United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-06-003
June 2006

Reregistration Eligibility Decision for Resmethrin

REREGISTRATION ELIGIBILITY

DECISION

for

Resmethrin

List A
Case No. 0421

Approved by:

_____
Debra Edwards, Ph.D.
Director, Special Review and
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_____
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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Executive Summary

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for resmethrin and is issuing its risk management decision and tolerance reassessment. There is currently one tolerance being reassessed for resmethrin for use as an insecticide in food handling establishments and storage areas. The revised risk assessments are based on the Agency's review of the required data supporting the use patterns of currently registered resmethrin products and additional information and comments received. After considering the risks identified in the revised risk assessment, public comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of resmethrin that pose risks of concern. As a result, the Agency has determined that resmethrin-containing products are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and labels are amended accordingly. The eligibility decision is discussed fully in this document.

Resmethrin is a member of the pyrethroid class of pesticides and was first registered in 1967. It is a broad spectrum, non-systemic, synthetic pyrethroid insecticide. Resmethrin is registered for use as a wide area mosquito abatement insecticide, for use in livestock and livestock housing, food item transportation, structures, buildings (including food handling establishments), and for residential use to control flying and crawling insects. Approximately 50,000 pounds of resmethrin are used annually, mostly for adult mosquito control. Resmethrin is currently classified as a Restricted Use Pesticide for wide area mosquito abatement.

Resmethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because there are multiple types of sodium channels, and it is currently unknown whether all pyrethroids have similar effects on all channels. In addition, the Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

Overall Risk Summary

The resmethrin human health risk assessment indicates low acute toxicity and no acute dietary endpoint was identified in the studies reviewed by the Agency. The chronic (non-cancer and cancer) dietary risks from food and drinking water sources are below the

Agency's level of concern. Residential handler (non-cancer and cancer) risks are below the Agency's level of concern. One residential post-application exposure scenario slightly exceeds the Agency's level of concern (MOE=900), but this can be mitigated with label language to reduce exposure.

All risk concerns for occupational handlers that mix, load, and/or apply resmethrin can be mitigated with personal protective equipment (PPE).

Resmethrin poses acute risk to some aquatic species, with the most vulnerable species being freshwater and estuarine/marine invertebrates. Terrestrial animals exposed to resmethrin are below the Agency's level of concern; however, resmethrin does pose an acute risk to non-target insects such as honeybees.

Dietary Risk

No acute dietary analysis was conducted for resmethrin because no acute oral endpoint of concern attributable to a single exposure was established in dietary studies reviewed by the Agency. Chronic (non-cancer) dietary risk from resmethrin is low and below the Agency's level of concern. The chronic dietary assessment indicates no risks of concern for the general population or any sub-population. Risk estimates are 2% of the cPAD for the general population and 7% of the cPAD for children 1-2 years old, the most highly exposed population sub-group. The drinking water exposure assessment for resmethrin from both ground and surface water sources is also below the Agency's level of concern.

Cancer dietary risk is below EPA's level of concern, as estimated lifetime cancer risk for the general U.S. population is conservatively estimated at 1.6×10^{-6}. The cancer dietary assessment likely overestimates exposure from registered uses of resmethrin. The only food use for resmethrin is in food handling establishments such as food processing /handling plants, restaurants, commercial food item transportation, and food storage facilities. The Agency conducted a conservative cancer risk estimate assuming that 10% of food handling establishments are treated with resmethrin. This is likely an overestimation of usage based on use data reviewed by the Agency. Additionally, for the resmethrin cancer dietary assessment, the Agency assumed that the full limit of detection (LOD) level was found for all non-residue detections in the Dietary Exposure Evaluation Model (DEEM-FCID).

Resmethrin degrades rapidly when exposed to light (photolysis), however, when not subject to photolysis, resmethrin tends to be more environmentally persistent. Resmethrin has low mobility and has a high affinity to bind to soils/sediments and organic carbon; therefore, it is not expected to leach to ground water. However, like several other chemicals in its class, it can reach surface waters by spray drift or in run-off events via erosion. Nonetheless, exposure from drinking water sources to resmethrin is low. Acute, chronic, and cancer dietary risk from food and water are below the Agency's level of concern.

Residential Risk

Resmethrin has a wide variety of residential uses, including use on pets, indoor and outdoor surfaces, garden crops, and residential outdoor mosquito control. Resmethrin is also used in residential areas for wide area mosquito abatement programs by Public Health Officials.

The Agency assessed residential handler and post-application exposure to resmethrin. All residential handler non-cancer and cancer scenarios are below the Agency's level of concern.

The post-application exposure assessment assumed individuals of varying ages can potentially be exposed to resmethrin as a result of being in an area that has been previously treated with resmethrin or have contact with treated companion animals. Most non-cancer risks from post-application exposure to resmethrin range from 2400 to 8.5 million and are not of concern to the Agency. However, the non-cancer risk estimate for a child exposed to an indoor aerosol space spray exceeds the Agency's level of concern (MOE = 900). This exposure may occur when a child enters a room within 10 minutes after a resmethrin indoor aerosol space spay application. This risk can be mitigated with label instructions informing homeowners to keep all people and pets out of sprayed rooms for 2 hours after application. Residential post-application cancer risk is below the Agency's level of concern for all assessed scenarios.

Aggregate Risk

An acute aggregate assessment has not been conducted because no appropriate endpoint attributable to a single exposure was identified in the resmethrin database. In addition, the Agency did not conduct any non-cancer aggregate risk assessment (short-, intermediate-, or long-term) because endpoints selected for the different routes of exposure are not based on common toxic effects.

The aggregate cancer assessment combines lifetime estimated dietary and residential risks. For resmethrin, aggregate dietary risk (food and drinking water) is 1.6×10^{-6}, and residential risk is 1×10^{-6}. The resulting aggregate risk estimate is 2.6×10^{-6}, and thus does not exceed the Agency's level of concern. Each component of aggregate exposure assessment (dietary, drinking water, and residential risk) is based on conservative exposure scenarios which are greater than what people are likely to experience. The probability of people experiencing all these high-end exposures together and for the durations assessed by the Agency is unlikely. Nonetheless, the Agency is requiring label changes and clarification on all homeowner product labels that will reduce exposure.

Cumulative Risk

Resmethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because there are multiple types of sodium channels, and it is currently unknown whether all pyrethroids have similar effects on all channels. In addition, the Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

FQPA Finding

EPA has determined with reasonable certainty that no harm to the general population or any sub-population will result from exposure to resmethrin.

Occupational Risk

Occupational handler exposures were assessed with baseline attire or minimal personal protective equipment. Non-cancer exposure and risk estimates indicate no MOEs of concern (i.e., all MOEs are greater than 100) at the maximum use rate for all occupational exposure scenarios assessed either at baseline or with the addition of chemical-resistant gloves. Cancer exposure and risk estimates are also below EPA's level of concern at the typical rate for all occupational exposure scenarios assessed when appropriate PPE or engineering controls are considered.

Post-application exposures occur as a result of being in an environment that has been previously treated with a pesticide. Occupational post-application scenarios were not assessed because most worker re-entry exposure is considered unlikely, i.e. resmethrin is not used on agricultural field crops, and worker re-entry exposures to treat food handling establishments warehouses, and outdoor premises are not expected to occur reoutinely for Pest Control Operators (PCOs). Also, there are few handler non-cancer or cancer occupational scenarios of risk concern, and all handler scenarios are able to be mitigated with minimal PPE. The only restricted-entry interval (REI) has been established according to the Worker Protection Standard (WPS) for greenhouses at 12 hours for workers re-entering after treatment with resmethrin. For professional applications to homes, food handling establishments or other buildings, no one will be allowed to enter for 4 hours following an application and the area must be ventilated with fresh air before anyone re-enters.

Ecological Risk

EPA's screening level assessment for resmethrin indicates potential exceedences of levels of concern (LOCs) for some classes of organisms. The scenario assessed for ecological risk was wide area mosquito abatement sprays at maximum (0.007 lb ai/acre) and typical rates (0.0035 lb ai/acre). The risk quotients, in general, are low (less than 7). Freshwater and estuarine/marine invertebrates show the highest acute RQs of all taxa (range from <0.05 to 6.5). The resmethrin screening level ecological risk assessment shows no acute or chronic risk to endangered or non-endangered mammals, and shows some risk to birds. Resmethrin does pose an acute risk to non-target insects such as honeybees. No data were submitted to evaluate the risk of resmethrin exposure to non-target terrestrial or aquatic plants; however, it is unlikely that resmethrin poses a phytotoxic concern based on its neurotoxic mode of action.

Summary of Mitigation Measures

EPA has determined that the currently registered uses of resmethrin are eligible for reregistration provided the mitigation measures outlined in this document are implemented through label amendments. Mitigation measures include:

For Residential Exposure:

To reduce post-application exposure to adults and children:

- Resmethrin homeowner products applied as indoor aerosol space sprays must be labeled to instruct users to keep all people and pets away from treated areas for 2 hours after application. Additionally, these products must be labeled to instruct the user to ventilate the room for 20 minutes with fresh air before re-occupying the treated area.
- Pest control operators (PCOs) applying indoor space sprays or fogs will be required to inform clients that they may not re-enter the treated area for 4 hours after application and that the client must ventilate the treated area before re-entering for 20 to 120 minutes depending on the size of the treated area.
- Manufacturing use labels must contain the following statements:
  "Not for formulation into end use products for use in indoor metered spray systems."
  "Not for formulation into end use products for use in outdoor misting systems."

For Occupational Exposure:

To reduce mixer, loader, handler and applicator exposure:

- All mixers, loaders, and applicators using liquid formulations of resmethrin are required to wear gloves for dermal protection.
- Applicators using foggers in indoor spaces are required to wear a respirator for protection against inhalation risk and coveralls over long pants and shirts for dermal protection.
- Applicators using ready-to-use aerosol formulations are required to wear gloves for dermal protection.

- For products intended for wide area mosquito abatement programs, chemical-resistant gloves are required for all mixers, loaders and handlers except applicators.
- The Agency incident report recommends appropriate protective respiratory equipment for individuals who are likely to have substantial contact with resmethrin. Because mosquito abatement handlers may be exposed to resmethrin on a regular basis, enclosed cabs are required for ULV truck-mounted mosquito abatement spray applications, and enclosed cockpits are required for ULV aerial mosquito abatement spray applications.
- A 12-hour restricted entry interval (REI) is required for workers re-entering treated greenhouses after resmethrin applications. In addition, the greenhouse must be ventilated with fresh air prior to re-entry.

For Ecological Exposure:

To reduce ecological exposure:
- Products labeled for wide area mosquito abatement must state a maximum application rate of 0.007 lb ai/acre, and state a maximum yearly application limit of 0.2 lb ai/acre.
- Release height requirement for rotary wing of no less than 75 feet above the ground or canopy, for fixed wing of no less than 100 feet above the ground or canopy.
- Environmental hazard statements informing user of toxicity to fish, aquatic invertebrates, and oysters/shrimp.
- Statement informing user of toxicity to bees visiting treated area.

Previously, resmethrin labels often did not specify label rates. The rates below will serve as maximum application rates for registered resmethrin products.
- Products labeled for use on Livestock, Farm Animals, and Pets (Direct Application): Product must contain 0.35% ai. or less.
- Products labeled for use in Outdoor Sites (Commercial, Recreational, Domestic Outdoor Sites, Agricultural Structures, Agricultural Premises, and Agricultural Equipment): 0.25 lb ai per acre.
- Products labeled for use in Space Applications (Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment; Domestic Structure Premises and Equipment): 0.001 lb ai per 1000 ft^2.
- Products labeled for use in Surface Crack and Crevice Application (Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment; Domestic Structure Premises and Equipment): 0.242 lb ai per 1000 ft^2.

Stewardship Language
- To lessen potential risks to aquatic organisms from resmethrin use around the home, the Agency is requiring directions for use on both professional and consumer-use products for use in residential settings. These use directions include best management and stewardship practices which are formulation specific and will serve to reduce the potential run-off and drift that can occur from applications of these products.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as EPA review of all submitted data. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

Resmethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because there are multiple types of sodium channels, and it is currently unknown whether all pyrethroids have similar effects on all channels. In addition, the Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

The Agency made its reregistration eligibility determination (RED) based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of resmethrin are eligible for reregistration provided the mitigation and labeling

outlined in the RED are implemented. The document consists of six sections: Section I, the introduction, contains the regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides, and in the Public Docket under docket number EPA-HQ-OPP-2005-0284.

II. Chemical Overview

A. Regulatory History

Two chemicals are included in the resmethrin case, resmethrin and bioresmethrin, as listed below in Table 1. Resmethrin was first registered in the U.S. in 1967. Bioresmethrin was initially registered in the U.S. in 1973. Resmethrin and bioresmethrin are in the same chemical case because of their similar chemical structures and use patterns. The Registration Standard and associated data call-ins (DCIs) were issued for these two chemicals in December of 1988. Resmethrin is classified as a General Use Pesticide for all uses except for the ultra-low volume (ULV) mosquito control use. The resmethrin ULV spray for mosquito control is classified as a Restricted Use Pesticide due to acute aquatic organism toxicity.

Another DCI was issued for resmethrin in October 1995 that required a foliar dissipation study and dermal and inhalation passive dosimetry exposure studies for resmethrin and bioresmethrin. This RED reflects a reassessment of all the data reviewed to date on resmethrin. As of October 28, 2005, registrants of all products containing bioresmethrin have requested voluntary cancellation, and therefore products containing bioresmethrin were not included in any risk assessments.

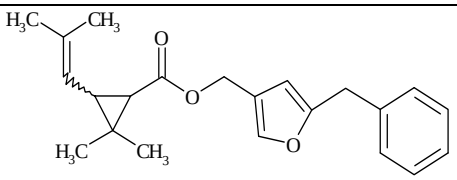
TABLE 1. Ingredients in Resmethrin Chemical Case (0421)

PC Code	Chemical Name	CAS Number	Status
097801	Resmethrin	10453-86-8	Dietary and non-dietary uses being reregistered.
097802	Bioresmethrin	28434-01-7	Since all bioresmethrin products have been proposed for voluntary cancellation and no bioresmethrin products are currently sold in the U.S., bioresmethrin was not assessed. Because it is expected that no registrations for bioresmethrin will remain, bioresmethrin will not be reregistered.

There are currently two manufacturing-use product registrants, Valent BioScience and Bayer Environmental Science. Valent BioScience supports the household and

commercial uses of resmethrin, and Bayer Environmental Science supports the mosquito adulticide use.

B. Chemical Identification

TABLE 2. Resmethrin Nomenclature	
PC Code 097801 Resmethrin	
Chemical structure	
Common name	Resmethrin
Molecular Formula	$C_{22}H_{26}O_3$
Molecular Weight	338.45
IUPAC name	5-benzyl-3-furylmethyl (1*RS*,3*RS*;1*RS*,3*SR*)-2,2-dimethyl-3-(2-methylprop-1-enyl)- cyclopropanecarboxylate or 5-benzyl-3-furylmethyl (1*RS*)-*cis*-*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)- cyclopropanecarboxylate or 5-benzyl-3-furylmethyl (±)-*cis*-*trans*-chrysanthemate
CAS name	[5-(phenylmethyl)-3-furanyl]methyl 2,2-dimethyl-3-(2-methyl-1-propenyl)-cyclopropanecarboxylate
CAS #	10453-86-8

C. Resmethrin Use Profile

Type of Pesticide: Insecticide

Summary of Use: Resmethrin is a synthetic Type I pyrethroid insecticide registered for control of insects in residential, commercial and industrial settings, and in animal living areas. Resmethrin is also registered for use in food handling establishments and as a restricted use pesticide when used in ULV spray to control adult mosquitoes in the interest of public health.

