns may be used in future

probabilistic exposure assessments. This approach has not been used for the phenothrin assessment, however, due to the lack of information regarding precise use patterns (i.e., how often one applies phenothrin per day/week/month), longitudinal daily activities for the assessed subpopulations (i.e., how often and for how long a child plays on carpeting per day/week/month) and lack of information regarding residue dissipation over time.

## **7.0 UNCERTAINTIES**

Uncertainties identified by BEAD regarding the NPMA survey data used to determine potential exposures to PCO should also be noted. Regarding the robustness and validity of the NPMA survey data BEAD drew the following conclusions. Given that there are approximately 19,000 PCO firms in the U.S., it is highly unlikely that a sample size of 67 represents a statistically valid sample. The use of a retrospective survey methodology may have introduced errors in the data. Pesticide survey firms like Doane use a prospective survey instrument sent to growers in advance thus allowing them to keep detailed accounts of their pesticide usage in real time throughout the year. Despite its small size and retrospective methodology, however, the information collected is more robust than BEAD typically gets when asking questions of this nature. BEAD typically contacts 1-5 PCO's and asks chemical specific questions which may bias the responses if PCO's value the chemical under review. HED believes the NPMA survey provides reasonable estimates of average number of buildings treated per day by PCOs.

Maximum label application rates were based on data provided by the registrant. Many of the active labels for phenothrin residential use do not provide clear information on application rates. These labels need to be revised to clearly reflect the maximum allowable application rates. Data on dissipation of phenothrin on carpets and vinyl flooring after residential indoor application of fogger, aerosol, and powder products would help refine the residential exposure assessment.

## Attachment 1 – CARES User Inputs

### Scenarios & Methods

Scenario	During/Post	Route	Method
Pet Care - 1	Post	Ingestion (H-To-M)	Ingestion 109: EPA SOP
Pet Care - 2	Post	Ingestion (H-To-M)	Ingestion 109: EPA SOP
Indoor Fogger Use - 1	Post	Ingestion (H-To-M)	Ingestion 109: EPA SOP
Indoor Treatment - 1	Post	Ingestion (H-To-M)	Ingestion 109: EPA SOP

### Scenarios & Products

Scenario	Product	CAS	Product Probability
Pet Care	Product 1;Pet Spot-on	026022-80-2	1
Pet Care	Product 2;Pet Spray	026022-80-2	1
Indoor Fogger Use	Product 3;Fogger	026022-80-2	1
Indoor Treatment	Product 4;Carpet Powder	026022-80-2	1

### Scenario Probabilities

Scenario	Scenario Probability	Market Share (Chemical Probability)
Pet Care - 1	1	1
Pet Care - 2	1	1
Indoor Fogger Use - 1	1	1
Indoor Treatment - 1	1	1

### Event Allocation

#### Monthly Probabilities (Jan-Jun)

Scenario	Jan	Feb	Mar	Apr	May	Jun
Pet Care - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Pet Care - 2	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Indoor Fogger Use - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Indoor Treatment - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833

#### Monthly Probabilities (Jul-Dec)

Scenario	Jul	Aug	Sep	Oct	Nov	Dec
Pet Care - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Pet Care - 2	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Indoor Fogger Use - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833
Indoor Treatment - 1	0.0833	0.0833	0.0833	0.0833	0.0833	0.0833

### Day of Week Probabilities

Scenario	Sun	Mon	Tue	Wed	Thr	Fri	Sat
Pet Care - 1	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429
Pet Care - 2	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429
Indoor Fogger Use - 1	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429
Indoor Treatment - 1	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429	0.1429

### Annual Use & Treatment Interval

Scenario	# Uses	Treatment Interval (Days)
Pet Care - 1	Single (10)	Single (30)
Pet Care - 2	Single (10)	Single (30)
Indoor Fogger Use - 1	Single (10)	Single (30)
Indoor Treatment - 1	Single (10)	Single (30)

### Co-Occurrence

Scenario 1	Scenario 2	Co-Occurrence
Pet Care - 1	Pet Care - 1	0
Pet Care - 1	Pet Care - 2	0
Pet Care - 1	Indoor Fogger Use - 1	0

Pet Care - 1	Indoor Treatment - 1	0
Pet Care - 2	Pet Care - 1	0
Pet Care - 2	Pet Care - 2	0
Pet Care - 2	Indoor Fogger Use - 1	0
Pet Care - 2	Indoor Treatment - 1	0
Indoor Fogger Use - 1	Pet Care - 1	0
Indoor Fogger Use - 1	Pet Care - 2	0
Indoor Fogger Use - 1	Indoor Fogger Use - 1	0
Indoor Fogger Use - 1	Indoor Treatment - 1	0
Indoor Treatment - 1	Pet Care - 1	0
Indoor Treatment - 1	Pet Care - 2	0
Indoor Treatment - 1	Indoor Fogger Use - 1	0
Indoor Treatment - 1	Indoor Treatment - 1	0

