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TOXIC SUBSTANCES

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MEMORANDUM

**SUBJECT:** Prallethrin: Human Health Risk Assessment for the Public Health Use of Mosquito Adulticides Containing Prallethrin. (DP Barcode: D289335; Chemical Number: 128722)

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RC  
12/03

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## 1.0 EXECUTIVE SUMMARY

A new use is requested for the active ingredient, prallethrin (ETOC®), (RS)-2-Methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl(IR)-cis,trans-chrysanthemate, a quick knockdown synthetic pyrethroid insecticide. Prallethrin is currently registered for use in/on all food items in food handling establishments where food and food products are held, processed, or prepared to control nuisance and food product contaminating insects such as ants, cockroaches, fleas and ticks. A tolerance is established at 1.0 ppm on all food items to cover the food handling use (40 CFR 180.545). There are no agricultural uses or international tolerances (CODEX or Mexican Maximum Residue Limits (MRLs)) for prallethrin.

A Section 3 registration is being requested for the end-use products, Multicide® Fogging Concentrate 2798 and Responde'® insecticide, containing 1% and 9% prallethrin, respectively for use as mosquito abatement treatments. Outdoor and recreational areas will receive mosquito abatement treatments by aerial, truck-fogger and backpack application.

The HED Hazard Identification Assessment Review Committee (HIARC) met on 9/2/99 to evaluate the toxicology data base and to re-assess the chronic Reference Dose (RfD) as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments that were established in 1995 for prallethrin. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to prallethrin, as required by the Food Quality Protection Act (FQPA) of 1996 (09/02/99; TXR No. 013779).

On May 15, 2003, the HIARC re-evaluated the previously selected chronic Reference Dose (RfD) and respective toxicological endpoint. HIARC decided to reverse the previous decision to lower the NOAEL for the study and raise it back to 5.0 mg/kg/day. Furthermore, HIARC re-evaluated the potential for increased susceptibility of infants and children from exposure to prallethrin as required by FQPA according to the 2002 OPP 10x Guidance Document. The HIARC concluded that the toxicology database for prallethrin is adequate for FQPA assessment. A complete complement of acceptable developmental, reproduction and mammalian neurotoxicity studies are available; however, a developmental neurotoxicity study in rats with prallethrin is required for characterization. No special FQPA Safety Factor is needed (i.e., 1X), since there are no residual uncertainties for pre- and postnatal toxicity. HIARC determined that the 10X database uncertainty factor ( $UF_{DB}$ ) can be reduced to 1X because the available data does provide a basis to support reduction of the default 10X factor (06/27/03; TXR No. 0051993).

Prallethrin is not a carcinogen under the conditions of the carcinogenicity studies. In 1995, it was classified by the RfD Committee as a category E (evidence of noncarcinogenicity for humans) chemical for carcinogenicity. This classification was confirmed by the HIARC, which updated the classification to a "not likely" human carcinogen.

In conducting this risk assessment, HED has considered acute and chronic dietary exposures, including food and drinking water; occupational exposure, and non-occupational/non-dietary

exposures, including incidental oral, dermal and inhalation exposures. Since any residues on crops from the proposed mosquito control use are expected to be negligible compared to those from the registered food handling use, the dietary (food only) exposures estimates are provided from the "Human Health Risk Assessment for the Use of Prallethrin in Food Handling Establishments", P. Hurley, D239112, 03/08/2000. Dietary (food only) exposure estimates were greatest for the population subgroup composed of children ages 1-6 years. Acute exposure is estimated to be 0.044305 mg/kg/day (95<sup>th</sup> percentile of exposure), which is equal to 89% of the acute population-adjusted dose (aPAD). Chronic exposure is estimated to be 0.002152 mg/kg/day which is equal to 4.3% chronic population-adjusted dose (cPAD).

An estimate of residential/non-occupational dermal, inhalation and incidental oral exposure resulting from the use of prallethrin as a mosquito abatement is provided in this assessment. Residential exposure to airborne prallethrin, as well as to residues on turf following aerial and ground-based ultra low volume (ULV) application for public health mosquito vector control may occur to both adults and toddlers during short- and intermediate-term exposure durations. These proposed uses for application of prallethrin as a mosquito abatement are performed by mosquito control officials and trained pest control operators only. Therefore the exposure risk for certified and trained applicators/handlers will be addressed in the Occupational Exposure section of this assessment and not addressed in the residential/non-occupational section. An assessment of dermal, inhalation and incidental oral exposure from this prallethrin use resulted in MOEs for individual routes of exposure that were all above the targets, and therefore, are not of concern to HED. Likewise, when exposure from dermal, inhalation and incidental oral routes were combined, these scenarios exceeded target MOEs and are not of concern to HED.

Monitoring data were not available to assess residues of prallethrin in drinking water; therefore, potential residues of prallethrin were not used quantitatively in determining aggregate exposure. Rather, HED determined drinking water levels of comparison (DWLOCs) for prallethrin and compared them to modeled estimated environmental concentrations (EECs) supplied by the Environmental Fate and Effects Division. The surface water acute and chronic EECs (0.591 ppb and 0.0375 ppb, respectively) were greater than the ground water estimate (0.00104 ppb) and were used for comparison to the DWLOCs.

Aggregate risk estimates for prallethrin were calculated based on food and drinking water pathways for acute and chronic exposure scenarios, and on food, drinking water, and post-application dermal, inhalation and a total oral exposure (hand-to-mouth, object-to-mouth, and soil ingestion) for short- and intermediate-term scenarios. Registered residential uses (indoor fogger, pet mousse, carpet spray, pet spray) result in significantly higher exposures than the proposed mosquito control use and were therefore used for the short- and intermediate-term assessment. The acute aggregate exposure results in DWLOCs that range from 57 ppb (children 1-6 years old) to 1,300 ppb (males 20+) and are greater than the acute surface water EEC of 0.591 ppb. Short- and intermediate-term DWLOCs are numerically equivalent and range from 290 ppb (children 1-6 years old) to 1000 ppb (adults). These are all significantly greater than the chronic

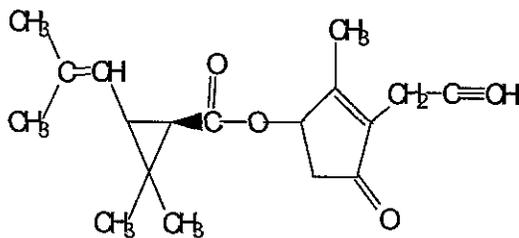
EEC of 0.0375 ppb. The chronic DWLOCs range from 480 ppb (all infants) to 1,700 ppb (U.S. Population) and are greater than the chronic EEC of 0.0375 ppb.

All the acute, short- and intermediate-term, and chronic DWLOCs are based on conservative estimates of dietary and non-dietary exposures and are greater than their respective EECs; therefore, aggregate exposure to prallethrin resulting from the requested uses is not expected to exceed HED's level of concern for any population subgroup, including those of infants and children.

An occupational exposure and risk assessment was conducted for certified, licensed operators and handlers of mosquito abatement equipment only. Since the dermal and inhalation endpoints were based on the same toxicological effects, routes of exposure were aggregated for short- and intermediate terms exposures into a Total MOE. No chemical-specific handler exposure data were submitted in support of this use. Therefore, an exposure assessment for each scenario was developed, where appropriate data are available, using the Pesticide Handlers Exposure Database (PHED) Version 1.1. The total occupational MOEs for short- and intermediate term handlers ranged from 110 to 8400. The handler MOEs were all greater than the target MOE of 100, and therefore did not exceed HED's level of concern.