Use sites: Food uses include crack and crevice spray and enclosed space fog in food handling establishments such as food processing/handling plants, restaurants, commercial food item transportation, and food storage facilities. There are no agricultural uses registered for resmethrin.

Non-food uses include animal kennel and sleeping quarters; commercial warehouses; indoor and outdoor use in commercial, institutional, and industrial premises; hospitals; indoor and outdoor use in domestic dwellings; and application to ornamental plants.

Public health uses include wide area treatments for mosquito control as an ultra-low volume (ULV) liquid spray.

Target Organisms: Resmethrin is used to control a broad spectrum of flying and crawling insects.

Mode of Action: Resmethrin works by interacting with sodium channels in the peripheral and central nervous system of target organisms.

Tolerances: There is currently one tolerance established for resmethrin under 40 CFR 180.525. The tolerance is established at 3.0 parts per million (ppm) for use of resmethrin as an insecticide in food handling and storage areas as a space spray, spot treatment, or crack and crevice treatment.

The Agency is not proposing any new tolerances.

Use Classification: Commercial and residential use: General Use Pesticide

Public health mosquito abatement use: Restricted Use Pesticide

Formulations: Resmethrin is formulated as ready-to-use pressurized liquid spray, emulsifiable concentrate, and soluble concentrate.

Methods of Application: Equipment: Applications are made with hand held equipment such as ready-to-use spray containers, aerosol cans, thermal fog generators, electric foggers, backpack sprayers, and hand held sprayers. Applications are also made with aircraft and ground equipment such as truck-mounted sprayers.

Application Methods: Application methods include aerial and truck-mounted ULV sprays, animal shampoos and sprays, ready-to-use spray, and other sprays using hand-held application equipment.

Use rates: Maximum single application rates range from 0.007 pound active ingredient per acre (lb./a.i./A) for mosquito control to 0.25 lb./a.i./A for outdoor commercial, recreational, and domestic sites, and agricultural/farm structures. The maximum indoor crack and crevice application rate is 0.242 lb./a,i./1000 feet squared (ft^2), and

the maximum enclosed area space application is 0.001 lb./a.i./1000 ft^3.

There are currently no limits on the number of applications per year for any use site.

Application Timing: Resmethrin products used indoors may be applied at any time of the year. Outdoor products are generally applied during warmer months of the year when nuisance flying and crawling insects are active. Resmethrin mosquito abatement products are applied when adult mosquitoes are active or when mosquito borne diseases are a concern.

Annual usage: An estimated 50,000 pounds of resmethrin are used annually. The majority of resmethrin is used for adult mosquito control. Resmethrin is also used by homeowners for indoor and outdoor insect control, by pest control operators for insect control, by industrial and commercial service personnel for crack and crevice treatment, and for insect control on pets.

Technical registrants: Valent BioSciences and Bayer Environmental Science

III. Summary of Resmethrin Risk Assessments

The following is a summary of EPA's human health and environmental fate and effects findings and conclusions for resmethrin as presented fully in the documents, "Resmethrin HED Revised Risk Assessment for Reregistration Eligibility Document (RED) PC Code 097801; DP Barcode No. 326088," revised per comments received during the 60-day public comment period, dated February 23, 2006, and "EFED RED Chapter for Resmethrin, Revision Phase 3; DP Barcode No. D326094;" revised per comments received during the 60-day public comment period and dated March 8, 2006.

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for resmethrin for the purposes of making a reregistration eligibility decision. The Agency evaluated the toxicology, product and residue chemistry, and occupational/residential exposure studies and determined that the data are adequate to support a reregistration decision. Details of the risk assessments and separate supporting disciplinary documents are available in the electronic docket. A summary of the human health risk assessment findings and conclusions are provided below.

1. Toxicity

(For a complete discussion, see Section 4.0 of the human health risk assessment.)

The toxicological database for resmethrin is considered adequate to characterize potential hazards and for FQPA determination. Resmethrin has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant nor is it a skin sensitizer. Table 3 below shows the acute toxicity profile for resmethrin.

Table 3. Acute Toxicity Profile - Resmethrin

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	42076201	LD_{50} = 6091mg/kg (m) 4639 mg/kg(f)	III
870.1200	Acute dermal [rabbit]	42076202	LD_{50} > 2000 mg/kg	III
870.1300	Acute inhalation [rat]	42153701	LC_{50} = 5.28 mg/L	IV
870.2400	Acute eye irritation [rabbit]	42076203	PIS = 2.3 at 1 hr. only	IV
870.2500	Acute dermal irritation [rabbit]	42076204	PIS = 0.0	IV
870.2600	Skin sensitization [guinea pig]	42153702	Negative - Buehler	No

Subchronic and Chronic Effects

Liver toxicity is the most sensitive endpoint following resmethrin subchronic and chronic exposure by the oral route. The liver effects include increased weight, hepatocellular vacuolization and hypertrophy at higher doses, and increased enzymes. A subchronic oral study in the rat demonstrated histopathological liver toxicity and a range-finding study in the mouse showed increased hepatic vacuolization and liver enlargement. A subchronic oral dog study revealed slightly increased liver weight that was not associated with microscopic changes or clinical pathology. The chronic oral gavage dog study showed decreased body weight gain and food consumption in both sexes, cataract development in male dogs, and increased liver weight in both sexes of dogs. The two-year oral study in mice indicates slight increases in mortality, and the two-year rat oral toxicity study indicates slight decreases in body weight in females and anemia in males.

Evidence of Neurotoxicity

Resmethrin elicits adverse neurotoxic effects by interacting with sodium channels in the peripheral and central nervous system of target organisms. Neurotoxic effects, such as tremors, nasal discharge, blanching of the feet, and tear-shedding, were observed in two non-guideline modified neurotoxicity screening batteries in rats.

Dermal and Inhalation Toxicity

No systemic effects were observed in a three-week dermal toxicity study in rabbits. A subchronic rat inhalation study produced behavioral effects (sneezing, agitated grooming), decrease in body weight for females, and decrease in glucose levels in males at the lowest dose tested.

Developmental Toxicity

In an oral rat developmental study, both maternal and developmental effects were observed, including decreased maternal body weight and maternal food consumption and delayed ossification and decreased fetal body weight in rat fetuses.

There are two rabbit developmental studies for resmethrin. In a 1979 rabbit study, no maternal toxicity was observed at any dose level; however, developmental toxicity was observed. Effects included increased incidence of fused sternebrae and extra sternebrae. In the more recent (1991) rabbit developmental study, maternal toxicity (decreased body weight gain) was observed at the low dose and developmental toxicity at the high dose. The more recent rabbit developmental study replaces the older study.

Reproductive Toxicity

Two rat reproduction studies were used to determine the chronic dietary endpoint. Reproductive effects, such as increased mortality, decreased survival in pups, decreased pup birth weight and lactation weight, and increased incidence of stillborn pups, were observed in a two-generation rat reproduction study. A three-generation rat reproduction study is considered co-critical for the chronic dietary endpoint with effects of mortality and decreased pup body weight.

FQPA Safety Factor

Resmethrin did not demonstrate qualitative or quantitative evidence of increased susceptibility in the rat developmental study or the two-generation or three-generation rat reproduction studies, and there is a low degree of concern for residual uncertainties for pre- or postnatal susceptibility. In rat developmental and reproduction studies, maternal or parental effects occurred at the same doses at which the fetal or offspring effects were found to occur. Additionally, there was no increase in severity of the fetal or offspring effects in comparison to the parental effects. In contrast, resmethrin did display increased quantitative susceptibility in the 1979 rabbit developmental study since developmental effects occurred in the absence of the maternal toxicity at the same dose level. The endpoint selected is protective of developmental effects.

The 10X FQPA Safety Factor was retained in addition to the conventional uncertainty factor of 100x (10x for interspecies variability and 10x for intraspecies variability), due to database uncertainty (the absence of subchronic and developmental neurotoxicity studies). The Agency is requiring a developmental neurotoxicity study at this time for the following reasons: the toxicology data base for resmethrin lacks a guideline acute and 13-week neurotoxicity study in rats; resmethrin is a member of the class of synthetic pyrethroids, which are neurotoxic chemicals; and there is evidence of quantitative increases in susceptibility in a rabbit developmental study.

Dermal Absorption

A dermal absorption estimate of 2.0% was selected based in part on a recent dermal absorption study for pyrethrins (2004) in humans that indicated 0.22% dermal absorption. This study was further corroborated by other human dermal estimates with cypermethrin showing dermal absorption of 0.3-1.8%. EPA's use of human dermal absorption studies in the resmethrin risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

Carcinogenic Potential

(For more information on the classification of carcinogenic potential, see section 4.4.9 of the human health risk assessment.)

Resmethrin was classified as "Likely to be Carcinogenic to Humans" by the Cancer Assessment Review Committee (CARC) of the Office of Pesticide Programs in March 2005. This classification is based on increased incidences of benign and malignant liver tumors in female rats and male mice. A low-dose extrapolation approach was applied to the experimental animal data in order to estimate human cancer risk. The unit risk, Q^*_1 $(mg/kg/day)^{-1}$ of resmethrin based upon male mouse liver combined adenoma and/or carcinoma tumor rates is 5.621×10^{-2} in human equivalents.

Mutagenicity

Resmethrin is not mutagenic, as demonstrated in the Ames assay, in vitro chromosome aberration assay in Chinese hamster ovary cells, and the unscheduled DNA synthesis (UDS) assay in rat hepatocytes.

Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies for resmethrin submitted for registration purposes, there was no estrogen, androgen, and/or thyroid mediated toxicity. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, resmethrin may be subject to additional screening and/or testing.

A summary of the resmethrin studies reviewed for risk assessment are available in section 4.0 of the human health risk assessment. A summary of the endpoints selected for risk assessment is presented in Table 4 below.

Table 4. Summary of Toxicological Doses and Endpoints for Resmethrin for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all population)	No endpoint of concern		
Chronic Dietary (all populations) **(MRID)**	Dose for risk assessment = 35 mg/kg/day UF = 1000 (10 for intraspecies variation, 10 for interspecies extrapolation, and FQPA 10 for database uncertainty) Chronic RfD = 0.035 mg/kg/day	FQPA SF = 10 cPAD = 0.035 mg/kg/day [The FQPA safety factor is retained due to database uncertainty and is included in the calculation of the RfD.]	2-Generation Reproduction Study - rat Reproductive/Offspring LOAEL = 70.8 mg/kg/day based on decreased mating index in males and females during the second F1 mating, decreased viability index and decreased pup weight in all generations at birth and during lactation, and possible slight increase in stillborn pups in the F1a and F2a generations. 3-generation reproduction study is co-critical - LOAEL = 47 mg/kg/day
Incidental Oral Short-, Intermediate-Term	Maternal toxicity NOAEL = 40 mg/kg/day	Residential LOC for MOE = 1000 [The FQPA safety factor is retained due to database uncertainty.] Occupational LOC for MOE = NA	Rat Developmental Toxicity Study Maternal LOAEL = 80 mg/kg/day based on reduced weight gain and reduced food consumption during gestation
Dermal Short-, Intermediate-, and Long- Term	Oral Developmental NOAEL = 30 mg/kg/day (dermal absorption rate = 2%)	Residential LOC for MOE = 1000 [The FQPA safety factor is retained due to database uncertainty.] Occupational LOC for MOE = 100	Oral Rabbit Developmental Toxicity Study Developmental LOAEL = 100 mg/kg/day based on increased incidence of skeletal variations and a possible marginal increase in resorbed litters in the absence of maternal toxicity
Inhalation Short-, Intermediate-, and Long- Term	Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day)	Residential LOC for MOE = 1000 [The FQPA safety factor is retained due to database uncertainty.] Occupational LOC for MOE = 100	90-Day Inhalation Toxicity Study Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day) based on clinical signs within the first month, decreased glucose levels in males, a decrease (-13%) in body weight gain during weeks 1-4 and an increase in BUN (32%) at week 12 in females.

Table 4. Summary of Toxicological Doses and Endpoints for Resmethrin for Use in Human Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**FQPA SF* and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	**Classification:** The CARC (4/13/05) classified resmethrin as "likely to be carcinogenic to humans" and recommended a low-dose linear extrapolation Q1* for resmethrin. Oral Q1* =5.621 x 10^{-2} in human equivalents based upon male mouse liver combined adenoma and/or carcinoma tumor rates		

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

2. Dietary Risk (Food + Water)

(For a complete discussion, see Section 6.0 of the human health risk assessment.)

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. The risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the FQPA Safety Factor. EPA is concerned when estimated dietary risk exceeds 100% of the PAD.

3. Acute Dietary Risk

No acute dietary analysis was completed because no acute oral endpoint of concern attributable to a single exposure was established in acute dietary studies.

4. Drinking Water Dietary Exposure and Risk

(For a complete discussion, see section 6.2 of the human health risk assessment)

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of increasing refinement, but is designed to provide high-end estimates of exposure.

The drinking water assessment for resmethrin considers contribution from resmethrin alone. Since no monitoring data were available for resmethrin, estimated drinking water concentrations (EDWCs) were calculated from models. The EDWCs were incorporated directly into the chronic and cancer aggregate dietary exposure assessment. The EDWCs were based on application methods, rates, and use sites that would likely yield the highest drinking water concentrations.

The most important environmental route of dissipation for resmethrin is photodegradation. The aqueous photolysis half-life for resmethrin is 22 minutes in seawater and 47 minutes in distilled water. Resmethrin is generally slow to biodegrade in the environment under aerobic and anaerobic conditions; half-lives are 198 days for aerobic soil metabolism, 37 days for aerobic aquatic metabolism, and 682 days for anaerobic soil metabolism. Hydrolysis occurs slowly at a range of pH values (half-life >89 days at pHs 5-9). Resmethrin has relatively low mobility in soils and may be expected to adsorb to suspended solids, organic matter, and sediment (Koc range 508-3179). Like other pyrethroids, it appears to have a low potential to reach groundwaters, but it may reach bodies of waters adjacent to the treated areas via runoff events accompanies by erosion. Volatilization is not expected to be an important transport process for resmethrin due to its low vapor pressure and Henry's Law constant.

Surface water – Tier II EDWCs were calculated using Pesticide Root Zone Model (PRZM) v 3.12 beta and Exposure Analysis Modeling System (EXAMS) v 2.98.04.02. As shown in Table 5 below, the Agency calculated a chronic EDWC in surface water of 0.13 ppb, based on the annual average surface water estimate using the PRZM Florida turf scenario. Resmethrin is not used as a turf application, but this scenario was used to conservatively estimate residues when resmethrin is used as a mosquito adulticide over parks, golf courses, and other grassy areas without a canopy.

Ground water – Tier I EDWCs for ground water were calculated using the Screening Concentration in Ground Water (SCI-GROW) model. The Agency calculated a chronic EDWC in ground water of 0.016 ppb.

Monitoring Data – No monitoring data for resmethrin were found in searches of the United States Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) database or the EPA Storage and Retrieval (STORET) database.

Results of a relatively limited monitoring study are available for resmethrin in Suffolk County, New York, before and after mosquito spraying in 2002-2004. The maximum concentration of resmethrin was 0.291 ppb. This concentration is in the range of values predicted for the most conservative scenario.