### Method-Specific

Group	Variable Name	Unit	Value
Pet Care - 1 ; Ingestion 109: EPA SOP	Contact Frequency (Hand-to-Mouth)	event/hr	Triangular (1,13,26)
Pet Care - 1 ; Ingestion 109: EPA SOP	Transfer Efficiency per Contact (Hand-to-Mouth)	unitless	Uniform (0.2,0.5)
Pet Care - 1 ; Ingestion 109: EPA SOP	Exposure Duration	hr/day	Triangular (0.03,0.108,1.03)
Pet Care - 1 ; Ingestion 109: EPA SOP	Surface Area - Hands (Mouthed)	cm <sup>2</sup>	Triangular (1,7,20)
Pet Care - 2 ; Ingestion 109: EPA SOP	Contact Frequency (Hand-to-Mouth)	event/hr	Triangular (1,13,26)
Pet Care - 2 ; Ingestion 109: EPA SOP	Transfer Efficiency per Contact (Hand-to-Mouth)	unitless	Uniform (0.2,0.5)
Pet Care - 2 ; Ingestion 109: EPA SOP	Exposure Duration	hr/day	Triangular (0.03,0.108,1.03)
Pet Care - 2 ; Ingestion 109: EPA SOP	Surface Area - Hands (Mouthed)	cm <sup>2</sup>	Triangular (1,7,20)
Indoor Fogger Use - 1 ; Ingestion 109: EPA SOP	Contact Frequency (Hand-to-Mouth)	event/hr	Triangular (1,13,26)
Indoor Fogger Use - 1 ; Ingestion 109: EPA SOP	Transfer Efficiency per Contact (Hand-to-Mouth)	unitless	Uniform (0.2,0.5)
Indoor Fogger Use - 1 ; Ingestion 109: EPA SOP	Exposure Duration	hr/day	Uniform (1,5)
Indoor Fogger Use - 1 ; Ingestion 109: EPA SOP	Surface Area - Hands (Mouthed)	cm <sup>2</sup>	Triangular (1,7,20)
Indoor Treatment - 1 ; Ingestion 109: EPA SOP	Contact Frequency (Hand-to-Mouth)	event/hr	Triangular (1,13,26)
Indoor Treatment - 1 ; Ingestion 109: EPA SOP	Transfer Efficiency per Contact (Hand-to-Mouth)	unitless	Uniform (0.2,0.5)
Indoor Treatment - 1 ; Ingestion 109: EPA SOP	Exposure Duration	hr/day	Uniform (1,5)
Indoor Treatment - 1 ; Ingestion 109: EPA SOP	Surface Area - Hands (Mouthed)	cm <sup>2</sup>	Triangular (1,7,20)

### Product-specific

Group	Variable Name	Unit	Value
Product 1; Pet Spot-on	Application (AI per Area Treated)	kg/m <sup>2</sup>	Single (0.0037)
Product 1; Pet Spot-on	Fraction AI Dislodgeable in Surface	unitless	Single (0.02)
Product 1; Pet Spot-on	HalfLife	day	Single (0.000001)
Product 2; Pet Spray	Application (AI per Area Treated)	kg/m <sup>2</sup>	Single (0.001)
Product 2; Pet Spray	Fraction AI Dislodgeable in Surface	unitless	Single (0.02)
Product 2; Pet Spray	HalfLife	day	Single (0.000001)
Product 3; Fogger	Application (AI per Area Treated)	kg/m <sup>2</sup>	Single (0.000032)
Product 3; Fogger	Fraction AI Dislodgeable in Surface	unitless	LogNormal (0.032,0.018,0.01,0.19)
Product 3; Fogger	HalfLife	day	Single (0.000001)
Product 4; Carpet Powder	Application (AI per Area Treated)	kg/m <sup>2</sup>	Single (0.00022)
Product 4; Carpet Powder	Fraction AI Dislodgeable in Surface	unitless	Single (0.05)
Product 4; Carpet Powder	HalfLife	day	Single (0.000001)

## Attachment 2 - Default Unit Exposure Values

<b>Table 17. PHED/ORETF Inhalation Unit Exposure Values Used In Phenothrin ORE Assessment</b>			
<b>Scenario</b>	<b>Unit Exposure (µg/lb ai )</b>	<b>Replicates</b>	<b>Grade/Confidence</b>
Mixing Loading Liquids	1.2	85	AB/High Confidence
Airblast Application - Open Cab	4.5	47	AB/High Confidence
Mix/Load/Apply Liquids High Pressure Handwand	120	13	A/Low Confidence
Mix/Load/Apply Liquids Low Pressure Handwand	30	80	ABC/Medium Confidence
Aersol Spray Application - Worker	1300	30	ABC/Medium Confidence
Aerosol Spray Application - Residential	2400	15	AB/High Confidence