HED has no objection to prallethrin being granted a registration for use as a mosquito abatement control.

## 2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION



Prallethrin, (ETOC®) [(RS)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate] is an insecticide in the synthetic pyrethroid class of compounds. There are eight potential isomeric forms. In its technical form, it is a yellow to yellow-brown liquid. It is miscible with most organic solvents at 20-25°C and is practically insoluble in water. The log  $K_{ow}$  is 4.49. This factor indicates that it is likely to have low dermal absorption. It has a vapor pressure of  $3.5 \times 10^{-5}$  mm Hg at 20°C. As a note, the volatility of this pesticide is very close to a recommended value which would consider this pesticide to be non-volatile for indoor uses:  $7.5 \times 10^{-5}$  mm Hg (i.e., if the potential for human inhalation exposure for a particular chemical is very low and if the vapor pressure is  $7.5 \times 10^{-5}$  or less, then the chemical would be a candidate for a

waiver for an inhalation study). However, the vapor pressure is significantly higher than other pyrethroids (most have ca  $10^{-7}$  to  $10^{-8}$  mm Hg based on the EFGB One Liner Data Base). For prallethrin, the current and requested uses are likely to result in significant inhalation exposure. Therefore, risk assessments need to be conducted for potential inhalation exposure.

### 3.0 HAZARD CHARACTERIZATION (See Pamela Hurley, TXR No. 0051993, 6/27/2003)

#### 3.1 Hazard Profile

Table 1 provides a summary of the toxicity categories for the technical acute studies.

GDLN	Study Type	MRID	Results	Tox Category
81-1	Acute Oral	42030903	LD <sub>50</sub> : 640 mg/kg (♂) 460 mg/kg (♀)	II
81-2	Acute Dermal	41321812	LD <sub>50</sub> > 5000 mg/kg (♂+♀)	IV
81-3	Acute Inhalation	42030904 41321813	LC <sub>50</sub> : 288 mg/m <sup>3</sup> (♂) 333 mg/m <sup>3</sup> (♀)	II
81-4	Primary Eye Irritation	42030905 41321814	Minimally irritating PIS 3.7 (1 hr.) 0.3 (24 hr.) 0.0 (48 hr.)	III
81-5	Primary Skin Irritation	42030905 41321814	Non-irritating PIS 0.0	IV
81-6	Dermal Sensitization	41321815	Not a sensitizer (Maximization procedure)	N/A

The HED Hazard Identification Assessment Review Committee (HIARC) met on 9/2/99 to evaluate the toxicology data base and to re-assess the chronic Reference Dose (RfD) as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments that were established in 1995. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to prallethrin, as required by the Food Quality Protection Act (FQPA) of 1996 (09/02/99; TXR No. 013779).

On May 15, 2003, the HIARC re-evaluated the previously selected chronic Reference Doses (RfD) and respective toxicological endpoint. HIARC decided to reverse the previous decision to lower the NOAEL for the study and raise it back to 5.0 mg/kg/day. Furthermore, HIARC re-evaluated the potential for increased susceptibility of infants and children from exposure to

prallethrin as required by FQPA according to the 2002 OPP 10x Guidance Document. The HIARC concluded that the toxicology database for prallethrin is adequate for FQPA assessment. A complete complement of acceptable developmental, reproduction and mammalian neurotoxicity studies are available; however, a developmental neurotoxicity study in rats with prallethrin is required for characterization (06/27/03; TXR No. 0051993). The revised toxicological endpoints are summarized in Table 2.

Table 2. Summary of Toxicology Endpoint Selection for Prallethrin			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 5 mg/kg/day UF = 100 <b>Acute RfD = 0.05 mg/kg</b>	FQPA SF = 1 aPAD = <u>acute RfD</u> FQPA SF  = 0.05 mg/kg	Chronic dog study (capsule) LOAEL = 10 mg/kg/day based on trembling observed during week 1.
Chronic Dietary (All populations)	NOAEL= 5 mg/kg/day UF = 100 <b>Chronic RfD = 0.05 mg/kg/day</b>	FQPA SF = 1 cPAD = <u>chronic RfD</u> FQPA SF  = 0.05 mg/kg/day	Chronic dog study (capsule) LOAEL = 10 mg/kg/day based on trembling, rapid eye blinking, hunched posture, panting, increased serum cholesterol, phospholipids and alkaline phosphatase activity.
Incidental Oral Short- and intermediate-term	NOAEL= 5 mg/kg/day	<b>Residential LOC</b> for MOE = 100  <b>Occupational</b> = NA	Chronic dog study (capsule) LOAEL = 10.0 mg/kg/day based on trembling, rapid eye blinking, hunched posture, panting, increased serum cholesterol, phospholipids and alkaline phosphatase activity.
Dermal All Durations	Dermal NOAEL= 30 mg/kg/day	<b>Residential LOC</b> for MOE = 100  <b>Occupational LOC</b> for MOE = 100	21-day Dermal Rat LOAEL = 150 mg/kg/day based on observed clinical signs of toxicity (fixation, abnormal gait, tremors, sensitivity to external stimuli, vocalization, twitching and writhing spasms), all beginning between days 1 and 3 of a 21 day dermal study in rats.
Inhalation (All Durations)	Inhalation NOAEL= 1.01 mg/m <sup>3</sup> (0.174 mg/kg/day)	<b>Residential LOC</b> for MOE = 100  <b>Occupational LOC</b> for MOE = 100	28-Day Inhalation Rat LOAEL = 0.765 mg/kg/day based on increased evidence & severity of irregular respiration, decreased spontaneous activity, nasal discharge during exposure, starting on day 1 of a 28 day rat inhalation study.
Cancer (oral, dermal, inhalation)	<b>Classification: Not likely</b>		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

### 3.2 Special FQPA Safety Factor

No special FQPA Safety Factor is needed (i.e., 1X), since there are no residual uncertainties for pre- and postnatal toxicity. HIARC determined that the 10X database uncertainty factor ( $UF_{DB}$ ) can be reduced to 1X because the available data does provide a basis to support reduction of the default 10X factor (see 2<sup>nd</sup> HIARC Report on Prallethrin, June 27,2003, TXR NO. 0051993).

## 4.0 EXPOSURE ASSESSMENT

In this document, HED presents its assessment of the potential human health risks from public health insect vector control exposure to prallethrin. This document includes only those new product formulations intended for outdoor public health insect control use.

### 4.1 Summary of Proposed New Use(s)

The manufacturer, MGK, requests registration for two products, Multicide® Fogging Concentrate 2798 and Responde'® insecticide, containing 1% and 9% prallethrin, respectively. Both of the proposed labels, Multicide Fogging Concentrate 2798 and Responde', contain prallethrin in a petroleum distillate solution. Uses are summarized in Table 3.