Table 5. Estimated Drinking Water Concentrations (EDWCs) for Resmethrin

Duration of Exposure	Surface Water EDWCs	Ground Water EDWCs
Chronic	0.13 ppb	0.016 ppb

5. Chronic Non-Cancer Dietary Risk (Food + Water)

The chronic endpoint for all populations is based on a two-generation rat oral study in which reproductive effects such as decreased survival in pups, decreased pup birth weight and lactation weight, and increased incidence of stillborn pups, were observed at the LOAEL of 70.8 mg/kg/day. The NOAEL was 35 mg/kg/day. A total uncertainty factor of 1000X was applied for the chronic dietary assessment, incorporating 10X for interspecies extrapolation, 10X for intraspecies variability and a 10X FQPA

safety factor for database uncertainty. The chronic population adjusted dose (cPAD) was calculated to be 35 mg/kg/day divided by a safety factor of 1000 = 0.035 mg/kg/day.

Resmethrin residues may remain in or on food items, resulting from its use in food handling areas and storage areas as a space treatment, spot application, or crack and crevice treatment. Resmethrin is not applied to agricultural food crops so separate tolerances for residues in or on specific plant or animal commodities do not exist. There is only one tolerance established for resmethrin in 40 CFR 180.525 set at 3.0 ppm for residues of resmethrin in or on food items resulting from its use in food handling and storage areas. The chronic dietary exposure assessments for resmethrin were based on data from a residue study conducted with a crack and crevice spray in food handling establishments. Data pertaining to the nature and magnitude of resmethrin residue in or on food items resulting from the currently registered use in food handling establishments have been evaluated and deemed adequate by the Agency. The chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM FCID, Version 2.03).

Residue data from a study on the magnitude of the residues in foods from application of resmethrin in food handling establishments as a crack and crevice treatment was used for dietary analysis. Data on percent of food handling establishments treated was conservatively estimated at 10% of all food handling establishments nationwide based on registrant-submitted data. DEEM default processing factors were used. An EDWC point estimate value for drinking water contribution to exposure was used. The surface annual average EDWC was 0.13 ppb using a Tier 2 aquatic model PRZM-EXAMS. The groundwater annual average EDWC was 0.016 ppb.

Estimated exposure to resmethrin from food and drinking water is below the Agency's level of concern for all population subgroups at 2% of the cPAD for the U.S. population and 7% of the cPAD for children 1-2 years old, which is the subgroup with the highest estimated exposure.

Table 6. Resmethrin Chronic Dietary and Drinking Water Exposure Estimate and Percent of Chronic PAD

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.035	0.000736	2
Children 1-2 years old	0.035	0.002463	7

The resmethrin dietary exposure assessment overestimates the use of resmethrin due to several factors. The Agency assumes that 10% of food handling establishments are treated with resmethrin. The Agency believes this is an overestimate of resmethrin use in food handling establishments because, according to a proprietary survey of food handling establishments, less than 10% of food handling establishments are expected to be treated with resmethrin. A study on the magnitude of the residues in foods was used for the resmethrin dietary assessment (MRID 41239901). In this study a single application of a 0.25% ai ready-to-use resmethrin product was applied to representative food handling establishments as a crack and crevice treatment. Of the 226 food samples

analyzed, detectable residues of resmethrin (greater than 0.003 ppm) were found in or on only 15 samples of food. An upper-bound residue of 0.38 ppm (the highest detect in a non-tissue commodity) was used for all commodities in DEEM-FCID except meat, poultry and eggs. For meat, poultry and eggs, 0.125 ppm was used since this was the highest detect in a tissue commodity. Because the highest detected residue was assumed for all commodities despite residues found in only 15 of 226 samples, these residue estimates likely overestimate the resmethrin residues found on food commodities.

6. Cancer Dietary Risk (Food + Water)

The cancer dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM FCID, Version 2.03). The resmethrin dietary and drinking water cancer risk assessment was slightly refined using residue data from a study on the magnitude of the residues in foods from application of resmethrin to food handling establishments as a crack and crevice treatment. In this study a single application of a 0.25% ai ready-to-use resmethrin product was applied to representative food handling establishments as a crack and crevice treatment. A residue of 0.01 ppm , the average of all detected residues in food in the study mentioned above, was used for all commodities except water in the cancer dietary exposure analysis. An EDWC (residue level) of 0.13 ppb was used for water in the cancer dietary exposure analysis (for surface water analysis the PRZM Florida turf scenario was used because it yields a high-end residue value). The results of the cancer analysis indicate the estimated dietary and drinking water cancer risk associated with the resmethrin uses do not exceed EPA's level of concern, as estimated excess lifetime cancer risk for the general U.S. population was 1.6×10^{-6}, as shown in Table 7 below.

TABLE 7. Resmethrin Cancer Dietary and Drinking Water Exposure/Risk Estimate

Population Subgroup	Q1*	Exposure (mg/kg/day)	Cancer Risk
General U.S. Population	0.05621	0.000028	1.6×10^{-6}

The cancer dietary assessment overestimates the likely risks from use of resmethrin. The only food use for resmethrin is use in food handling establishments such as food processing/handling plants, restaurants, commercial food item transportation, and food storage facilities. The cancer risk estimate assumes that 10% of all food handling establishments are treated with resmethrin. The assumption is an overestimation of exposure according to a proprietary survey food handling establishments use of pesticides. Additionally, in the resmethrin cancer dietary assessment, the Agency assumed that the full limit of detection (LOD) level was found for all non-residue detections in the Dietary Exposure Evaluation Model (DEMM-FCID). In the past the Agency has used ½ of the LOD value for all non-residue detections when calculating dietary risk. In using the full LOD, the Agency has conservatively estimated dietary risk. Additional data may allow refinement of this estimate. Cancer dietary and drinking water risk from resmethrin is not of concern to the Agency.

7. Residential Risk

(For a complete discussion, see section 7.0 of the human health risk assessment.)

Residential handlers can be exposed to a pesticide while mixing, loading, or applying (handling) a pesticide, or after entering areas where the pesticide had previously been applied by a professional applicator of public health official. Residential non-cancer risks are measured by a margin of exposure (MOE), which determines how close the residential exposure comes to a no observed adverse effect level (NOAEL) taken from animal studies. For resmethrin residential exposures, a MOE of 1000 is considered protective for inhalation, dermal, and incidental oral residential exposure and risk. The MOE includes a 10x for interspecies extrapolation, a 10x for intraspecies variation, and a 10x FQPA safety factor for database uncertainty due to missing toxicology studies.

The Agency calculates the residential risks with the assumption that the residential handler wears shoes, socks, short-sleeved shirt, and shorts. For non-cancer risk, both short- and intermediate-term exposures were assessed for residential handlers and residential post-application exposures based on use and exposure patterns of registered resmethrin products. Inhalation, dermal, and incidental ingestion were considered to be the routes of exposure for citizens exposed to resmethrin. Maximum labeled rates were used for the non-cancer residential handler and non-cancer residential post-application risk assessments.

Residential cancer risks are estimated by calculating the probability that an exposed person may develop cancer. Cancer risk estimates below $1x\ 10^{-6}$ are generally below the Agency LOCs. However, given the many conservative assumptions in its low dose, linear extrapolation cancer model, the Agency generally considers risks up to $3x\ 10^{-6}$ to be within the negligible risk range, and therefore below the level of concern. For the residential space spray application exposure scenario, the Agency assumed that a private citizen can be exposed to a pesticide throughout their lifetime (70 years) via non-handler exposure, or 50 years for handler exposure (mixing, loading, or applying a pesticide). The exposure frequency used for the resmethrin residential handler cancer risk assessment was assumed to be 3 days per year at average or typical application rates for resmethrin. Inhalation and dermal exposure were considered to be the routes of exposure for the cancer risk assessment for residential handlers exposed to resmethrin.

The endpoints selected for residential uses of resmethrin for non-cancer and cancer risk assessment are presented in Table 8 below.

Table 8. Summary of Toxicological Doses and Endpoints for Resmethrin for Use in the Residential and Occupational Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment	Level of Concern for Risk Assessment	Study and Toxicological Effects

Table 8. Summary of Toxicological Doses and Endpoints for Resmethrin for Use in the Residential and Occupational Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Incidental Oral Short-, Intermediate-Term	Maternal toxicity NOAEL = 40 mg/kg/day	Residential LOC for MOE = 1000 (LOC for residential exposures includes an FQPA safety factor of 10 due to database uncertainty) Occupational = NA	Rat Developmental Toxicity Study Maternal LOAEL = 80 mg/kg/day based on reduced weight gain and reduced food consumption during gestation
Dermal Short-, Intermediate-, and Long- Term	Oral Developmental NOAEL = 30 mg/kg/day (dermal absorption rate = 2%)	Residential LOC for MOE = 1000 (LOC for residential exposures includes an FQPA safety factor of 10 due to database uncertainty) Occupational LOC for MOE = 100	Oral Rabbit Developmental Toxicity Study Developmental LOAEL = 100 mg/kg/day based on increased incidence of skeletal variations and a possible marginal increase in resorbed litters in the absence of maternal toxicity
Inhalation Short-, Intermediate-, and Long- Term	Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day)	Residential LOC for MOE = 1000 (LOC for residential exposures includes an FQPA safety factor of 10 due to database uncertainty) Occupational LOC for MOE = 100	90-Day Inhalation Toxicity Study Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day) based on clinical signs within the first month, decreased glucose levels in males, a decrease (-13%) in body weight gain during weeks 1-4 and an increase in BUN (32%) at week 12 in females.
Cancer (oral, dermal, inhalation)	**Classification:** The Agency classified resmethrin as "likely to be carcinogenic to humans" and recommended a low-dose linear extrapolation of a Q1* for resmethrin. Oral Q* =5.621 x 10^{-2} in human equivalents based upon male mouse liver combined adenoma and/or carcinoma tumor rates		

NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

8. Residential Handler Risk

(For a complete discussion, see 7.2 of the human health risk assessment.)

The residential handler assessment considered both dermal and inhalation exposures for adults applying resmethrin in outdoor areas with a hand held fogger and low pressure hand wand, and in indoor areas applying resmethrin as an aerosol spray. The exposure duration considered for non-cancer risk assessment was short- and intermediate-term based on resmethrin use and exposure patterns. For cancer risk, the Agency assumes that a residential handler is exposed to a pesticide for 50 years for handler exposure (mixing, loading, or applying a pesticide). Application rates for all

exposure scenarios assessed are based on information provided by a review of active labels. For the non-cancer assessment, maximum labeled rates are used. For the cancer assessment, typical or average rates are used in risk assessment. Data from the Pesticide Handler Exposure Database (PHED) or Occupational and Residential Exposure Task Force (ORETF) data bases were used to assess residential handler exposures.

Residential Handler Exposure Scenarios

- Mixing, loading, and applying liquid spray formulation by low-pressure handwand for indoor surface spray and crack and crevice treatment application
- Mixing, loading, and applying liquid formulation by fogger for general outdoor application.

Residential Handler Non-Cancer Risk

All MOE estimates for residential handlers range from 2400 to 8.5 million and are not of concern to the Agency. All residential handler risks are below the Agency's level of concern (all MOEs are above 1000).

Residential Cancer Risk

Cancer risk estimates are within the acceptable range for residential handlers (i.e., less than $3x\ 10^{-6}$). The cancer estimates for residential handler exposure to resmethrin range from $1x\ 10^{-6}$ to $2.4x\ 10^{-6}$.

9. Residential Post-application Risk

(For more information, see section 7.2 of the human health risk assessment.)

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Resmethrin can be used in many areas that can be frequented by the general population including residential areas (indoor and outdoor areas). As a result, individuals can be exposed by entering these areas if they have been previously treated. Resmethrin can also be used on companion animals, which can lead to exposure by contact with the treated animals. Further, resmethrin is used in wide area mosquito abatement programs as a mosquito adulticide. It can be applied to wide areas through ultra-low volume (ULV) spraying, which can result in post-application exposure to the general population.

The residential post-application non-cancer risk assessment considered both dermal and inhalation exposures on a short- and intermediate-term basis. Scenarios assessed include adults and children exposed to an outdoor mosquito adulticide application, adults and children re-entering treated lawns, and adults and children exposed to an indoor space spray application. Other non-cancer exposures assessed include incidental ingestion risks to toddlers reentering treated lawns, playing on vinyl floor and carpet after indoor fogger treatment, and incidental ingestion and dermal risks to toddlers playing with pets after the pets have been treated with a resmethrin spray formulation. Application rates for all exposure scenarios assessed are based on active labels. For non-cancer assessment, maximum labeled rates are used. Post application

exposure estimates were developed using OPP standard operating procedures, Non-Dietary Exposure Task Force Exposure (NDETF) data, Spray Drift Task Force Exposure data, and Residential Exposure Joint Venture (REJV) data.

Residential Post-Application Exposure Scenarios

- Inhalation exposure from application of mosquito adulticide from fixed wing aircraft and/or helicopter
- Inhalation exposure from application of mosquito adulticide from ULV truck-mounted sprayer
- Toddler incidental ingestion of residue from exposed turf grass via hand-to-mouth activities
- Toddler incidental ingestion of residue via object-to-mouth activity while on exposed turf grass
- Toddler incidental ingestion of soil from treated area
- Toddler incidental ingestion of residues deposited on carpet via hand-to-mouth activities after use of total release foggers
- Toddler incidental ingestion of residues deposited on vinyl flooring via hand-to-mouth activities after use of total release foggers
- Toddler incidental ingestion of residues on pets via hand-to-mouth activities and dermal exposure after pet treatment
- Inhalation exposure by adult applicator handler scenarios during and after aerosol space spray application; post-application inhalation exposure to aerosol spray by child
- Dermal Exposure to adults and children reentering treated lawns

Post-Application Non-Cancer Risk

Most risk estimates for residential post-application risk range from 2400 to 8.5 million and are not of concern to the Agency. Most residential post-application risks are below the Agency's level of concern (most MOEs are above 1000).

The non-cancer risk estimate for a child exposed to an indoor aerosol space spray exceeds the Agency's level of concern (MOE = 900). This exposure may occur when a child enters a room within 10 minutes after a resmethrin indoor aerosol space spray application. This risk can be mitigated by label instructions that inform residents to keep all people and pets out of sprayed rooms for 2 hours after application.

Post-Application Cancer Risk

Resmethrin is used to kill adult mosquitoes by exposing them directly to spray containing resmethrin. Resmethrin is used by public health officials with federal, state, county, or local governments; mosquito control districts; military officials in charge of public health for military installations; or contractors or others employed by public health agencies.

For cancer risk, the Agency assumes that a private citizen can be exposed to a pesticide for 70 years. For the resmethrin residential post-application cancer risk assessment, typical rates were used. Data from the Occupational and Residential Exposure Task Force (ORETF) data bases were used to assess residential post-

application exposures. Additionally, the registrants submitted Residential Exposure Joint Venture (REJV) data to estimate resmethrin residential use frequency.