Formulation	Method of Application	Maximum Application	Use Site
Multicide®Fogging Concentration 2798 (EPA Reg# 1021-mn-2) 1.0% A.I.; Liquid	ULV Aerial, ground truck-fogger, low pressure handwand, backpack	0.0008 lb ai/A	Outdoor residential and recreational areas
Responde (EPA Reg# 1021-MN-2) 9.05% A.I.; Liquid	ULV ground-truck aerosol generator and aerial application	0.002 lb ai/A	Outdoor residential and recreational areas. <b>To be applied by certified personnel only.</b>

### 4.2 Dietary Exposure and Risk Pathways

Based on the low application rates ( $\leq 0.002$  lb ai/A) and the nature of the proposed use (fine particle spray intended to remain airborne for control of flying mosquitoes), very low residues, if any, would be expected on crops. Such residues would be negligible compared to those from the registered food handling uses. Therefore, the 1 ppm tolerance on all foods would also cover the mosquito use. In addition, the dietary risk assessment for the food handling use is still adequate as a measure of total exposure from residues in food. For additional information regarding Dietary Exposure and Magnitude of Residues see Pamela Hurley, D239112, 03/08/2000.

#### 4.2.1 Acute Dietary Exposure (William Cutchin, 3/8/2000, DP Barcode D263778)

HED has conducted a Tier 2 (anticipated residues and 100 percent food handling facilities treated) acute dietary (food only) exposure assessment for prallethrin (W. Cutchin, 3/8/2000, DP Barcode D263778) using the Dietary Exposure Evaluation Model (DEEM™). The DEEM acute analysis estimates the distribution of single-day exposures for the overall U.S. population and

certain subgroups. This model incorporates individual food consumption as reported by respondents in the USDA 1989-91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. The DEEM™ acute exposure analysis was performed using anticipated residues levels (maximum residue levels observed in food handling studies) and 100% percent food treated to estimate the exposure for the general population and subgroups of interest. The DEEM™ acute dietary analysis indicates that exposure to prallethrin from dietary (food only) sources will be below HED's level of concern for all population subgroups [100% of the acute Population-Adjusted Dose (aPAD)]. The estimated exposure will occupy 88.6% of the aPAD for children 1-6 years (the most highly exposed population subgroup). Acute dietary risk to all other population subgroups is less than that of children 1-6 years (Table 4).

#### 4.2.2 Chronic Assessment (William Cutchin, 03/08/2003, D262478)

HED has conducted a Tier 3 (anticipated residues and percent food handling facilities treated data) chronic dietary (food only) exposure assessment for prallethrin (W. Cutchin, 1/24/2000, DP Barcode D262478) using the Dietary Exposure Evaluation Model (DEEM™). This model incorporates individual food consumption as reported by respondents in the USDA 1989-91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. The DEEM™ chronic exposure analysis was performed using anticipated residues levels and 12% percent food handling facilities treated [worst-case estimate; e-mail from J. Alsadek (Biological and Economic Analysis Division) to W. Cutchin, dated 1/14/2000] to estimate the Anticipated Residue Concentration (ARC) for the general population and subgroups of interest. The DEEM™ chronic dietary analysis indicates that exposure to prallethrin from dietary (food only) sources will be below HED's level of concern for all population subgroups [100% of the chronic Population-Adjusted Dose (cPAD)]. The estimated exposure will occupy 4.3% of the cPAD for children 1-6 years (the most highly exposed population subgroup). Chronic dietary risk to all other population subgroups is less than that of children 1-6 years (Table 4)

Population Subgroup <sup>1</sup>	Acute		Chronic	
	Exposure (mg/kg/day)	%aPAD 2	Exposure (mg/kg/day)	%cPAD 3
U.S. Population	0.022822	46	0.000879	2
All Infants (<1 yr)	0.040394	81	0.001683	3
Children (1-6 years old)	0.044305	89	0.002151	4
Children (7-12 yrs)	0.027826	56	0.001323	3
Females 13-19 (np/nn)	0.017048	28	0.000750	2
Males (13-19 yrs)	0.018586	37	0.000837	2
Females 20+(np/nn)	0.013489	27	0.000634	1
Males 20+	0.013604	27	0.000646	1

<sup>1</sup>Population subgroups shown include the U.S. General Population and the maximally exposed subpopulation of adults, infants and children, and women of child-bearing age.

<sup>2</sup> aPAD is equal to  $RfD \div FQPA \text{ Safety Factor}$  ( $RfD \div 1$  in this case):  $\% RfD \text{ (aPAD)} = \text{Exposure (mg/kg/day)} \div RfD \text{ (mg/kg/day)} \times 100$

<sup>3</sup>cPAD is equal to  $RfD \div FQPA \text{ Safety Factor}$  ( $RfD \div 1$  in this case):  $\% RfD \text{ (cPAD)} = \text{Exposure (mg/kg/day)} \div RfD \text{ (mg/kg/day)} \times 100$

### 4.3 Water Exposure and Risk Pathways

The Environmental Fate and Effects Division (EFED) has completed a drinking water assessment for prallethrin (memo from Jose Luis Melendez, EFED, 06/30/03, D274758). The memo presents the Tier 1 Estimated Environmental Concentrations (EECs) for prallethrin, calculated using FIRST (v.1.0, surface water) and SCIGROW (v.2.2, groundwater). The surface water acute and chronic EECs (0.591 ppb and 0.0375 ppb, respectively) were greater than the ground water estimate (0.00104 ppb) and were used for comparison to the DWLOCs. The results of these models are summarized in Table 5.

Product	Application Rate (lb/ai.A)	Acute (peak) Surface Water Conc (ppt)	Annual Average Surface Water Conc (ppt)	Ground Water Conc. (ppt)
MULTICIDE®	0.0008	236	15	0.41
RESPONDE®	0.002	591	37.5	1.04

The values in Table 5 generally represent upper bound estimates of the concentrations that might be found in surface water and groundwater due to the use of prallethrin on outdoor residential sites, at the maximum application rate, which represents an adverse case scenario.

Since there is no minimum application interval or number of applications per season, various runs were performed with different number of applications. Using 150 daily applications and 365 daily applications, it was found that the peak and annual average value did not increase substantially. It was assumed that the prallethrin would be applied daily for 365 days

### 4.4 Residential (Non-Occupational) Bystander Exposure and Risk Pathways

The bystander/residential exposure and risk assessment presented here is based on the proposed public health use for adult mosquito control, either by aerial or ground fogging, based on maximum rates on the MGK labels.

#### 4.4.1 Handler Exposure

These proposed uses for application of prallethrin as a mosquito abatement are performed by mosquito control officials and trained pest control operators only. Therefore the exposure risk for certified and trained applicators/handlers will be addressed in the Occupational Exposure section of this assessment

#### 4.4.2 Postapplication Exposure Scenarios

HED has determined that there are potential postapplication exposures to adults and children from the ultra low volume (ULV) aerial and ground-based fogger applications for public health mosquito control uses in the vicinity of residential dwellings. This assessment has been developed to ensure that the potential exposures are not underestimated and to represent a

conservative model that encompasses potential exposures received in other recreational areas (e.g., school playgrounds, parks, athletic fields). Only short-term postapplication exposure is expected following public health mosquito control applications due to the intermittent use pattern of the compound. The following scenarios are likely to result in postapplication exposures:

- Inhalation (adult and toddler).
- Dermal exposure from residues deposited on turf at residential, park, and school sites (adult and toddler);
- Incidental nondietary ingestion of residues deposited on turf at residential, park, and school sites from hand-to-mouth transfer (toddler);
- Incidental nondietary ingestion of residues deposited on turf at residential, park, and school sites from object-to-mouth transfer/ingestion of pesticide treated turf (toddler);
- Incidental ingestion of soil from treated areas (toddler)

The inhalation component of postapplication exposure is usually negligible in comparison to the contribution of dermal exposure, and is not included in most determinations of postapplication risk. However, potential inhalation exposure is the primary concern following outdoor ULV or fogger use, and therefore is included.

#### **4.4.2.1 Data and Assumptions for Postapplication Scenarios**

Chemical-specific exposure data for mosquito uses have not been submitted by the registrant. Therefore, potential residential bystander exposure from these uses are assessed using assumptions and approaches developed specifically for the *malathion* public health mosquitocide exposure assessment (J. Arthur, D283741, July 17, 2002). Dermal, oral (hand-to-mouth transfer, ingestion of treated turf, ingestion of soil), and inhalation (estimating air concentrations from truck-fogger) exposures were assessed using the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment and equations and assumptions from published literature studies. Inhalation exposure resulting from aerial applications was also assessed using the AgDisp (airborne exposure) model.

No proprietary data from the Spray Drift Task Force (SDTF) was used in this assessment. Additionally, AgDRIFT was recently presented before the FIFRA Science Advisory Panel. Modifications to the model are possible as a result of the SAP comments. These modifications, however, are anticipated by HED not to significantly alter the results of this assessment. Any significant modifications to the model may require further refinement of this assessment. Even given the potential for modification of the model, the assessment is much more refined than assuming 100 percent of the application rate is deposited on the turf in residential areas where aerial ULV applications occur. The latter approach (i.e., 100% deposition) is recognized by HED as completely unrealistic given what is known concerning the engineering aspects of malaria vector control and other aerial ULV applications.

A list/description of the literature studies, the AgDisp model, assumptions and equations used to assess inhalation exposure are provided below.

Ground-based ULV Literature Studies

(For additional information see G. Bangs, D293820, 9/30/03)

1. *Downwind Drift and Deposition of Malathion on Human Targets From Ground Ultra-Low Volume Mosquito Sprays*: J.C. Moore, J.C. Dukes, J.R. Clark, J. Malone, C.F. Hallmon, and P.G. Hester; Journal of the American Mosquito Control Association; Vol. 9, No. 2 (June, 1993)
2. *Mass Recovery of Malathion in Simulated Open Field Mosquito Adulticide Tests*: N.S. Tietze, P.G. Hester, and K.R. Shaffer; Archives of Environmental Contamination and Toxicology; 26: 473-477 (1994)

Aerial ULV - AgDisp Model

To calculate airborne concentrations and deposition from aerial ULV applications, HED used *AgDisp* (version), a model developed and validated by the US Forest Service. The *AgDisp* model determines what percentage of the application volume remained aloft and what percentage of the resulting droplets deposited on the surfaces in the treatment area as well as downwind from the treatment area. The model allows for the estimation of air concentrations in the breathing zones of adults and toddlers, as well as residues depositing on turf for use in calculating the risks to individuals residing in areas being treated by aerial application of prallethrin. HED selected the maximum deposition rate and highest airborne concentrations to use for a screening-level assessment of bystander prallethrin exposure. Because all deposition rates were less than 100% of the application rate, the dermal risk from residues deposited at 100% of the application rate was also assessed.

Deposition from aerial ULV applications is assumed to be uniform throughout the drift zone even though *AgDisp* indicates minor fluctuations in the region of interest. The deposition region and input parameters used in the *AgDisp* model for this risk assessment are provided in detail in the Residential and Occupational Exposure Assessment for Prallethrin (G. Bangs, D293820, 9/30/03)

## Data and Assumptions:

- Postapplication was assessed on the same day the pesticide is applied because it was assumed that the homeowner could be exposed to turfgrass immediately after application. Therefore, postapplication exposures were based on day 0.
- Adults were assumed to weigh 70 kg. Toddlers (3 years old), used to represent the 1 to 6 year old age group, were assumed to weigh 15 kg.
- The maximum labeled application rate (ULV) for aerial or ground mosquito control is 0.002 lb ai/acre. (based on proposed Responde'<sup>®</sup> ULV label)
- *AgDisp* model used to estimate airborne concentration at approximately 6 feet above ground from aerial application = 0.000317 mg/m<sup>3</sup>.
- Dilution of truck fogger airborne concentration of 1 to 100 (i.e., 1 percent (0.01) of product released is available for inhalation exposure .
- Adult breathing rate for short-term exposure (light activity) = 16.7 L/min
- Human exposure time is 20 minutes (0.33 hours) for inhalation; 2 hours for dermal route.
- Animal exposure time is 6 hours
- full application rates for a ground-based fogger truck (with a one percent dilution factor) is available in the breathing zone of the residential bystander, thus turning an application rate expressed as lbs. ai/ft<sup>2</sup>, into a concentration expressed in a per cubic foot (ft<sup>3</sup>) basis.

Equations:

$$\text{Inhalation MOE} = \frac{\text{NOAEL}_{\text{animal}} \text{ (mg/kg/day)} \times \text{Exposure Duration}_{\text{animal}} \text{ (6 hrs)}}{\text{Airborne Conc (mg/m}^3\text{)} \times \text{Active Minute Vol/Resting Minute Vol} \times \text{Exposure Duration (hrs)}}$$

$$\text{Dermal MOE} = \frac{\text{TTR (ug/cm}^2\text{)} \times \text{Tc (cm}^2\text{/hr)} \times 0.001 \text{ mg/ug} \times \text{Exposure Duration (2 hrs/day)}}{\text{Body Weight (15 kg Toddler; 70 kg Adult)}}$$

$$\text{Hand-to-Mouth MOE} = \frac{\text{TTR (ug/cm}^2\text{)} \times \text{SA (cm}^2\text{/event)} \times \text{FO (events/hr)} \times 0.001 \text{ mg/ug} \times \text{SE (.5)} \times \text{Duration (hrs/day)}}{\text{BW (15 kg)}}$$

$$\text{Ingestion of Pesticide Treated Turf} = \frac{\text{Grt (ug/cm}^2\text{)} \times \text{IgR (cm}^2\text{/day)} \times 0.001 \text{ mg/ug}}{\text{BW (15 kg)}}$$

$$\text{Incidental Soil Ingestion} = \frac{\text{Srt (ug/g)} \times \text{IgR (mg/day)} \times 1\text{E-6 g/ug}}{\text{BW (15 kg)}}$$

#### 4.4.2.2 Inhalation Postapplication Exposure and Risk

The risk estimates for postapplication inhalation exposure via truck fogger and aerial application were greater than the target MOE of 100 and therefore do not exceed HED's level of concern. Calculations for estimating the inhalation MOEs for aerial and truck-fogger ULV are provided below.