Two residential bystander post application cancer risk scenarios were assessed for adults exposed to resmethrin when it is used as an ultra-low volume (ULV) mosquito adulticide spray. (EPA did not assess cancer risk separately for children in residential post-application scenarios because cancer risks are assessed assuming 70 years of exposure; thus they are included in the adult cancer assessment.) The resmethrin risk assessment estimates that an adult could be exposed to resmethrin when applied as an aerial ULV mosquito adulticide spray up to 365 times a year for 70 years before the Agency's cancer risk level of concern is exceeded. When resmethrin ULV mosquito adulticide spray is applied through a truck-mounted sprayer, the Agency estimates that an adult could be exposed up to 125 days a year for 70 years before exceeding the Agency's cancer risk level of concern. Assumptions used in the residential post-application risk assessment include an adult breathing rate is 1.0 meters cubed (m^3) per hour and an exposure duration is less than or equal to 20 minutes. Typical rates were used in the residential post-application cancer risk assessment. In addition, for the truck mounted ULV spray application, a dilution factor of 0.01 was applied to the airborne concentration at the maximum application rate (i.e., 1% of product released was considered to be available for exposure). EPA does not expect residential bystander exposures to approach 125 days a year for 70 years, therefore residential bystander risk is not of concern.

Table 9. Estimated Resmethrin Post-application Inhalation Cancer Risks - Mosquito Adulticide and Estimated Number of Exposure Days Per Year at which Cancer Risks are Not of Concern (Risk $\leq 1x10^{-6}$)

Exposed Individual	Average Application Rate lb ai/acre	Breathing Zone Concentration (mg/m^3)	Lifetime Average Daily Dose (mg/kg/day)	Number of Exposure Days
Aerial Spray (Fixed Wing and Rotary Aircraft)				
Adult	0.003	0.0015	0.00004	>365
Truck Mounted ULV Sprayer				
Adult	0.003	0.0110	0.0003	125

10. Aggregate Risk

(For a complete discussion, see section 8.0 of the human health risk assessment.)

In accordance with the FQPA, the Agency must consider pesticide exposures and risks from all potential sources. These usually include food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or

PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. For this assessment, EPA aggregated exposures from resmethrin in food and water with exposure from residential uses.

Acute Aggregate Risk

An acute aggregate risk assessment is not required, since no appropriate endpoint attributable to a single exposure was identified in the resmethrin database.

Short-, Intermediate-, and Long-Term Aggregate Non-Cancer Risk

Aggregate non-cancer risk is normally estimated as the risk associated with exposures through food and drinking water, as well as residential exposures through the oral, dermal, and inhalation routes. An aggregate non-cancer risk assessment for resmethrin was conducted only for food and water, however, because endpoints selected for the residential routes of exposure are not based on common toxic effects. As described earlier, aggregate non-cancer risk estimates for food and water do not exceed the Agency's level of concern.

Aggregate Cancer Risk

The aggregate cancer assessment combines lifetime estimated dietary and residential risks. For resmethrin, aggregate dietary risk (food and drinking water) is 1.6 x 10-6, and residential risk is 1x 10-6. The resulting aggregate risk estimate is 2.6x 10-6, which falls generally within the range of acceptable risk to the Agency.

Table 10. Estimated Aggregate Cancer Risk from Dietary/Drinking Water and Residential Exposures to Resmethrin

Dietary/Drinking water Risk	Residential Exposure Risk*	Aggregate Cancer Risk
$1.6x10^{-6}$	$1x10^{-6}$	$2.6x10^{-6}$

*Estimated risk from indoor aerosol application assuming reentry 2 hrs after application

EPA has concluded that aggregate cancer risks are likely overestimates, based on several factors. First, food risks are only somewhat refined. The cancer risk estimate assumes that 10% of food handling establishments are treated with resmethrin. This assumption is an overestimation of exposure according to a proprietary survey of pesticides used in food handling establishments. Additionally, in the resmethrin cancer dietary assessment, the Agency assumed that the full limit of detection (LOD) level was found for all non-residue detections in the Dietary Exposure Evaluation Model (DEEM-FCID). In the past the Agency has used ½ of the LOD value for all non-residue detections when calculating dietary risk. In using the full LOD, the Agency has conservatively estimated dietary risk, which results in high-end estimates of exposures to residues in food. Second, drinking water exposure estimates were developed using the Tier 2 model PRZM-EXAMS which also results in high-end estimates of potential exposure to resmethrin. Finally, the residential exposure scenario which was aggregated with the dietary risks is the one with the highest estimated exposure and risk (indoor aerosol space spray) of all the residential scenarios assessed. For the indoor aerosol space spray scenario, the Agency assumes that a residential handler performing an indoor

aerosol space spray application does so three times a year for 50 years, and is additionally exposed for 70 years to post-application residues. These are high-end exposure assumptions. Additionally, given the relatively low usage of resmethrin (50,000 lbs ai per year) the probability of co-occurrence of these exposures is low.

11. Cumulative Risk

Resmethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids because there are multiple types of sodium channels, and it is currently unknown whether all pyrethroids have similar effects on all channels. In addition, the Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

12. Occupational Risk

(For a complete discussion, see section 10.0 of the human health risk assessment.)

Workers can be exposed to a pesticide while mixing, loading, or applying a pesticide, or re-entering a treated site. Handler non-cancer risks are measured by a margin of exposure (MOE), which determines how close the occupational exposure comes to a NOAEL taken from animal studies. For resmethrin non-cancer risk, an MOE greater than or equal to 100 has been determined to be adequately protective for short-term (1 to 30 days), intermediate-term (1 to 6 months) and long-term (greater than 6 months) exposures and risk.

Handler cancer risks are estimated by calculating the probability that an exposed handler may develop cancer. For agricultural workers, the Agency will typically seek to reduce the individual risks to be greatest extent feasible, preferably to 10^{-6} or less. The Agency seeks to reduce risks between 10^{-6} and 10^{-4} to the greatest extent feasible, through requiring additional protective clothing or equipment or changes in application methods, taking benefits into account. For cancer risk estimates, the Agency typically assumes that handler exposure duration to a pesticide is 240 days a year for 35 years. Typical application rates were used in the occupational cancer risk assessment. Inhalation and dermal were considered to be the routes of exposure for the handler cancer risk assessment.

Occupational Toxicity

The following table lists the endpoints used for the occupational risk assessment for resmethrin.

Table 11. Summary of Toxicological Doses and Endpoints for resmethrin for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-, Intermediate-, and Long- Term	Oral Developmental NOAEL = 30 mg/kg/day (dermal absorption rate = 2%)	Occupational LOC for MOE = 100	Oral Rabbit Developmental Toxicity Study Developmental LOAEL = 100 mg/kg/day based on increased incidence of skeletal variations and a possible marginal increase in resorbed litters in the absence of maternal toxicity
Inhalation Short-, Intermediate-, and Long- Term	Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day)	Occupational LOC for MOE = 100	90-Day Inhalation Toxicity Study Inhalation LOAEL = 0.1 mg/L (28.2 mg/kg/day) based on clinical signs within the first month, decreased glucose levels in males, a decrease (-13%) in body weight gain during weeks 1-4 and an increase in BUN (32%) at week 12 in females.
Cancer (oral, dermal, inhalation)	**Classification:** The Agency (4/13/05) classified resmethrin as "likely to be carcinogenic to humans" and recommended a low-dose linear extrapolation of a Q1* for resmethrin. Oral Q* =5.621 x 10^{-2} in human equivalents based upon male mouse liver combined adenoma and/or carcinoma tumor rates		

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

Occupational Handler Exposure

The Agency initially calculates the handler risks using baseline work clothing (e.g., long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at this level, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the exposure. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, and a respirator. Common examples of engineering controls include enclosed cabs, closed loading systems, and water-soluble packaging.

Occupational handlers of resmethrin include mixers, loaders, or applicators in indoor and outdoor environments. EPA assessed risk scenarios for pesticide control operator handlers, wide area mosquito abatement, and direct application to pets and some farm animals.

Pesticide Control Operator Handler Scenarios

- Mixing, loading, and applying liquids with a high pressure hand wand sprayer in a non-food greenhouse
- Mixing, loading and applying liquids with a low pressure hand wand sprayer in a non-food greenhouse
- Mixing, loading and applying liquids with a fogger in a greenhouse
- Mixing, loading and applying liquids with a fogger in outdoor sites
- Mixing, loading and applying liquids with a low pressure hand wand for indoor crack and crevice treatment
- Mixing, loading and applying liquids with a low pressure hand wand in food handling/processing/eating establishments and warehouses for crack and crevice treatment
- Mixing, loading and applying liquids with a low pressure hand wand in grain storage facilities.

Mosquito Abatement Scenarios

- Mixing, loading liquid for aerial application
- Mixing, loading liquid for ULV truck-mounted spray application
- Mixing, loading, and applying liquids for truck-mounted ULV ground spray
- Mixing, loading, and applying liquids with a low pressure hand wand application.

Direct Application to Pets and Farm Animals

- Spray application.

Exposure analyses were performed using PHED, ORETF data, or the National Pest Management Association (NPMA) Survey.

a. Occupational Non-cancer Handler Summary

Occupational handler exposures were assessed with baseline or minimal personal protective equipment. Non-cancer exposure and risk estimates indicate no MOEs of concern (i.e., all MOEs are greater than 100) at the maximum use rate for all occupational exposure scenarios assessed either at baseline or considering the use of chemical-resistant gloves.

When workers apply resmethrin with a low pressure handwand with no PPE, the MOE is calculated to be 90. When gloves are added for this scenario, the MOE is calculated to be 20,000 and is not of concern.

b. Occupational Cancer Handler Summary

The cancer risk estimates for pesticide control operators and mosquito abatement personnel are presented in Table 12 below.

TABLE 12. Estimated Resmethrin Exposure & Cancer Risk Estimate for Pesticide Control Operator & Mosquito Abatement

Exp Scenario	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Use Site	Typical Application Rate	Daily Area Treated Or Amount Handled	Cancer Risk Baseline	Cancer Risk Dermal PPE (Baseline + Gloves)
Greenhouse - Non Food Mix/Load/Apply Liquid Formulation							
High Pressure Handwand	2.5	120	Greenhouse	0.001 lb/ai gal	1000 gal/day	4.E-05	NA
Low Pressure Handwand	100	30	Greenhouse	0.001 lb/ai gal	40 gal/day	1.E-03	4.E-06
Handheld Fogger	14	190	Greenhouse	0.001 lb/ai gal	10 gal/day	4.E-05	NA
Outdoor Sites Mix/Load/Apply Liquid Formulation							
Handheld Fogger	14	190	Patio/Yards/ Recreational Areas	0.05 lb ai/acre	2 acre/day	1.E-05	NA
Indoor Homes/Buildings Mix/Load/Apply Liquid Formulation							
Low Pressure Handwand	100	30	Contact Spray/Crack & Crevice	0.02 lbs/1000 ft2	1 building/day avg area - 1600 ft^2	2.E-05	NA
Indoor Food Handling/Processing/Eating Establishments/Non-Food Warehouses Mix/Load/Apply Liquid Formulation							
Low Pressure Handwand Sprayer	100	30	Contact Spray/Crack & Crevice	0.02 lbs/1000 ft^2	1 facility/ per day 10000 ft^2 / facility	1.E-04	NA
Indoor Grain Storage Units Mix/Load/Apply Liquid Formulation							
Low Pressure Handwand	100	30	Contact Spray/Crack & Crevice	0.02 lbs/1000 ft^2	1 bin/day 1000 ft^2 / bin	1.E-05	NA
Mosquito Abatement Mix/Load Liquid Formulation							
ULV Truck Mounted Spray (Open Cab)	2.9	1.2	Adulticide	0.003 lb ai/acre	3000 acre/day	1.E-04	NA
ULV Aerial	2.9	1.2	Adulticide	0.003 lb ai/acre	7500 acre/day	4.E-04	1.E-05
Mosquito Abatement Apply Liquid Formulation							
ULV Truck Mounted Spray (Open Cab)	0.36	4.5	Adulticide	0.003 lb ai/acre	3000 acre/day	3.E-05	NA
Mosquito Abatement Mix/Load/Apply Liquid Formulation							
Low Pressure Handwand	100	30	Adulticide	0.003 lb ai/acre	2 acre/day	3.E-06	NA
Pet Groomer and Veterinarian Apply Aerosol							
Aerosol	190	1300	Pet Spray	0.003 lb ai per 16 oz can	1 pet/day ½ can spray/pet	2.E-06	NA

In use scenarios where cancer risk estimates exceeded 10^{-4}, the Agency is requiring personal protective equipment (gloves) to reduce exposure. For most other scenarios, estimated cancer risks are between 10^{-6} and 10^{-4}. However, because the exposure inputs to these estimates are conservative and likely overestimate actual exposure, no additional mitigation will be required at this time. For pest control operator and mosquito abatement scenarios, assuming full day, long-term application for each application method may significantly overestimate total exposure. Based on usage data

of likely resmethrin containing pesticides presented in a National Pest Management Association survey, this assumption would result in significant overestimate of exposure for PCOs. Similarly, assuming continuous usage of resmethrin containing pesticides for mosquito abatement applications would also significantly overestimate total exposure based on personal communication with mosquito control district officials regarding current usage of these products. Further, based on current usage, the assumption for cancer risk assessment that workers are exposed for 240 days per year for 35 years should be considered highly conservative. Default assumptions regarding acres treated per day for aerial and truck mounted ULV sprayer applications for mosquito abatement should also be considered conservative based on resmethrin specific information provided by the registrant. The agency used default assumptions of 7500 acres per day for aerial applications and 3000 acres per day for ULV applications. The registrant cites information from the American Mosquito Control Association that typically, no more than 4000 acres per day are treated by aerial application and no more than 400 acres per day are treated by truck-mounted ULV spray applications.

c. Postapplication Occupational Risk

Post-application exposures occur as a result of being in an environment that has been previously treated with a pesticide. Occupational post-application scenarios were not assessed because worker re-entry exposure is considered unlikely in most situations, i.e. resmethrin is not used on agricultural field crops, and worker re-entry exposures to treated food handling establishments, warehouses, greenhouses, and outdoor premises are not expected to occur routinely for Pest Control Operators (PCOs).

The only restricted-entry interval (REI) currently established under the WPS is for greenhouses. The REI will be maintained at 12 hours for workers re-entering a greenhouse after treatment with resmethrin.

13. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from five sources including the OPP Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), National Pesticide Information Center (NPIC), and National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR). The majority of cases involved systemic and respiratory effects, such as headache, nausea, coughing, dizziness, and shortness of breath. The Agency incident report recommends appropriate protective respiratory equipment for individuals who are likely to have substantial inhalation exposure to resmethrin. See Chapter IV for a description of measures to address this concern.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for resmethrin is presented below. More detailed information associated with the environmental risk from

the use of resmethrin can be found in the "EFED RED Chapter for Resmethrin, Revision Phase 3; DP Barcode No. D326094;" revised per comments received during the phase 3 60-day public comment period and dated March 8, 2006.

1. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure associated with resmethrin use. However, EPA intends to issue a DCI as part of this RED to require submission of additional data for resmethrin to address areas of uncertainty. These data are expected to confirm the conclusions of this environmental risk assessment.

EPA expects all the isomers of resmethrin to have similar environmental fate characteristics. The most important route of dissipation for resmethrin is photolysis. The aqueous photolysis half-life for resmethrin is very short (22 minutes in seawater and 47 minutes in distilled water). No data were submitted regarding the potential for resmethrin to undergo photodegradation on soil surfaces; however, current labels recommend that resmethrin be applied in the early morning or in the evening to prevent photodegradation, which indicates that resmethrin may be subject to relatively rapid photodegradation in the terrestrial environment.

Other than when subjected to photolysis, resmethrin is generally slow to degrade. The aerobic soil metabolism half-life is 198 days, the aerobic aquatic metabolism half-life is 37 days, and resmethrin is relatively stable to anaerobic soil metabolism. Hydrolysis occurs slowly at a range of pH values. In hydrolysis studies, the resmethrin half-life is greater than 89 days at pH values 5 to 9.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of resmethrin products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD50) or the median lethal concentration (LC50). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern. These risks of concern may be addressed by further refinements of the risk assessment or mitigation measures. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 13. EPA's Levels of Concern and Associated Risk Presumptions			
Risk Presumption	**LOC Terrestrial Animals**	**LOC Aquatic Animals**	**LOC Plants**
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

Restricted Use

Resmethrin products used for wide area mosquito abatement are classified as Restricted Use due to aquatic toxicity. All applicators for wide area mosquito abatement must be certified applicators trained in pesticide application or be under the direct supervision of someone who has been trained in pesticide application.

a. Risk to Aquatic Organisms

i. Fish and Invertebrate Exposures and Toxicity

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. The aquatic exposure assessment is based on the Tier II models Pesticide Root Zone Model (PRZM) which simulates fate and transport on the agricultural field, while the water body is simulated with Exposure Analysis Modeling System (EXAMS). Simulations are run for multiple years based on the thirty years of daily values generated during the simulation.

Wide Area Mosquito Abatement

The default values of application efficiency (95%) and spray drift (5%), currently used for applications to agricultural crops, are not appropriate for applications for a mosquito adulticide like resmethrin. Instead, to calculate the level of drift from this type of application, the Agency used the Agricultural Dispersal model (AGDISP) version 8.07. AGDISP provides a better estimate of spray drift for ULV applications. AGDISP estimates for resmethrin ULV spray include an application efficiency of 40% and a spray drift value of 60.0%.

PRZM/EXAMS modeling of resmethrin was done for use on turf to simulate mosquito abatement scenarios. The registrant-defined maximum application rate, maximum number of applications per year, and minimum application interval were modeled to represent an upper-end of exposure potential. Scenarios were assessed for aerial and ground applications. Simulations are run for multiple (usually 30) years and the reported EECs represent the values that are expected once every ten years based on the thirty years of daily values generated during the simulation.

The maximum application rate for resmethrin is 0.007 lb ai/A. Resmethrin registrants have defined the maximum number of applications per year to be 50, however, limitations in PRZM/EXAMS prevented modeling more than 26 applications per year. The estimate of 26 applications per year is closer to the registrant-reported typical number of applications per year. An application frequency of twice per week (every 3 or 4 days) was modeled. Aquatic estimated environmental concentrations (EECs) generated for this assessment may underestimate actual environmental exposure to resmethrin since more than 26 applications may be applied per year. Table 14 and 15 below show the water column and pore water EECs.

When typical rates were modeled (0.0035 lb ai/A, 3-day application interval, 26 applications per year), the resulting EECs were approximately one-half the values observed for the maximum application rate. This applies for the peak, 21-day, and 60-day EECs. A complete listing of EECs, including those used for resmethrin RQ calculations included in this summary, can be found in the risk tables in the resmethrin ecological risk assessment.

Table 14. Water column EECs (ppb or µg/L) ecological risk assessment for ponds of various depths based on resmethrin use on turf (using maximum application rate of 0.007 lb ai/acre).

Application Interval	Time-point for EEC	Average Pond Depth
		6.6 ft. = 2 m.
3 days	Peak Value	0.777
	21 Day Value	0.575
	60 Day Value	0.547

Table 15. Pore water EECs (ppb or µg/L) ecological risk assessment for ponds of various depths based on resmethrin use on turf (using typical application rate of 0.007 lb ai/acre).

Application Interval	Time-point for EEC	Average Pond Depth
		6.6 ft. = 2 m.
3 days	Peak Value	0.347
	21 Day Value	0.338
	60 Day Value	0.309

"Down-the-Drain"

To address potential resmethrin release to domestic wastewater treatment through indoor household use, EPA used the Exposure and Fate Assessment Screening Tool (E-FAST). The "down-the-drain" module of E-FAST is designed to address sources of resmethrin that could potentially be disposed in wastewater. The acute surface water EEC for resmethrin is 1.15×10^{-4} ppb. The 60-day EEC for resmethrin is 8.9×10^{-6} ppb.

(For more information, see section III.B.2.b. of the EFED assessment)

Aquatic Toxicity

The acute fish and invertebrate toxicity data, outlined in table 16 below, indicate that resmethrin is very highly toxic to freshwater fish and invertebrates and to estuarine/marine fish and invertebrates.

Table 16. Summary of Acute Aquatic Toxicity Data for Resmethrin

Toxicity Study	Test Species	LC50 or EC50 (ppb)	Toxicity Category	MRID/Accession No.
Freshwater Fish (96-hour)	Rainbow trout *Oncorhynchus mykiss* (TGAI)	0.28	Very highly toxic	40098001
Freshwater Invertebrate (48-hour)	Water flea *Daphnia magna* (TGAI)	3.10	Very highly toxic	40991210
Estuarine / Marine Fish	Sheepshead minnow *Cyprinodon variegates* (TGAI)	11	Very highly toxic	40991218
Estuarine / Marine Invertebrates	Pink shrimp Penaeus duorarum (TGAI)	1.30	Very highly toxic	40991217
Estuarine / Marine Mollusks	No Data			

Both freshwater fish and estuarine/marine fish early life-stage chronic toxicity tests were used to evaluate the chronic toxicity of resmethrin. Results from the freshwater fish early life-stage toxicity test indicated at the No Observed Adverse Effect Concentration (NOAEC) of 0.32 ppb and an associated Lowest Observed Adverse Effect Concentration (LOAEC) of 0.59 ppb. The basis of these effect levels was an observed decrease in larval survival of resmethrin-exposed fish. An estuarine/marine early fish life-stage study was used to evaluate the toxicity of resmethrin to estuarine/marine fish. The most sensitive endpoint was juvenile survival with a NOAEC of 1.9 ppb and a LOAEC of 4.1 ppb. There were no chronic freshwater invertebrate or estuarine/marine invertebrate toxicity data available for this assessment.

Table 17. Summary of Chronic Aquatic Toxicity Data for Resmethrin

Toxicity Study	Test Species	NOAEC / LOAEC (ppb)	Effects at LOAEC	MRID/Accession No.
Freshwater Fish Early Life-Stage	Rainbow trout *Oncorhynchus mykiss*	0.32 / 0.59	Larval survival	40991223

	(TGAI)			
Estuarine / Marine Fish Early Life-Stage	Sheepshead minnow *Cyprinodon variegates* (TGAI)	1.90 / 4.05	Juvenile survival	43858304

ii. Fish and Invertebrate Risk

Risks presented in this section are estimates of fish and invertebrate risk that may occur due to the wide area mosquito abatement use of resmethrin, or from exposure modeled for the "down the drain" scenario.

Freshwater Fish

The acute risk level of concern (LOC) (0.5) and acute endangered species LOC (0.05) are exceeded for freshwater fish exposed to resmethrin. The RQ range is from 2.78 for the technical product and 1.73 for the formulated product. The LOC for chronic risk (1) is exceeded only for freshwater fish at 1.71 for the 3-day modeled interval.

Estuarine/Marine Fish

The acute risk LOC (0.5) is not exceeded in acute risk estimates for estuarine/marine fish. The endangered species acute risk LOC (0.05) is exceeded for estuarine/marine fish exposed to formulated resmethrin (RQ 0.48) and estuarine/marine fish exposed to technical resmethrin (RQ = 0.07). Chronic risks of concern (1) associated with estuarine/marine fish exposed to resmethrin are not likely based on the RQs calculated which range (highest RQ = 0.29).

Freshwater Invertebrates

The acute risk LOC (0.5) and endangered species LOC (0.05) is exceeded for resmethrin formulated products. The RQ range for freshwater invertebrates acutely exposed to resmethrin in formulated products is 2.81 to 6.48. The endangered species LOC (0.05) is slightly exceeded for freshwater invertebrates exposed to technical resmethrin (RQ range = 0.25 to 0.11) No chronic freshwater invertebrate data were submitted for resmethrin. Chronic data from a similar pesticide, the pyrethrins, show reproductive effects in freshwater invertebrates with a NOAEC value of 0.86 ppb, which indicates that there may be potential for chronic reproductive effects to aquatic invertebrates exposed to resmethrin.

Estuarine/Marine Invertebrates

The acute risk LOC (0.5) and endangered species LOC (0.05) is exceeded for some estuarine/marine invertebrates exposed to technical resmethrin. The RQ range for acute risk to estuarine/marine invertebrates is 0.25 to 0.58. RQs for estuarine/marine invertebrates exposed to formulated resmethrin range from 1.47 to 3.38, which indicates

potential acute risk and acute endangered species risk to estuarine/marine invertebrates. Chronic data from a similar pesticide, the pyrethrins, show reproductive effects in freshwater invertebrates with a NOAEC value of 0.86 ppb, which indicates that there may be potential for chronic reproductive effects to aquatic invertebrates exposed to resmethrin.

Freshwater Benthic Organisms

RQs for freshwater benthic organisms were calculated from water column studies in the absence of sediment toxicity data for resmethrin. The acute risk LOC (0.5) was not exceeded for freshwater benthic organisms; however the acute endangered species LOC was exceeded for freshwater benthic organisms in water (RQs = 0.11). No chronic freshwater or estuarine/marine benthic organism data were submitted to the Agency. However, based on the potential for chronic risk to freshwater fish due to exposure to technical resmethrin, chronic invertebrate data from other synthetic pyrethroids, and the affinity of resmethrin to partition to sediment, there may be potential for resmethrin to cause chronic effects in benthic organisms.

Estuarine/Marine Benthic Organisms

RQs for estuarine/marine benthic organisms were calculated from water column studies in the absence of sediment toxicity data for resmethrin. These risk estimates do not exceed the acute risk LOC (0.5) for estuarine/marine benthic organisms exposed to technical resmethrin. However, the acute endangered species LOC (0.05 is exceeded for estuarine/marine benthic organisms in water 1 foot, 1 meter, and 2 meters deep (RQs range from 0.05 to 0.26). No chronic freshwater or estuarine/marine benthic organism data were submitted to the Agency. However, based on the potential for chronic risk to freshwater fish due to exposure to technical resmethrin, chronic invertebrate data from other synthetic pyrethroids, and the affinity of resmethrin to partition to sediment, there may be potential for resmethrin to cause chronic effects in benthic organisms.

"Down-the-Drain" Risk to Aquatic Organisms

Acute and chronic RQs for freshwater and estuarine fish and invertebrates are below 0 and are therefore below the Agency's level of concern for acute risk (0.5) and chronic risk (1.0).

iii. Non-target Aquatic Plants Exposure, Toxicity, and Risk

No data were submitted to evaluate the risk of resmethrin exposure to non-target aquatic plants. However, the Agency has determined that resmethrin will have no effect on listed plants. Because of its neural toxic mode of action, resmethrin poses no phytotoxic concern. Also, no incident reports have reliably linked resmethrin or any other synthetic pyrethroid to phytotoxic effects despite the fact that pyrethroids are often applied on or near agricultural crops.

b. Risk to Terrestrial Organisms

Risks presented in this section are estimates of avian and mammalian risk that may occur due to the wide area mosquito abatement use of resmethrin. No other resmethrin uses were assessed for ecological risk because most uses are used indoors only, or used on a limited basis outdoors by residential handlers.

i. Birds and Mammals Exposure and Toxicity

The Agency assessed exposure to terrestrial organisms by first predicting the amount of resmethrin residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items is based on the Fletcher nomogram, which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994), and the current maximum application rates for resmethrin.

Estimated exposure concentrations for terrestrial receptors were determined using the standard screening-level exposure model, Terrestrial Residue Exposure model (TREX) version 1.1, which is a simulation model that, in addition to incorporating the nomogram relationship, also includes pesticide degradation in the estimation of EECs. TREX considers exposure only in the area where resmethrin is applied. In general, the underlying assumption is that most, if not all, of the applied pesticide will settle in the use area. However, because resmethrin is used as a mosquito adulticide and when applied is intended to drift, the Agency considered that 40% of resmethrin settles within the area treated and 60% drifts away from the treated area. Resmethrin is applied as a ULV spray from aerial and truck-mounted sprayers.

EPA's estimates of resmethrin residues on various wild animal food items are summarized in table 18. EPA used these EECs and standard food consumption values to estimate dietary exposure levels to birds and mammals for resmethrin. Exposure modeling was done for the mosquito adulticide use with maximum and typical rates, application frequencies, and number of applications per year.

Table 18. Residue EECs on Avian and Mammalian Food Items

Scenario	**Application Rate lb a.i./A**	**Number Applications / Interval (days)**	**Range of EECs Based on Mean Residues for:** 1) Short grass; 2) Tall grass; 3) Broadleaf plants/small insects; 4) Fruits, pods, seeds, and large insects **(ppm)**
Mosquito Adulticide	Max rate: 0.007	50 / 3 25 / 3	0.8 (fruits, etc.) – 9.8 (short grass) 0.6 (fruits, etc.) – 8.0 (short grass)

		50 / 4 25 / 4	0.6 (fruits, etc.) – 7.6 (short grass) 0.5 (fruits, etc.) – 6.7 (short grass)
	Typical rate: 0.0035	25 / 3	0.3 (fruits, etc.) – 3.9 (short grass)
		25 / 4	0.3 (fruits, etc.) – 3.4 (short grass)

The acute toxicity of resmethrin to mammals was evaluated using the common laboratory rat to calculate an LD50 of 4639 mg a.i./kg. This classifies resmethrin as practically non-toxic to mammals on an acute basis. Chronic studies in the rat show that the endpoints most sensitive to resmethrin exposure are reproductive endpoints such as decreases in female body weight gain during gestation, no weight gain during lactation, decreased pup weight in all generations and slight increases in stillborn pups.

Avian acute toxicity was measured using the red-winged blackbird to calculate an LD50 value of 75 mg ai/kg body weight, which classifies resmethrin as moderately toxic to birds on an acute basis. A subacute dietary study was performed with bobwhite quail to determine an LC50 for resmethrin. The subacute dietary study with bobwhite quail showed an LC50 of greater than 5000 ppm. This categorizes resmethrin as practically non-toxic to avian species on a subacute dietary basis. Chronic studies in the mallard duck show that the endpoint most sensitive to resmethrin is increased incidence of early embryonic deaths in the 60 ppm treatment group. The NOAEC in the chronic mallard study was 12 ppm. Table 19 below presents the acute and chronic toxicity data for terrestrial organisms exposed to resmethrin.