The inhalation MOEs are calculated using the following "Route-Specific Inhalation MOE" equation:

$$\text{MOE} = \frac{\text{NOAEL (}\mu\text{g/m}^3\text{)} \times D_A}{\text{Inhalation Exposure Concentration (}\mu\text{g/m}^3\text{)} \times D_H \times \left( \frac{\text{Human BR}_{\text{ACTUAL}}}{\text{Human BR}_{\text{REST}}} \right)}$$

where,

$D_A$	=	Duration of daily animal exposure in study (hrs/day)
$D_H$	=	Duration of daily human exposure (hrs/day)
$BR_{\text{ACTUAL}}$	=	Breathing Rate for exposure scenario (L/min)
$BR_{\text{REST}}$	=	Breathing Rate at rest (L/min)

This equation is based on 6/10/98 HED memo from J. Whalan/HED to M. Stasikowski/HED, Inhalation Risk Characterizations with Aggregate Risk Index. This equation accounts for the differences in the duration of daily exposure for animals ( $D_A$ ) and humans ( $D_H$ ), and the increased respiration and exposure that results from the increased activity.

Breathing rate assumptions for humans were based on the 1997 EPA Exposure Factors Handbook Volume III. Mean breathing rates recommended for short-term exposures during rest, sedentary, light, and moderate activities are 6.7, 8.3, 16.7, and 26.7, respectively. A resting breathing rate for humans of 6.7 L/min was used. The L/min units cancel out in the equation, resulting in a minute volume ratio to account for activity level. The ratio of minute volumes at rest and at various activity levels are similar for children and adults. Therefore, only the adult MOEs are calculated here.

### Aerial ULV

$$\text{Inhalation MOE} = \frac{\text{NOAEL (mg/kg/day)}_{\text{animal}} * \text{exposure duration}_{\text{animal}} \text{ (6hrs)}}{\text{Airborne concentration (mg/m}^3\text{)} * \text{inhalation rate/resting rate} * \text{exposure duration}}$$

$$\frac{1.01 \text{ mg/m}^3 * 6 \text{ hrs}}{0.000317 \text{ mg/m}^3 * 0.55/0.40 \text{ m}^3/\text{hour} * 0.33 \text{ hrs}} = 23,000$$

### ULV Truck-fogger

$$\text{Inhalation MOE} = \frac{\text{NOAEL (mg/kg/day)}_{\text{animal}} * \text{exposure duration}_{\text{animal}} \text{ (6hrs)}}{\text{Airborne concentration (mg/m}^3\text{)} * \text{inhalation rate/resting rate} * \text{exposure duration}}$$

- Application rate of 0.002 lb ai/acre x 1 acre/43,560 ft<sup>2</sup> = 4.6 E-08 lbs ai/ft<sup>2</sup>
- Expressed as an airborne concentration = 4.6 E-08 lbs ai/ft<sup>3</sup>  
 $4.6 \text{ E-08 lbs ai/ft}^3 * 35.3 \text{ ft}^3/1 \text{ m}^3 = 1.6 \text{ E-06 lbs ai/m}^3$   
 $1.6 \text{ E-06 lbs ai/m}^3 * 4.54 \text{ E+05 mg/lb} = 0.736 \text{ mg/m}^3$
- Application concentration (0.736 mg/m<sup>3</sup>) x dilution factor (0.01) = 0.00736 mg/m<sup>3</sup>

$$\frac{1.01 \text{ mg/m}^3 * 6 \text{ hrs}}{0.00736 \text{ mg/m}^3 * 0.33 \text{ hrs} * 0.55/0.40 \text{ m}^3/\text{hour}} = 1000$$

#### 4.4.2.3 Dermal and Incidental Oral Exposure/Risk

All dermal and oral MOEs are greater than the target MOE of 100 and therefore do not exceed HED's level of concern. The summary of postapplication dermal and incidental oral MOEs are presented in Table 6. Turf transferable residues for dermal and oral exposure estimates were adjusted (0.35 for air; 0.05 for ground) for drift deposition provided by the AgDisp Model.(see footnote b in Table 6).

Table 6. Short-Term Dermal and Incidental Oral Postapplication Risks Using AgDisp												
Scenario	Crop or Target	Receptor	Application Rate (AR) (lbs ai/sq ft) <sup>a</sup>	TTR/GRt (ug/cm <sup>2</sup> ) <sup>b</sup>	Srt (ug/g) <sup>d</sup>	Transfer Coefficient (Tc) (cm <sup>2</sup> /hr)	Exposure Time (ET) (hrs/day)	Surface Area (SA) (cm <sup>2</sup> /event)	Freq. (FQ) (events/hr)	IgR (cm <sup>2</sup> /day) or (mg/day) <sup>e</sup>	ADD (mg/kg/day) <sup>f</sup>	MOE <sup>g</sup>
Dermal	Turf (air ULV)	Adult	4.6 E-08	3.94e-04	-	14,500	2	-	-	-	1.60e-04	1.90e+05
		Toddler		-	5,200	2.73e-04					1.10e+05	
	Turf (grnd ULV)	Adult		5.62e-05	-	14,500	2	-	-	2.33e-05	1.29e+06	
		Toddler		-	5,200	3.90e-05				7.70e+05		
Hand-to-Mouth	Turf (air ULV)	Toddler	3.94e-04	-	-	2	20	20	-	1.05e-05	4.27e+05	
	Turf (grnd ULV)		5.62e-05	-	-	-	-	-	1.50e-06	3.33e+09		
Object-to-mouth Turfgrass	Turf (air ULV)	Toddler	3.94e-04	-	-	-	-	-	25	6.57e-07	7.60e+06	
	Turf (grnd ULV)		5.62e-05	-	-	-	-	9.37e-08	5.34e+07			
Incidental soil ingestion	Turf (air ULV)	Toddler	-	0.0053	-	-	-	-	100	3.53e-08	1.42e+08	
	Turf (grnd ULV)		0.00075	-	-	-	-	5.00e-09	1.00e+09			

a Application rates are estimated as follows: turf (air ULV) = (0.002 lb ai/A)/43,560 sq. ft. per A;  
b Turf transferrable residue (ug/cm<sup>2</sup>) = [AR (lbs ai/ft<sup>2</sup>) \* fraction ai retained on foliage (5% for dermal and for hand-to-mouth) \* deposition [ 0.35 for air ULV, or 0.05 for ground ULV] \* 4.54E+8 ug/lb \* 1.08E-3 ft<sup>2</sup>/cm<sup>2</sup>].  
c .Soil residue (ug/cm<sup>2</sup>) = [AR (lbs ai/ft<sup>2</sup>) [\* 0.35 for air ULV, or \* 0.05 for ground ULV] \* 4.54E+8 ug/lb \* 1.08E-3 ft<sup>2</sup>/cm<sup>2</sup> \* 0.67 cm<sup>3</sup>/g soil].  
e Ingestion rate: cm<sup>2</sup>/day for grass ingestion, and mg/day for incidental soil ingestion.  
f Average daily dose (ADD) (mg/kg/day)  
Dermal exposure: = [TTR (ug/cm<sup>2</sup>) \* Tc (cm<sup>2</sup>/hr) \* mg/1,000 ug \* ET ( hrs/day) \* absorption factor (100% for toddlers only)] / [BW (15 kg toddler, 70 kg adult)];  
Hand-to-mouth: = [TTR (ug/cm<sup>2</sup>) \* SA (cm<sup>2</sup>/event) \* FQ (events/hr) \* mg/1,000 ug \* Saliva extraction (50%) \* ET (hrs/day)] / [BW (15 kg toddler)];  
Object-to-mouth: = [GRt (ug/cm<sup>2</sup>) \* IgR (cm<sup>2</sup>/day) \* mg/1,000 ug] / [BW (15 kg toddler)]; and  
Incidental soil ingestion: = [SRt (ug/g) \* IgR (mg/day) \* g/1,000,000 ug] / [BW (15 kg toddler)].  
g MOE = NOAEL or LOAEL/ADD, where  
NOAEL (dermal) = 30 mg/kg/day , with a target MOE of 100;  
NOAEL (toddler incidental oral) = 5 mg/kg/day , with a target MOE of 100.