Table 19. Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms Exposed to Resmethrin

Species		**Acute Toxicity**				**Chronic Toxicity**	
		LD50 (mg/kg)	Acute Oral Toxicity (MRID)	LC50 (ppm ai)	Subacute Dietary Toxicity (MRID)	NOAEC/LOAEC (ppm) (MRID)	Affected Endpoints
Bird	Red-winged blackbird *Agelaius phoeniceus*	75	Moderately toxic (Acc.# 43653)	--	--	--	--
	Bobwhite quail *Colinus virginianus*	--	--	>5000 ppm ai	Practically non-toxic (41653601)	60.0 / 300.0 (41465002)	Decrease of adult male body weight
	Mallard duck *Anas platyrhychos*	--	--	>5000 ppm ai	Practically non-toxic (41653602)	12.0 / 60.0 (41465001)	Decrease in hatchling body weight, increase in embryonic death
Mammal	Laboratory rat *Rattus norvegicus*	4639	Practically non-toxic (42076201)	--	--	34.8 / 70.8 (43189101)	decrease in female body weight gain during gestation, no weight gain

							during lactation, decreased pup weight in all generations
Insect	Honey bee *Apis mellifera*	0.063 ug ai/bee	Highly toxic (VAORES01)	--	--	--	--

ii. Birds and Mammals Risk

Risk quotients were calculated for both birds and mammals using the dose-based and dietary-based toxicity values. Generally dose-based RQs are higher than those calculated using the dietary-based values because the dose-based RQs are calculated with the assumption that birds or mammals will experience a very short-term high intensity exposure from the pesticide. The dietary-based approach assumes that animals in the field are consuming food at a rate similar to that of confined laboratory animals despite the fact that energy content in food items differs between the field and the laboratory. There are benefits and uncertainties by considering both methods which are outlined in more detail in the environmental fate and effects chapter for resmethrin. RQs calculated using both methods are included in the discussion below.

In addition, in order to bound the estimates of RQs, mean Kenega residue values were calculated along with upper-bound values. Log-normal distributions were generated that describe residues levels on the various food items. The analysis demonstrates that Kenega values range from about 62-87 percent of the possible resmethrin residues values, indicating that 12 to 38 percent of the higher-end food item residue estimates are not captured in estimating exposure by using the mean Kenega values. For the upper-bound Kenega residue estimates, about 3-13 percent of the upper-end residue estimates were not captured. Using the mean Kenega residue values for calculating RQs would not protect birds and mammals that consume food items that have residues on the higher end of the residue distribution.

A range of RQs was calculated using dose and dietary-based toxicity values and mean or upper-bound Kenega residue values. A summary of the high- and low-end RQs are outlined in the following tables; for a complete list of calculated RQs, refer to Section 4.A.2 of the environmental fate and effects assessment for resmethrin.

Birds

Using dose-based (LD50 = 75 mg/kg-bw for red-winged blackbird) toxicity values acute endangered species level of concern was (0.1) exceeded for 20g and 100g birds that feed on short grass (RQ range = 0.13 to 0.17) when the maximum application rate was used. Using the dietary-based toxicity values (LC50 greater than 5000 mg ai/kg diet for mallard duck), no LOCs are exceeded for any scenario. The acute dietary RQs are listed in table 20 below.

Table 20. Dose-based acute RQs for birds (red-winged blackbird) exposed to resmethrin based on mean residues, maximum application rate (0.007 lb ai/acre), maximum number of

applications (50), and minimum application interval (3 days)					
Number of applications/ Application interval	**Body Weight**	**Short Grass**	**Tall Grass**	**Broadleaf Plants / Small Insects**	**Fruits/Pods/ Seeds/Large Insects**
		Avian Acute Risk Quotients			
50 / 3	20	0.17 [1]	0.07	0.09	0.01
	100	0.13 [1]	0.06	0.07	0.01
	1000	0.04	0.02	0.2	0.003
Dietary-based acute RQs for birds (mallard duck) exposed to resmethrin based on mean residues, maximum application rate (0.007 lb ai/acre), maximum number of applications (50), and minimum application interval (3 days)					
50 / 3		0.002	0.001	0.001	0.0002

[1] RQ exceeds LOC for acute endangered species (>0.1)

Chronic RQs are calculated using mean Kenaga residue values and a chronic NOAEC (12 mg ai/kg diet) from the dietary study in mallard duck. LOCs are not exceeded for birds that consume short grass, tall grass, and broadleaf plants/small insects when maximum application rates are used. See table 21 below for a summary of RQs.

Table 21. Dietary-based chronic RQs for birds exposed to resmethrin based on mean residue levels, maximum application rate (0.007 lb ai/acre), maximum number of applications (50), and minimum application interval (3 days).

Number of applications/ Application interval	Short Grass	Tall Grass	Broadleaf Plants / Small Insects	Fruits/Pods/ Seeds/Large Insects
50 / 3	0.82	0.35	0.43	0.07

Mammals

Acute mammalian risks were calculated using the acute oral LD50 of 4639 mg ai/kg body weight from a rat study, and chronic mammalian risks were calculated using a chronic NOAEL of 34.8 mg ai/kg body weight in rats. Chronic RQs were calculated using upper-bound Kenaga residue values and dose-based toxicity values. All acute RQs are below the LOCs for acute risk and acute endangered species risk. All chronic RQs are below the LOCs for chronic risk. Therefore, resmethrin is not likely to pose an acute or chronic risk to mammals.

iii. Non-Target Terrestrial Plant Toxicity, Exposure, and Risk

No data were submitted to evaluate the risk of resmethrin exposure to non-target terrestrial plants. However, the Agency has determined that resmethrin will have no effect on listed plants. Because of its neural toxic mode of action, resmethrin poses no phytotoxic concern. Also, no incident reports have reliably linked resmethrin or any other synthetic pyrethroid to phytotoxic effects despite the fact that pyrethroids are often applied on or near agricultural crops.

iv. Non-Target Insect Risk

Currently, the Agency does not estimate RQs for terrestrial non-target insects. However, based on a single contact study in honey bees, technical resmethrin is classified as highly toxic on an acute contact basis to non-target terrestrial insects (LD50 = 0.063 ug/ai per bee). Concern for acute toxicity to non-target insects is high when they are exposed directly to resmethrin. A label statement addressing this concern is required for all resmethrin occupational outdoor use products and wide area mosquito abatement products.

3. Ecological Incidents

A total of three incidents involving aquatic resmethrin exposure have been reported to EPA involving aquatic organisms allegedly exposed to resmethrin via spray drift. The organisms exposed in these incidents include blue claw crabs, goldfish, fish (general), and shrimp (general). Since no information regarding application rate, residue analysis, or time of event relative to application was provided, the strength of these incidents as an additional line of evidence is uncertain.

A total of four incidents involving terrestrial resmethrin exposure have been reported to EPA. The organisms exposed in these incidents include bees, ornamental plants, and corn. No information regarding application rate, residue analysis, or time of event relative to application was provided for any of these terrestrial incidents. In addition, the neurotoxic mode of action of resmethrin does not cause concern for phytotoxic effects. The strength of these incidents involving exposure of terrestrial plants as evidence of phytotoxic effects is highly uncertain.

4. Endangered Species Concerns

The Agency's screening level risk assessment indicates that uses of resmethrin will have no direct acute or chronic effects on aquatic or terrestrial plants. The Agency has determined that resmethrin will have no effect on listed terrestrial or aquatic plants. There are potential indirect effects to any listed species dependent on a species that is affected by the use of resmethrin. For the screening level assessment, potential risks to reptiles and terrestrial phase amphibians are estimated based on risks to birds; and potential risks to aquatic phase amphibians are estimated based on risks to freshwater fish. Because the screening level assessment shows potential risks for both birds and freshwater fish, the potential risks to reptiles, terrestrial phase amphibians, and aquatic phase amphibians cannot be precluded based on the screening level assessment.

A preliminary analysis of the co-occurrence of listed species and proposed re-registration of resmethrin uses was conducted using the Agency's LOCATES database. In general, for all labeled uses of resmethrin there is at least one, and usually more, listed species that may potentially occur in or near a use area. This preliminary analysis

indicates that there is a potential for resmethrin use to overlap with listed species and that a more refined assessment is warranted.

The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures, as appropriate, that address these impacts. In general, to assess the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that have been implemented at that time. A determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in limitations on the use of resmethrin, other measures to mitigate any potential impace, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by resmethrin. Rather, this assessment serves as a screen to determine the need for any species specific assessments that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for resmethrin result in the need to modify use of the pesticide, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to resmethrin at levels of concern.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility and Tolerance Reassessment

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic data to support reregistration of products containing resmethrin. The Agency has determined that the data are sufficient to support reregistration of resmethrin.

The Agency has completed its assessment of the dietary, occupational and ecological risk associated with the use of resmethrin apart from a species specific Endangered Species assessment as discussed above. Based on this assessment, the Agency has sufficient information on resmethrin to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that resmethrin-containing products are eligible for reregistration provided that label amendments are made as outlined in this RED. Appendix A summarizes the uses of resmethrin that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of resmethrin, the Agency has determined that resmethrin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of resmethrin. If all changes outlined in this document are incorporated into the product labels, then all current risks for resmethrin will be adequately mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained under "Endangered Species Concerns" above.

B. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with resmethrin. EPA has determined that risk from dietary (food + water) exposure is within its own "risk cup." An aggregate assessment was conducted for resmethrin for exposures through dietary (food + water) and residential (indoor and outdoor) pathways. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for resmethrin meet FQPA safety standards. In reaching this

determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, drinking water, and residential sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerance for resmethrin, with amendments and changes as specified in this document, meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, as amended by FQPA, and that there is a reasonable certainty no harm will result to the general population or any major identifiable subgroup from the use of resmethrin. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of resmethrin. As discussed in Section III, aggregate short-, intermediate-, and long-term risks from food, drinking water, and residential exposures are below the Agency's LOC.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerance for resmethrin, with amendments and changes as specified in this document, meets the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of resmethrin residues in this population subgroup. In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of resmethrin, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been retained at 10X. There are no residual uncertainties for pre- and/or post- natal toxicity, exposure is not underestimated, and there is no evidence of increased susceptibility. However, an FQPA safety factor due to database uncertainty is retained at 10X to account for lack of a developmental neurotoxicity study.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation

that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on resmethrin submitted for registration purposes, there was no estrogen, androgen, and/or thyroid mediated toxicity. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, resmethrin may be subject to additional screening and/or testing.

3. Cumulative Risks

Resmethrin is a member of the pyrethroid class of pesticides. Although all pyrethroids alter nerve function by modifying the normal biochemistry and physiology of nerve membrane sodium channels, EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroids. Although all pyrethroids because there are multiple types of sodium channels, and it is currently unknown whether all pyrethroids have similar effects on all channels. In addition, the Agency does not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

C. Tolerance Reassessment Summary

Table 23. Tolerance Reassessment Summary for Resmethrin (40 CFR §180.525)

Commodity	Current Tolerance (ppm)	Range of Residues (ppm)	Tolerance Reassessment (ppm)	Comment/*[Correct Commodity Definition]*
Food items	3.0	<0.003-0.377 [1]	To be determined	Additional information/data are required to upgrade the existing study supporting the use of resmethrin as a crack and crevice treatment, and new studies are required supporting space treatment uses in food and feed handling establishments.

[1] Resmethrin residues in/on representative food commodities following crack and crevice treatment to representative types of food handling establishments.

There are no dietary or aggregate risk concerns associated with the current tolerance and EPA considers it reassessed at the current tolerance level. However, additional data are necessary to confirm this tolerance level is appropriate for resmethrin.

There are currently no Codex or Canadian MRLs for resmethrin.

D. Regulatory Rationale

The Agency has determined that resmethrin is eligible for reregistration provided that the risk mitigation measures and label amendments specified in the RED are implemented. The following is a summary of the rationale for managing risks associated with the use of resmethrin.

1. Human Health Risk

a. Dietary (Food + Drinking Water) Risk

Non-Cancer Dietary Risk

There are no resmethrin non-cancer dietary (food + drinking water) risks that exceed the Agency's level of concern. This assessment is protective of the general U.S. population and all population subgroups, including infants and children. Therefore, no mitigation is necessary for these scenarios.

Cancer Dietary Risk

A slightly refined cancer dietary risk assessment was conducted for all supported resmethrin food uses. When both detections and non-detections are included in the resmethrin cancer dietary analysis, and the percentage of food handling establishment treated is conservatively estimated to be 10%, dietary and drinking water risks are not of concern to the Agency (lifetime dietary cancer risk for the general U.S. population is 1.6×10^{-6}). Food risks are only slightly refined, which results in high-end estimates of exposures to residues in food. Additionally, the LOD was used as the residue value for all non-detections in a crack and crevice residue study with resmethrin. This also is an overestimation of exposure. Drinking water exposure estimates were developed using the tier 2 model PRZM-EXAMs, which also results in high-end estimates of potential exposure to resmethrin. No mitigation is necessary for this scenario.

b. Residential Risk

Non-Cancer Residential Risk

Most estimates for residential risk are below EPA's level of concern. All residential risks are below the Agency's level of concern (MOEs are above 1000), except for post-application risk for a child exposed to indoor aerosol space sprays.

The non-cancer post-application inhalation risk estimate for a child exposed to an indoor aerosol space spray exceeds the Agency's level of concern with an MOE of 900. For the non-cancer post-application inhalation risk estimate, the Agency assumed that one 16 oz spray can containing 0.2% ai was used per application. This exposure may occur when a child enters a room within 10 minutes after a resmethrin indoor aerosol space spray application. Potential risk is below the Agency's level of concern if a child

waits 2 hours before entering a room where resmethrin has been applied as an indoor aerosol space spray. In order to mitigate this inhalation risk, resmethrin products applied as indoor aerosol space sprays must be labeled to instruct users to keep all people and pets out of sprayed rooms for 2 hours after application. When residents stay out of sprayed rooms for 2 hours, the post-application MOE for a child is 3500 which is below the Agency's level of concern for residential exposure. No additional mitigation is needed for this scenario.

Cancer Residential Risk

There are no residential cancer risks of concern when resmethrin is handled by residents or applied to residential areas. Residential handler risk, bystander risk, and residential post-application risk are below the Agency's level of concern for all scenarios. Additionally, the residential handler scenario with the highest exposure and risk (indoor aerosol space spray) was assumed to occur three times a year for 70 years. No mitigation is necessary for these scenarios.

c. Aggregate (Food + Drinking Water + Residential) Risk

Non-Cancer Aggregate Risk

Non-cancer residential risks cannot be aggregated with the resmethrin non-cancer assessment for food and drinking water because the toxicity endpoints for residential dietary, incidental oral, dermal, and inhalation exposures are not based on common effects. Therefore, no non-cancer aggregate risk assessment was conducted for resmethrin, other than the previously described aggregate assessment of food and drinking water.

Cancer Aggregate Risk

For the cancer aggregate risk analysis, a slightly refined dietary assessment was combined with the residential cancer risk scenario with the highest exposure and risk (residential indoor aerosol spray application). The slightly refined dietary assessment risk estimate was 1.6×10^{-6}, and the residential indoor aerosol spray application risk estimate was 1.0×10^{-6} when residents wait 2 hours before re-entering the space that was sprayed. The residential exposure scenario which was aggregated with dietary risks is the one with the highest estimated exposure and risk (indoor aerosol space spray) of all the residential scenarios assessed. EPA believes the estimated risks for each pathway of exposure (food, drinking water, and residential) are greater than what people are likely to experience, and the probability of people experiencing all these high-end exposures together over the course of a lifetime is low. When these scenarios are combined, the aggregate cancer risk estimate is 2.6×10^{-6}, which is within an acceptable range.