#### 4.4.2.3 Data Gaps and Confidence in Postapplication Exposure and Risk Estimates

The assessment of residential dermal, inhalation and incidental oral exposures following the public health use of prallethrin to control mosquitos indicates that **all the MOEs were greater than the target MOE of 100, and therefore, are not of concern to HED.** It is important to note that these estimated risks are based on conservative assumptions regarding the circumstances of exposure:

- Maximum label rates were used;
- For truck-foggers, individuals were assumed to be standing for 20 minutes in an air concentration that is based on the entire application rate (with a 1% dilution factor);
- No dissipation (breakdown) of prallethrin in the breathing zone concentration was assumed;
- The dermal transfer coefficient used for the toddler calculation, based on a Jazzercise activity, represents a bounding estimate of dermal exposure.
- The duration in which exposed populations are assumed to be in contact with treated turf (i.e., 2 hours/day for adults and toddlers) is an upper percentile estimate based on data available in the *EPA Exposure Factors Handbook*.

#### 4.5 Non-occupational Aggregate Exposures and Risks

Under the Food Quality Protection Act (FQPA), various exposure scenarios that could result in multiple non-occupational exposures to a particular pesticide must be aggregated. Since the dermal, and inhalation endpoints were based on the same toxicological effects, routes of exposure were aggregated for short- and intermediate terms exposures into a Total MOE.

Table 7 below shows the combined inhalation and dermal short-term risk estimates for adults, and combined dermal, inhalation and incidental oral risk estimates for toddlers from postapplication exposure following public health mosquito treatment. The combined short-term risks to adults and toddlers, from all routes of exposure following both ground and aerial prallethrin public health mosquito control treatments, do not exceed HED's level of concern.

It is important to note here that the conservative assumptions listed for the individual routes of exposure are combined here, leading to an upper-range to upper-bound estimate of combined risks. An example of the conservative nature of the estimate of combined exposures following truck-fogger application is the fact that the inhalation exposure (based on the full maximum application rate with a 1% dilution factor) is combined with the dermal and/or incidental ingestion exposure from residues depositing on the turf (based on an estimated deposition rate of 5 % for truck foggers).

Table 7: Combined Dermal, Inhalation and Incidental Oral Short-term Risks From Public Health Mosquito Control							
Scenario	Application Rate <sup>a</sup> (lb ai/A)	Dermal Dose <sup>b</sup> (mg/kg/day)	Dermal MOE <sup>c</sup>	Inhalation MOE <sup>c</sup>	Total Oral Dose <sup>d</sup> (mg/kg/day)	Total Oral MOE <sup>e</sup>	Total MOE <sup>e</sup>
Adult							
(1) Postapplication following Ground ULV truck fogger application	0.002	2.33e-05	1.3e+06	1000	Not Applicable	Not Applicable	1000
(2) Postapplication following Aerial ULV application.		1.6e-04	1.0e+05	23,000	Not Applicable	Not Applicable	19,000
Toddler							
(1) Postapplication following Ground ULV application	0.002	3.9e-05	7.7e+05	1000	1.6e-06	3.1e+06	1000
(2) Postapplication following Aerial ULV application		2.73e-04	1.1e+05	23,000	1.1e-05	4.5e+05	18,000

a. Application rate is based on the highest application rate of all products, Responde, EPA Reg# 1021-MN-2

b. Dermal Dose =  $\frac{TTR (\mu\text{g}/\text{cm}^2) \times Tc (\text{cm}^2/\text{hr}) \times 1000 \text{ mg}/\mu\text{g} \times ET (\text{hrs}/\text{day}) \times \text{absorption factor (100\% for dermal endpoint)}}{\text{Body Weight (70 kg adult; 15 kg child)}}$  (See Table 6 for further details)

c. MOE = NOAEL or LOAEL/ADD where

NOAEL (oral) = 5 mg/kg/day, with target MOE of 100

NOAEL (dermal) = 30 mg/kg/day, with a target MOE of 100

NOAEL (inhalation) = 1.01 mg/m<sup>3</sup>, with a target MOE of 100

d. Total Incidental oral dose = combined dose from hand-to-mouth, object -to-mouth, and soil ingestion (see Table 6)

e. Total MOEs equal to or greater than 100 do not concern HED

$$\text{Total MOE} = \frac{1}{\frac{1}{\text{Dermal MOE}} + \frac{1}{\text{Inhalation MOE}} + \frac{1}{\text{Oral MOE}}}$$

## 5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

In conducting this aggregate risk assessment, dietary, drinking water and residential pathways of exposure were considered. In lieu of water monitoring data, HED has calculated drinking water levels of comparison (DWLOCs) which are used as a point of comparison against modeled estimates of a pesticide's concentration in water (EEC). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide from agricultural and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weight. Default body weight and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 70 kg/2 L (adult male), 60 kg/2 L (adult female and youth 13 -19 yrs), and 10 kg/1 L (child). Actual body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer. Since HIARC determined that prallethrin was not likely to be classified as a carcinogen, a cancer DWLOC was not required for this assessment.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) will not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of pesticide residues in food and drinking water as a part of the aggregate risk assessment process.

### 5.1 Acute Aggregate Risk

Acute aggregate risk consists of dietary exposure pathways (acute food + drinking water). Drinking water levels of comparison for acute aggregate exposure are presented in Table 8. For all population subgroups, the DWLOC is greater than the acute surface or ground water EECs; therefore, aggregate acute exposure to prallethrin is not expected to exceed HED's level of concern.

**Table 8. Acute DWLOC Calculations.**

Population Subgroup	aPAD, mg/kg/day	Food Exposure, mg/kg/day	Max. Water Exposure, mg/kg/day <sup>a</sup>	Ground Water EEC, ppb	Surface Water EEC, ppb	Acute DWLOC, ppb <sup>b</sup>
U.S. Population	0.05	0.022822	0.027178	0.00104	0.591	950
All Infants (<1 year)		0.040394	0.009606			96
Children 1-6 years		0.044305	0.005695			57
Children 7-12 years		0.027826	0.022174			220
Females 13-19 yrs np/nn		0.017048	0.032952			990
Males 13-19 years		0.018586	0.031414			940
Females 20+ np/nn		0.013489	0.036511			1100
Males 20+ years		0.013604	0.036396			1300

<sup>a</sup> Maximum Water Exposure = aPAD - food exposure

<sup>b</sup> DWLOC = Maximum Water Exposure (mg/kg/day) × 1000 µg/mg × body weight (70 kg general population/ adult males, 60 kg adult females, and male and females 13 - 19, 10 kg infants and children) ÷ Water Consumption (2 L/day adults and youth 13-19 yrs, 1 L/day infants and children). Values have been rounded to two significant figures.