Because the residential indoor aerosol spray application risk estimate is dependant upon residents not entering sprayed spaces for 2 hours after application, a statement must be placed on aerosol space spray residential labels indicating that residents must not enter fogged spaces for 2 hours after application. A ventilation requirement will also be required on labels indicating that residents must ventilate the sprayed space for 10 minutes with fresh air before occupying the room. Similar label requirements must also

be placed on labels of products used by pest control operators (PCOs) that they must inform residents to not enter sprayed spaces for 4 hours and ventilate for 20-120 minutes depending on the size of the treated area before occupying the sprayed space. No additional mitigation is necessary for these scenarios.

d. Occupational Risk

Non-Cancer Occupational Risk

Concerns for workers mixing, loading, and applying the liquid formulations of resmethrin can be mitigated with PPE. All mixers, loaders, and appliers using liquid formulations of resmethrin are required to wear gloves for dermal protection. In addition, workers using foggers in indoor spaces are required to wear respirators for protection against potential inhalation risk and coveralls for protection against potential dermal risk. All applicators and other handlers using ready-to-use aerosol formulations will be required to wear gloves. For products intended only for wide area mosquito abatement programs, chemical-resistant gloves are required for all handlers except applicators.

Cancer Occupational Risk

There are some concerns for workers when mixing, loading, and applying the liquid formulations of resmethrin. All mixers, loaders, and appliers using liquid formulations of resmethrin are required to wear gloves for dermal protection. In addition, workers using foggers in indoor spaces are required to wear respirators for protection against potential inhalation risk and coveralls for protection against potential dermal risk. All applicators and other handlers using ready-to-use aerosol formulations will be required to wear gloves. For products intended only for wide area mosquito abatement programs, chemical-resistant gloves are required for all handlers except applicators.

Exposure Reduction

The Agency incident report recommends appropriate respiratory protective equipment for individuals who are likely to have substantial contact with resmethrin. Because mosquito abatement handlers may be exposed to resmethrin on a regular basis, enclosed cabs are required for ULV truck-mounted mosquito abatement spray applications, and enclosed cockpits are required for ULV aerial mosquito abatement spray applications. Additionally, as mentioned above, workers using foggers in indoor spaces must wear respirators for protection from inhalation risk and coveralls for protection from dermal risk.

A 12-hour REI is required for workers re-entering treated greenhouses after resmethrin applications. In addition, workers who enter a resmethrin-treated greenhouse before the REI has expired must wear coveralls over long-sleeve shirt and long pants, chemical-resistant gloves made of any waterproof material, and shoes plus socks.

2. Environmental Risk

The Agency has conducted a screening-level ecological risk assessment for the mosquito control use of resmethrin based on application of resmethrin to Florida turf.

Based on the available data, the Agency has identified potential acute and chronic risks of concern to freshwater fish, potential acute risks estuarine/marine fish, acute risks and potential chronic risks to freshwater and estuarine/marine invertebrates, and freshwater and estuarine/marine benthic organisms. Available data show potential acute and chronic risks to birds when a dose-based study is used. When a dietary-based study is used, acute and chronic risks to birds are considered not likely. There are no acute or chronic effects to mammals, aquatic plants, or terrestrial plants exposed to resmethrin when it is applied as a wide area mosquito abatement spray as modeled in the environmental fate and effects assessment.

While there are slight estimated exceedances of the LOCs for some terrestrial and aquatic species, based on its use pattern and usage information the ecological risks associated with resmethrin are expected to be limited. Resmethrin is used for wide area ULV mosquito abatement, in and around homes, commercial establishments, industrial areas, and food handling establishments to treat flying and crawling insects, and by pet groomers, veterinarians, and citizens for insect control on livestock and pets. Resmethrin use is estimated at 50,000 lbs per year, with over half of those pounds applied per year used for mosquito control.

Release-height restrictions on resmethrin aerial mosquitocide applications will reduce wildlife exposure. RQs were estimated with a 25 foot aerial boom height. The resmethrin registrants have agreed to nozzle heights of no less than 100 feet above ground or canopy for fixed wing applicators and no less than 75 feet above ground or canopy for rotary wing applicators. The higher release heights will reduce wildlife exposure to resmethrin.

The registrants for resmethrin have also agreed to set new application rates for resmethrin. Previously, resmethrin labels had often not specified application rates. The rates listed below will serve as maximum application rates for reregistered resmethrin products.

- Products labeled for use on Livestock, Farm Animals, and Pets (Direct Application): Product must contain 0.35% ai. or less.
- Products labeled for use in Outdoor Sites (Commercial, Recreational, Domestic Outdoor Sites, Agricultural Structures, Agricultural Premises, and Agricultural Equipment): 0.25 lb ai per acre.
- Products labeled for use in Space Applications (Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment; Domestic Structure Premises and Equipment): 0.001 lb ai per 1000 ft^2.
- Products labeled for use in Surface Crack and Crevice Application (Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment; Domestic Structure Premises and Equipment): 0.242 lb ai per 1000 ft^2.

Additionally, wide area mosquito control products must contain the following requirements:

- Products labeled for wide area mosquito abatement must state a maximum application rate of 0.007 lb ai/acre, and state a maximum yearly application limit of 0.2 lb ai/acre.
- Release height requirement for rotary wing of no less than 75 feet above the ground or canopy, for fixed wing of no less than 100 feet above the ground or canopy.
- Must contain environmental hazard statements informing user of toxicity to fish, aquatic invertebrates, and oysters/shrimp.
- Must contain a statement informing user of toxicity to bees visiting treated area.
- Must be in compliance with EPA PR Notice 2005-1.

Stewardship Language

The Agency cannot currently fully assess the potential risks to aquatic organisms from resmethrin use around the home. Therefore to lessen potential risks the Agency is seeking to reduce the drift and run-off of resmethrin into aquatic habits through explicit directions for use on both professional and consumer-use products for use in residential settings. These use directions include best management and stewardship practices which are formulation specific, and will serve to reduce the potential run-off and drift that can occur from applications of these products. Label statements implementing these measures are listed in the Label Changes Summary Table in Section V of this RED document.

a. Fish and Aquatic Invertebrate Risk

The following summary of ecological concerns does not reflect all of the mitigation measures mentioned above. Thus, the actual exposure to resmethrin will be less for all non-target species than current estimates reflect.

Acute and Chronic Freshwater and Estuarine/Marine Fish

For freshwater fish, the highest acute RQ value is 2.8 for freshwater fish in water 2 meters deep. This exceeds the acute risk LOC of 0.5 and the acute endangered species LOC of 0.05 and is of concern. The RQ decreases in shallow water because resmethrin is broken down through aqueous photolysis, and more light is available in shallow water. The RQ value for chronic risk to freshwater fish is 1.7 for fish exposed to the TGAI in a water body 2 meters deep at a 3 day application interval. This exceeds the chronic risk LOC of 1. When a release height of 75 feet for aerial applications is considered, the RQs for freshwater fish decrease to an acute RQ of 0.75 and a chronic RQ of 0.51. Thus, when the release height of 75 feet is considered, the acute risk level is still of concern, but the freshwater chronic risk level is no longer of concern.

For estuarine/marine fish, the RQ value does not exceed the acute risk LOC (0.5). However, the acute endangered species LOC (0.05) is exceeded for estuarine/marine fish (estimated value of 0.48 for formulated resmethrin). When a release height of 75 feet for aerial applications is considered, the acute RQ decreases to 0.13, which is still above the acute endangered species LOC. Chronic risks of concern for estuarine/marine fish are not likely (RQs range from 0.02 to 0.29, therefore less than the chronic LOC of 1).

Acute and Chronic Freshwater and Estuarine/Marine Invertebrates

For freshwater invertebrates, the acute RQ value exceeds the acute risk LOC (0.5) and acute endangered species LOC (0.05) for resmethrin formulated products with an estimated RQ value of 6.5. When a release height of 75 feet is considered for aerial applications, the acute RQ decreases to 1.74, which is still above the acute risk and acute endangered species LOCs. Chronic resmethrin exposure to freshwater invertebrate data was not available, but chronic data from a similar pesticide, the pyrethrins, shows reproductive effects in freshwater invertebrates with a NOAEC value of 0.86 ppb. This may indicate potential chronic risk for freshwater invertebrates exposed to resmethrin.

For estuarine/marine invertebrates, the maximum acute RQ value exceeds the acute risk LOC (0.5) and acute endangered species LOC (0.05) at 3.4 when estuarine/marine invertebrates are exposed to formulated resmethrin. When a release height of 75 feet is considered for aerial applications, the acute RQ decreases to 0.91, which is a level that still exceeds the acute risk and acute endangered species LOCs. Chronic resmethrin exposure to esturarine/marine invertebrates data was not available, but chronic data from a similar pesticide, the pyrethrins, shows reproductive effects in freshwater invertebrates with a NOAEC value of 0.86 ppb. This may indicate potential chronic risk for estuarine/marine invertebrates exposed to resmethrin.

Acute and Chronic Freshwater and Estuarine/Marine Benthic Organisms

RQs for freshwater benthic organisms were calculated from water column studies in the absence of sediment toxicity data for resmethrin. The maximum acute RQ value does not exceed the acute risk LOC (0.5) at 0.11 for technical resmethrin, however this level does exceed the acute endangered species LOC of 0.05. Registrants have agreed to a release height of 75 for aerial mosquito applications. When this is taken into account for aerial applications, the RQ decreases to 0.03, which is below the acute endangered species LOC of 0.05. Therefore, acute risk is not likely to be of concern for freshwater benthic organisms exposed to resmethrin. No chronic freshwater or estuarine/marine benthic organism data were submitted to the Agency. However, based on the potential for chronic risk to freshwater fish due to exposure to technical resmethrin, chronic invertebrate data from other synthetic pyrethroids, and the affinity of resmethrin to partition to sediment, there is potential for resmethrin to cause chronic effects in benthic organisms.

RQs for estuarine/marine benthic organisms were calculated from water column studies in the absence of sediment toxicity data for resmethrin. The maximum acute RQ value does not exceed the acute risk LOC (0.5) at 0.26 for technical resmethrin. However, the acute RQ does exceed the acute endangered species LOC 0.05. When a release height of 75 feet is considered for aerial applications, the acute RQ decreases to 0.08, which is still slightly above the acute endangered species level of concern. No chronic freshwater or estuarine/marine benthic organism data were submitted to the Agency. However, based on the potential for chronic risk to freshwater fish due to exposure to technical resmethrin, chronic invertebrate data from other synthetic

pyrethroids, and the affinity of resmethrin to partition to sediment, there is potential for resmethrin to cause chronic effects in benthic organisms.

Aquatic Plants

No aquatic vascular or non-vascular data plant data were submitted for resmethrin. However, the Agency has determined that resmethrin will have no effect on listed plants. It is unlikely that resmethrin poses a phytotoxic concern based on its neurotoxic mode of action, lack of toxic effects when plants are exposed to other pyrethroids, and lack of ecological incident reports for plants.

"Down-the-Drain" Assessment

Acute and chronic RQs for freshwater and estuarine fish and invertebrates are below 0 and are therefore below the Agency's level of concern for acute risk (0.5) and chronic risk (1.0). Therefore, no mitigation is necessary at this time to address resmethrin risk to aquatic organisms around wastewater plant releases.

b. Avian Risk

Terrestrial Birds

When mean residues are considered, the acute use LOC (0.5) is not exceeded for birds that feed on short grass, tall grass, and broadleaf plants/small insects when RQs are calculated with a dose-based red-winged blackbird study. The acute endangered species LOC of 0.1 is exceeded for 20g and 100g birds feed on short grass. The chronic LOC (1) is not exceeded for birds feeding on short grass, tall grass, and broadleaf plants/small insects when the dose-based study is used. The highest chronic RQ considering mean residues is 0.8.

When avian RQs are calculated with dietary-based toxicity values, no LOCs are exceeded for any acute or chronic scenario.

c. Mammalian Risk

Terrestrial Mammals

All acute and chronic RQs are below the respective acute and chronic LOCs for mammalian risk. Therefore, resmethrin is not likely to pose an acute or chronic risk to mammals.

d. Terrestrial Plant Risk

No terrestrial plant data were submitted to the Agency for resmethrin. However, the Agency has determined that resmethrin will have no effect on listed plants. It is unlikely that resmethrin poses a phytotoxic concern based on its neurotoxic mode of action, lack of toxic effects when plants are exposed to other pyrethroids, and lack of ecological incident reports for plants.

e. Non-Target Insect Risk

Currently, the Agency does not estimate RQs for terrestrial non-target insects. However, based on a single study in honey bees, technical resmethrin is classified as highly toxic on an acute contact basis to non-target terrestrial insects (LD50 = 0.063 ug/ai per bee). Label statements addressing bee risk are required for all resmethrin occupational and wide area mosquito abatement products used outdoors.

3. Ongoing Work on Pyrethoids

One of the risk assessment goals of the Office of Pesticide Programs (OPP) is to estimate pesticide exposure through all significant routes of exposure from both agricultural and non-crop uses. However, the ecological risk assessments for most pyrethroid insecticides focus predominantly on the agricultural uses for these insecticides, because pesticide transport models are available to estimate potential aquatic exposure. Based on laboratory toxicity tests with terrestrial and aquatic animals, aquatic exposure would be more likely to cause adverse effects in the environment.

However, sales data indicate that non-crop uses of the pyrethroids comprise a much larger fraction of total use than agricultural uses. The use of pyrethroids in urban and suburban settings has increased since the phase-out of these uses of the organophosphate insecticides diazinon and chlorpyrifos. Sales data indicate that the majority of urban use of pyrethroids is for structural pest control, such as for control of termites or ants. Other outdoor non-crop uses include landscape maintenance, and homeowner lawn and garden use. Indoor uses include insect control, and treatment of pets and clothing.

The Agency uses a “down-the-drain” model to perform a screening-level aquatic risk assessment for indoor uses of pesticides. In these simulations, waste water containing pesticide residue flows into a building drain and passes through a sanitary sewer and publicly owned treatment works (POTW) before being discharged to surface water. However, no analogous exposure model has been developed to allow a similar screening-level assessment for pesticides applied in an outdoor urban setting. As a result, the Agency has had to take a qualitative approach to characterize the potential aquatic risk from urban and suburban use of pyrethroids.

For outdoor urban uses, it is assumed that runoff water from rain and/or lawn watering may transport pesticides to storm sewers and then directly to surface water. Conceptually, a greater contribution to pyrethroid loading to surface water bodies would be expected from application to impervious surfaces such as walkways, driveways or the sides of buildings, than to lawns or bare ground, because of the pyrethroids’ strong affinity to bind to organic carbon in soils. However, the Agency is unaware of any model which can simulate the different application methods for urban use and the physical representation of the urban landscape, storm sewer and receiving water configuration.

There are models available which can be calibrated to simulate sites and pesticides for which extensive flow and pollutant data have been collected in advance.

The HSPF/NPSM model, for instance, which is included in the Office of Water's BASINS shell, has been used to calibrate stream flow and copper pesticide use data to simulate loading of these pesticides consistent with concentrations measured in surface water monitoring. Risk assessors with the California Department of Environmental Protection confirmed in conversations with the Agency that they also have used watershed models to calibrate to previously collected flow and pesticide monitoring data, but that they did not know of any models capable of predicting concentrations of pyrethroids that might occur because of outdoor urban uses.

Development of a screening model which could simulate the fate and transport of pesticides applied in an urban setting would require a large body of data which is currently unavailable. For instance, an urban landscape cannot be simulated as easily as an agricultural field. The PRZM model simulates runoff from an agricultural field using readily available data describing surface soil characteristics and laboratory data detailing the persistence and mobility of pesticides in these soils. The agricultural field simulated is homogenously planted to a single crop, and soil and water are transported from the field to a receiving water body with dimensions consistent with USDA farm-pond construction guidelines.