## 5.2 Short- and Intermediate-term Risk

In determining short- and intermediate-term aggregate risks, HED has examined the oral and non-oral routes of exposure. Since the oral, dermal, and inhalation endpoints were based on the same toxicological effects, routes of exposure were aggregated for short- and intermediate terms exposures into a Total MOE. Dietary Exposure estimates are found in Table 4. For purposes of this assessment, the food exposures were combined with the residential uses leading to highest exposure. In the case of children, the aggregate risk is based on post-application exposure through use of the indoor total release fogger and the pet mouse (as was done in Table 19 of the 3/8/2000 assessment for the food handling use). For adults the risk is based on the carpet broadcast spray being used in conjunction with the pet spray. These registered residential uses result in significantly higher exposures than the proposed mosquito control use. The latter would be unlikely to occur simultaneously with the indoor uses and was therefore not included in the aggregate assessment. For all population subgroups, the DWLOC is greater than the surface or ground water EECs; therefore, aggregate short- and intermediate-term exposure to prallethrin is not expected to exceed HED's level of concern. A summary of the short- and intermediate-term exposures is provided in Table 9.

Table 9. Short- and Intermediate-term Aggregate Risk and DWLOC Calculations (1/MOE Approach - All Target MOEs Identical)											
Population	Target Aggregate MOE <sup>1</sup>	Food MOE <sup>2</sup>	Oral MOE <sup>3</sup>	Dermal MOE <sup>4</sup>	Inhalation MOE <sup>5</sup>	Aggregate MOE (food & residential) <sup>6</sup>	Water MOE <sup>7</sup>	Allowable Water Exposure <sup>8</sup> (mg/kg/day)	Ground Water EEC ppb	Surface Water EEC, ppb	DWLOC ppb <sup>9</sup>
Adults	100	5700	NA	290	2400	250	170	0.029	0.00104	0.0375	1000
Children 1-6 years		2300	1200	670	850	250	170	0.029			290

<sup>1</sup> Target MOE's are 100 for all routes of exposure

<sup>2</sup> MOE food = [(short or intermediate-term oral NOAEL)/(chronic dietary exposure)] where NOAEL = 5 mg/kg/day and exposures determined by DEEM. The US Population exposure was used for adults since it exceeded exposures of any adult subpopulation. Children 1-6 years were chosen since they have the highest food exposure

<sup>3</sup> MOE oral = [(short or intermediate-term oral NOAEL)/(hand-to-mouth residential exposure)] where NOAEL = 5 mg/kg/day

<sup>4</sup> MOE dermal = [(short or intermediate-term dermal NOAEL)/(high-end dermal residential exposure)] where NOAEL = 30 mg/kg/day

<sup>5</sup> MOE inhalation = [(inhalation NOAEL)/(high-end inhalation residential exposure)] where NOAEL = 0.174 mg/kg/day

<sup>6</sup> Aggregate MOE (food and residential) = 1 ÷ [(1 ÷ MOE food) + (1 ÷ MOE oral) + (1 ÷ MOE dermal) + (1 ÷ MOE inhalation)]

<sup>7</sup> Water MOE = 1 ÷ [(1 ÷ Target Aggregate MOE) - (1 ÷ Aggregate MOE (food and residential))]

<sup>8</sup> Allowable water exposure = Short or Intermediate Term Oral NOAEL ÷ MOE water

<sup>9</sup> DWLOC(µg/L) = [allowable water exposure (mg/kg/day) x body weight (kg)]  
[water consumption (L) x 10<sup>-3</sup> mg/µg]

consumption = 2L/day for adults and 1L/day for children. Body weights of 70 kg and 10 kg were used for adults and children, respectively.

### 5.3 Chronic Risk

In determining chronic aggregate risk, HED has examined the dietary and non-dietary pathways of exposure. At this time, there are no non-dietary pathways of exposure for prallethrin that constitute a chronic exposure scenario; therefore, the chronic aggregate risk calculation includes only dietary (food and drinking water) sources of exposure. The DWLOCs for chronic risk are shown in Table 10. For all population subgroups, the chronic DWLOC is greater than the chronic surface or ground water EECs; therefore, aggregate chronic exposure to prallethrin is not expected to exceed HED's level of concern.

**Table 10. Chronic DWLOC Calculations.**

Population Subgroup	cPAD, mg/kg/day	Food Exposure, mg/kg/day	Max. Water Exposure, mg/kg/day <sup>a</sup>	Ground Water EEC, ppb	Surface Water EEC, ppb	Chronic DWLOC, ppb <sup>b</sup>
U.S. Population	0.05	0.000879	0.04912	0.00104	0.0375	1700
All Infants		0.001683	0.04832			480
Children 1-6 years		0.002152	0.04785			480
Children 7-12 yrs		0.001323	0.04868			490
Females 13-19 yrs np/nn		0.000750	0.04925			1500
Males 13-19 yrs		0.000837	0.04916			1700
Females 20+ np/nn		0.000634	0.04937			1500
Males 20+ years		0.000646	0.04935			1700

Maximum Water Exposure = cPAD - Food Exposure

<sup>b</sup> DWLOC = Maximum Water Exposure (mg/kg/day) × 1000 µg/mg × body weight (70 kg general population/ adult males, 60 kg adult females, and male and females 13 - 19, 10 kg infants and children) ÷ Water Consumption (2 L/day adults and youth 13-19 yrs, 1 L/day infants and children). Values have been rounded to two significant figures.

### 6.0 CUMULATIVE RISK

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

HED did not perform a cumulative risk assessment as part of this risk assessment for prallethrin because HED has not yet initiated a review to determine if there are any other chemical substances that have a

mechanism of toxicity common with that of prallethrin. For purposes of this petition, EPA has assumed that prallethrin does not have a common mechanism of toxicity with other substances.

On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether prallethrin shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for prallethrin need to be modified or revoked. If HED identifies other substances that share a common mechanism of toxicity with prallethrin, HED will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment.

HED has recently finalized its guidance for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance will be available from the OPP Website (<http://www.epa.gov/pesticides>). In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999).

## **7.0 OCCUPATIONAL EXPOSURES AND RISKS (G. Bangs, D293818, D293820, 9/2003)**

### **7.1 Handler Exposures and Risks**

EPA has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with prallethrin.

#### **7.1.1 Handler Exposure Scenarios**

Based on the use patterns identified in Table 3, several major occupational exposure scenarios were identified for prallethrin:

- (1) mixing/loading liquids for aerial (airplane or helicopter) ULV application;
- (2) mixing/loading liquids for ground fogger
- (3) applying sprays with a fixed-wing aircraft (also covers use of helicopter application);
- (4) applying sprays with a fogger;
- (5) mixing/loading/applying liquid with hand-directed fogger

#### **7.1.2 Handler Exposure Scenarios -- Data and Assumptions**

No chemical-specific handler exposure data were submitted in support of the reregistration of prallethrin. Therefore, an exposure assessment for each scenario was developed, where appropriate data are available,

using the Pesticide Handlers Exposure Database (PHED) Version 1.1.<sup>7</sup> The PHED data are considered a reasonable surrogate for the mixer/loaders of the liquid formulations and for the aerial applicators. There were no scenario-specific data available to the HED for exposure during use of ULV ground fogging equipment, either vehicle- or backpack-mounted. The airblast sprayer scenario was used as a surrogate to calculate dermal and inhalation exposure for the truck-mounted fogger. No suitable surrogate was available for the hand fogger and that scenario was not assessed..

The following assumptions and factors were used to complete this exposure assessment:

- Average body weight of an adult handler is 70 kg. This body weight is used in both the short- and intermediate-term assessment, since the endpoint of concern is not sex-specific (i.e., the neurotoxicity could be assumed to occur in males or females).
- Daily acres and volumes (as appropriate) to be treated in each scenario include:
  - 7,500 acres for ULV aerial applications to mosquitoes (based on multiple sources and has been used in recent EPA risk assessments including malathion);
  - 3,000 acres for ULV ground fogging vehicle applications (At 20 mph \* 4 hrs \* 5280 ft/mile \* 300 ft swath / 43,500 ft<sup>2</sup>/acre = 3000 acres/day)

#### Equations and Calculations:

Potential daily dermal exposure was calculated using the following formula:

$$\text{Daily Dermal Exposure} \left( \frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left( \frac{\text{mg ai}}{\text{lb ai}} \right) \times \text{Use Rate} \left( \frac{\text{lb ai}}{\text{A}} \right) \times \text{Daily Acres Treated} \left( \frac{\text{A}}{\text{day}} \right)$$

A dermal absorption value was not needed for dermal exposure because the dermal NOAEL was based on a 21-day dermal study.

Potential daily inhalation exposure was calculated using the following formula:

$$\text{Daily Inhalation Exposure} \left( \frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left( \frac{\mu\text{g ai}}{\text{lb ai}} \right) \times \text{Conversion Factor} \left( \frac{1\text{mg}}{1,000 \mu\text{g}} \right) \times \text{Use Rate} \left( \frac{\text{lb ai}}{\text{A}} \right) \times \text{Daily Acres Treated} \left( \frac{\text{A}}{\text{day}} \right)$$

A 100 percent inhalation absorption value was assumed.

The daily dermal and inhalation dose was calculated using a 70 kg body weight for both short-term and intermediate-term exposure as follows:

$$\text{Daily Dermal Dose} \left( \frac{\text{mg ai}}{\text{Kg/Day}} \right) = \text{Daily Dermal Exposure} \left( \frac{\text{mg ai}}{\text{Day}} \right) \times \left( \frac{1}{\text{Body Weight (Kg)}} \right)$$

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

The calculations of both the daily dermal dose and the daily inhalation dose of prallethrin received by handlers were used to calculate the short-term and intermediate-term dermal and inhalation MOEs. The dermal MOE was calculated using a NOAEL of 30 mg/kg/day; because the inhalation unit exposures for PHED are in mg/kg/day, the inhalation MOE was calculated using a NOAEL of 0.174 mg/kg/day. The following formula describes the calculation of a dermal MOE:

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

The following formula describes the calculation of an inhalation MOE:

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

The target dermal and inhalation MOE, including short-, intermediate and long-term exposure periods, is 100. Daily prallethrin exposure for more than six months is not expected for handlers, but the risk estimates would be the same numerically. Because the endpoints are based on signs of neurotoxicity, the exposure by dermal and inhalation routes may be combined; however, the NOAELs differ for each route of exposure, so the separate risks were combined mathematically.

In order to calculate a Total MOE, the reciprocals of the dermal and inhalation MOEs are combined and divided into 1. The above operations are represented as follows:

$$\text{Total MOE} = \frac{1}{\frac{1}{\text{MOE}_{\text{dermal}}} + \frac{1}{\text{MOE}_{\text{inhalation}}}}$$

A total MOE  $\geq$  100 does not present a concern for handler exposure.

### 7.1.3 Handler Exposure Risk Estimates

A summary of the occupational MOEs is provided in Table 11. The total occupational MOEs for short- and intermediate term handlers ranged from 110 to 8400. The handler MOEs were greater than the target MOE of 100, and therefore did not exceed HED's level of concern.

**Risk Characterization: Uncertainties and Data Gaps:**

There were no chemical-specific data submitted for the public health use of prallethrin. The PHED data were used, which are considered a reasonable surrogate for the mixer/loaders of the liquid formulations and for the aerial applicators. There were no scenario-specific data available to the HED for exposure during use of ULV ground fogging equipment, either vehicle- or backpack-mounted. As this equipment is used outdoors, the airblast sprayer scenario is reasonably close to the truck mounted fogger, but there is considerable uncertainty as to the comparability of these exposures. For the ground ULV applications, it is considered likely that dermal exposure may be less and inhalation greater than for mixing/loading/applying liquids via sprays. This is supported by the study data supplied by MGK Company in MRID 458693-01: wherein a handler is exposed to significant airborne concentrations of prallethrin during use of an indoor ULV sprayer. Although all exposures were estimated using the maximum label rate, the degree of conservatism, (whether the risk is over- or under-estimated) in the ground application risk estimates is unknown.

Table 11: Prallethrin Handler Exposure and Risk Estimates: Baseline Table										
Exposure Scenario (Scenario #)	Mitigation Level	Dermal Unit Exposure (mg/lb ai) <sup>1</sup>	Inhalation Unit Exposure (ug/lb ai) <sup>2</sup>	Application Rate <sup>3</sup> (lb ai/A)	Daily Area Treated <sup>4</sup>	Dermal Dose (mg/kg/day) <sup>5</sup>	Dermal MOE <sup>6</sup>	Inhalation Dose <sup>7</sup> (mg/kg/day)	Inhalation MOE <sup>8</sup>	Total MOE <sup>9</sup>
Mixer/Loader										
Mixing/Loading Liquids for Aerial application (1)	single layer, gloves	0.023	1.2	0.002	7500 Acres per day	0.0049	6100	0.00026	680	610
Mixing/Loading Liquids for ULV Ground Fogger application (2)	Baseline	2.9	1.2	0.002 lb ai per acre	3000 Acres per day	0.25	120	0.00010	1700	110
Applicator										
Sprays for Aerial application (3)	Engineering Controls	0.005	0.068	0.002 lb ai per acre	7500 Acres per day	0.0011	28,000	0.000015	12000	8400
Sprays for Other application (4)	Baselines	0.36	4.5	0.002 lb ai per acre	3000 Acres per day	0.031	970	0.00039	450	310

<sup>1</sup>Baseline dermal unit exposures represent long pants, long sleeved shirts, shoes, and socks. 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>Baseline 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>3</sup>Application rates are based on maximum values found on proposed labels

<sup>4</sup>Amount treated is based on the area or gallons that can be reasonably applied in a single day for public health uses; see text for background

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

<sup>6</sup>Dermal MOE = NOAEL (30 mg/kg/day) / Daily Dermal Dose (mg/kg/day). Target Dermal MOE is 100

<sup>7</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 (acres or gallons)] / Body weight (70 kg).

<sup>8</sup> Inhalation MOE =Inhalation NOAEL= 1.01 mg/m<sup>3</sup>[0.174 mg/kg/day] / Daily Inhalation Dose. Target Inhalation MOE is 100

<sup>9</sup>. Total MOE = 1/[1/MOE dermal + 1/MOE Inhalation]

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- 5) PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. August 1998.
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