By contrast, an urban landscape or suburban housing development consists of impervious surfaces such as streets and sidewalks, and pervious surfaces such as lawns and parkland. One could expect much greater mobility for pesticides applied to impervious surfaces, but laboratory soil metabolism studies may not provide an accurate measure of the persistence of pesticides on these surfaces. The path runoff water and eroded sediment might take is less obvious for an urban setting than an agricultural field. First, an urban landscape cannot be considered homogeneous, as the proportion of impervious and pervious surfaces varies for different locations. In addition, the flow path of runoff water and sediment is not necessarily a direct path over land, but can pass below ground through storm sewer networks, or be directed or slowed by pumping stations or temporary holding ponds.

Finally, the timing and magnitude of urban uses is less well defined for urban uses than agricultural uses. While agricultural uses would occur within a predictable window during the growing season, the need for urban uses could occur at different times each year, and might occur at different times within the same watershed. In addition, since records of how and to what extent pyrethroids are applied by homeowners are less well defined than for professional applications, it is harder to estimate the total load to model.

Pyrethroid monitoring data

The Agency considers surface water monitoring data in addition to modeling results when they are available. However, surface water monitoring for pyrethroids has been limited, perhaps because the pyrethroids would more likely be associated with aquatic sediment than the water column. The USGS NAWQA program included permethrin as the only pyrethroid among its pesticide analytes, and detected it in 0.15% of 1185 agricultural stream samples from 78 sample locations. Permethrin was not

detected in 803 urban stream samples taken from 33 sample locations. The NAWQA program also analyzed for *cis*-permethrin in bed sediments, and had similar detection rates in between the agricultural (1.5%) and urban (1.0%) land use sites; *trans*-permethrin was detected in 0.8% of bed sediment samples. Resmethrin was not detected in the USGS NAWQA survey.

More recently, researchers from the University of California-Berkeley have published studies which reported transport of pyrethroids to stream bed sediment as a result of urban uses. In 2004, Weston, et al. collected sediment from creeks draining a residential area in Rosedale, California. The sediments were analyzed for 7 pyrethroids (including permethrin and cypermethrin, which are currently in the reregistration process), as well as for other insecticides. The sediments were not analyzed for resmethrin. All of the pyrethroids were detected in the bed sediment from at least one sampling location. The researchers exposed the aquatic amphipod *Hyalella azteca* to the 21 sediment samples they collected; pesticide concentrations in 9 of these samples was sufficient to cause 90% mortality in the amphipods after a 10-day exposure. The concentrations of pyrethroids detected in the sediments were above the level expected to cause 50% mortality in *H. azteca*, suggesting that the pyrethroids were responsible for the observed toxicity.

In a subsequent study, Weston, et al. collected samples from 15 urban creeks in California and 12 in Tennessee. Toxicity to *H. azteca* was observed at least once with sediments taken from 12 of the 15 California sampling sites. In most cases, the toxicity could be accounted for by the concentrations of pyrethroids detected in the sediment. Pyrethroids were rarely detected in the Tennessee sediment samples, and exposure to the Tennessee sediments did not prove to be toxic to *H. azteca*.

Future steps

The results of the Weston, et al. studies has led a number of organizations, such as the California State Water Resources Control Board (SWRCB) to submit comments to the Agency during the reregistration process of several pyrethroid insecticides, calling for mitigation measures to prevent pyrethroid surface-water contamination. However, the lack of knowledge which makes it difficult to develop an urban pesticide transport model also makes it difficult to identify meaningful mitigation at this time. The Agency has developed some initial mitigation options during the reregistration process, and intends to identify steps which can be taken to allow a greater understanding of potential ecological risk from urban pyrethroid uses.

One reason that broad mitigation measures cannot be adopted during reregistration is that only three pyrethroid insecticides are required to be reviewed for reregistration in accoradance with FQPA. If use restrictions were placed on one of these three pesticides, one of the other pyrethroids would likely replace it for that use. It is important, as some commenters have suggested, to perform a risk assessment for all of the pyrethroids at the same time. The Weston papers indicated that the sediments which proved toxic to the tested aquatic invertebrate were contaminated not only with the

pyrethroids undergoing reregistration, but also other pyrethroids such as bifenthrin and lambda-cyhalothrin.

The next opportunity to assess the pyrethroids as a group will occur during the Registration Review program, for which the Agency issued a proposed rule in July 2005 and plans to issue the final rule and implement the program in 2006. The purpose of Registration Review is to ensure the periodic review of all pesticides to make sure they continue to meet current scientific and regulatory requirements, with the goal of reviewing each pesticide every fifteen years. The pyethroids are tentatively scheduled for re-evaluation under the proposed Registration Review program in 2010.

A number of steps are planned for the intervening years which should improve the Agency's ability to assess the level of aquatic exposure to pyrethroids from urban use. One step is to better identify what conditions in an urban setting might lead to greater vulnerability to transport to urban water bodies. Although the Weston papers reported sediment toxicity from samples from California but not Tennesse, the authors could only speculate what differences in use or geography made an area more vulnerable to exposure than the other.

Further investigation into the dominant urban uses and application practices of pyrethroids around the country would help provide a clearer picture of relative vulnerability. The SWRCB commented that structural pest control is likely a major source of pyrethroids in urban runoff, and suggested best management practices (BMP). The Pyrethroid Working Group (PWG) indicated that irrigation of lawns in areas of California with little rainfall during the application season could be a major contributor, and has contacted organizations such as Responsible Industry for a Sound Environment (RISE) and the Coalition for Urban/Residential Environmental Stewardship (CURES) to develop BMPs as part of their product stewardship plan. As further sediment monitoring studies are published describing parts of the country with different weather and pest pressures, more detailed usage data will make it easier to correlate the causes of pyrethroid use practices.

The Agency will also continue in its efforts to develop a screening-level model for urban pesticide uses. Advances in the resolution of GIS databases may allow better representation of the impervious and pervious portions of a typical urban landscape. As it becomes clearer which uses are most likely to lead to transport of pyrethroids to surface water, the conceptual model of how urban transport should be simulated will be more focused.

Finally, the Agency will evaluate available published literature and call-in data to resolve data gaps to ensure a robust comparison of the potential ecological risk of all the pyrethroids during Registration Review. Toxicity data cited by several commenters from published literature are included in the Agency's ECOTOX database. The Agency will evaluate the quality of studies to identify those to be included in the risk assessments during Registration Review. The PWG is currently performing specific toxicity studies identified by the Agency as data gaps, such as sediment invertebrate toxicity tests.

V. What Registrants Need to Do

The Agency has determined that resmethrin is eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (table XX). The Agency intends to issue Data Call- Ins (DCIs) requiring generic and product specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of resmethrin for currently registered uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 24. Guideline Requirements for Resmethrin

Data Requirement	Old Guideline No.	New OPPTS Guideline No.
Environmental Fate and Ecological Effects Data Requirements		
Photodegradation of parent and degradates in soil (Photodegradation in Soil of Resmethrin)	161-3	835.2410
Aquatic invertebrate life cycle (freshwater and estuarine/marine invertebrates)	72-4	850.1350 850.1300
Acute sediment testing (freshwater and estuarine/marine) (Freshwater held in reserve)	74-1	850.1735 850.1740
Chronic sediment testing (freshwater and estuarine/marine)	EPA/600/R-99/064 EPA/600/R01/020	
Avian reproduction test (with bobwhite quail)	71-4	850.2300
Fish early life-stage toxicity test (freshwater and estuarine/marine)	72-4	850.1400
Fish acute toxicity test (freshwater and marine)	72-1 72-3	850.1075
Aquatic invertebrate acute toxicity test, freshwater daphnids	72-2	850.1010
Mysid acute toxicity test	72-3	850.1035
Bivalve acute toxicity test (embryo larval)	72-3	850.1055
Oyster acute toxicity test (shell deposition)	72-3	850.1025
Human Health Effects Data Requirements		
90-Day neurotoxicity screening battery		870.6200b

Developmental neurotoxicity study	83-6	870.6300
Nature of the residue - plants	171-4	860.1300
Multiresidue Method	171-4	860.1360
Storage Stability Data	171-4	860.1380
Magnitude of the Residue – food handling – food items	171-4	860.1460
Magnitude of the Residue – meat, milk, poultry, eggs	171-4	860.1480

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 25. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 25: Summary of Labeling Changes for Resmethrin

Description	Manufacturing Use Products	Placement on Label
Formulation instructions required on all manufacturing use products	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." "Not for formulation into end use products for use in indoor metered spray systems." "Not for formulation into end use products for use in outdoor misting systems."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Environmental Hazards This product is toxic to fish, aquatic invertebrates, and oysters/shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End Use Products Intended for Occupational Use Excludes Products Intended for Use in Wide Area Mosquito Abatement Programs (See below requirements)		
PPE Requirements Established by the RED[1] for Liquid Formulations (excludes formulations applied via ready-to-use aerosols)	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart. All mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes, and - chemical resistant gloves. Applicators using handheld fog equipment must wear: - coveralls over long sleeved shirt and long pants, - chemical-resistant gloves, - chemical-resistant footwear plus socks, - chemical-resistant headgear, if overhead exposure, - chemical-resistant apron when mixing, loading, and cleaning equipment or spills, and - A NIOSH-approved respriator with -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N* R, P, or He filter." *Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for Ready-to-use Aerosol Products	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart. All applicators and other handlers must wear: - long sleeved shirt, long pants, and - socks plus shoes, and	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	- chemical-resistant gloves.”	
User Safety Requirements	“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	“User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards for All Products that have outdoor use sites Note: Products with indoor uses only see below	“Environmental Hazards This pesticide is toxic to fish, aquatic invertebrates, and oysters/shrimp. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through runoff. This product has a potential for runoff for several days after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, steams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product’s contribution to surface water contamination.”	Precautionary Statements immediately following the User Safety Recommendations
Environmental Hazards for products that only contain indoor use sites	Note to registrant: Products labeled solely for indoor use except as noted below may omit the Environmental Hazards statements. Such products must have the following statement in the Directions for Use:	Precautionary Statements immediately following the User Safety Recommendations

	"For indoor use only."	Precautionary Statements
Environmental Hazards for Indoor Use Products packaged in containers equal to or greater than 5 gallons or 50 lbs	"This pesticide is toxic to fish, aquatic invertebrates, and oysters/shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	
Restricted-Entry Interval for products with directions for use within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box
Entry Restrictions for all products with indoor use sites AND directions for use outside the scope of the WPS.	<u>For products applied as crack and crevice and surface sprays:</u> "Do not enter or allow other people (or pets) to enter the treated area until sprays have dried." <u>For products applied as space sprays or fogs:</u> "Close doors, windows and shut off all ventilation equipment before application. Leave the treated area. Post signs on entrances stating that the area has been treated with resmethrin and that it is to remain closed for at least 4 hours after application. Do not re-enter and do not allow anyone else to re-enter the site for 4 hours. Ventilate thoroughly before anyone is allowed to re-enter. - Ventilate thoroughly for 20 minutes for treatment of less than 10,000 cubic feet of space. - Ventilate thoroughly for 60 minutes for treatment of less than 50,000 cubic feet of space. - Ventilate thoroughly for 120 minutes for treatment of greater than 50,000 cubic feet of space."	If no WPS uses on the product, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions If the product also contains WPS uses, then create a NonAgricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - coveralls, - shoes plus socks - chemical-resistant gloves made of any waterproof material."	Directions for Use Inside the Agricultural Use Requirements Box
General Application	"Do not apply this product in a way that will contact workers or other persons, either directly or	Place in the Direction for Use

Restrictions	through drift. Only protected handlers may be in the area during application."	directly above the Agricultural Use Box.
Use-Specific Application Restrictions	<u>Labeling required on all products:</u> "Do not use in indoor metered spray systems." "Do not use in automatic misting systems." Note: Registrants must amend the label to include the maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated products per acre or 1000 ft^2, not just as pounds active ingredient per acre or 1000 ft^2. <u>Products labeled for use on Livestock, Farm Animals, and Pets (Direct Application):</u> "Do not apply with product containing more than 0.35% ai." <u>Products labeled for use in Outdoor Sites (Commercial, Recreational, Domestic Outdoor Sites, Agricultural Structures, Agricultural Premises, and Agricultural Equipment):</u> "Do not apply more than 0.25 lb ai per acre." OR For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.25 lb ai per acre. <u>Products labeled for use in Space Applications (Greenhouses; Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment; Domestic Structure Premises and Equipment):</u> "Do not apply more than 0.001 lb ai per 1000 ft^2." OR For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.001 lb ai per 1000 $ft^{2.}$ <u>Products labeled for use in Surface Crack and Crevice Application (Greenhouses; Indoor Food Handling/Processing/Eating Establishments; Commercial Structure Premises and Equipment;</u>	Directions for Use

	Domestic Structure Premises and Equipment): "Do not apply more than 0.242 lb ai per 1000 ft^2." OR For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.242 lb ai per 1000 ft^2 Products labeled for indoor use sites: "Remove pets, birds, and cover aquariums and turn off air pumps before application. In food processing operations, homes, or any other location where food is prepared or served, do not apply this product while food is exposed or being processed. Cover or remove all exposed food, packaging material, and food contact surfaces. Do not apply directly to food, packaging material, or any food contact surfaces. Remove or cover dishes, utensils, food processing equipment and food preparation surfaces before use of this product. All food processing surfaces and equipment in the treatment area must be covered or washed with an effective cleaning compound followed by a potable water rinse after use of this product."	
For End-Use Products Intended for Wide Area Mosquito Abatement Programs Only		
Restricted Use Pesticide	"Restricted Use Pesticide. Due to Acute Fish Toxicity. For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Direct supervision for this product is defined as the certified applicator being physically present during mixing, loading, equipment repair and equipment cleaning. Certified applicators must ensure that all persons involved in these activities under their direct supervision are informed of the precautionary statements."	Top front panel
PPE Requirements Established by the RED[1]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	All mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes, and - chemical-resistant gloves for all handlers except applicators. See engineering controls for additional requirements."	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	Engineering Controls: "Applicators using ground mechanical application equipment must use an enclosed cab that has a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the cab. Must be provided and have immediately available for use upon exiting the cab chemical-resistant gloves." "Pilots must use an enclosed cockpit. The cockpit must have a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the cab. Pilots must wear the PPE specified in this label for applicators."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Environmental Hazards	"This pesticide is toxic to aquatic organisms, including fish, crustaceans, and oysters. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to fish, crustaceans, and oysters." "Do not apply when bees are visiting the treatment area, except when applications are made to prevent or control a threat to public and/or animal health determined by a state, tribal, or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort." "Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist." "Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters."	Precautionary Statements immediately following the User Safety Recommendations
Application Restrictions	"Do not apply more than 0.007 lb ai/acre per application." "Do not apply more than 0.2 lb ai/acre per year in any treated area. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal, or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort." "Products must comply with EPA PR Notice 2005-1."	Directions for Use
Spray Drift Label Language for ALL Products Intended for	SPRAY DRIFT MANAGEMENT	Directions for Use under General Precautions and Restrictions

ULV Mosquito Abatement Programs Only	"A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product." WIND SPEED: "Do not apply when wind speed is 0 mph." DROPLET SIZE: "Ground-based application: Spray equipment must be adjusted so that the volume median diameter is less than microns (Dv 0.5 < 8-30 um) and that 90% of the spray is contained in droplets smaller than microns (Dv 0.9 < 50 um). Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a laxer-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated." "Aerial Application: Spray equipment must be adjusted so that the volume median diameter produced is less than microns (Dv 0.5 < 60 um) and that 90% of the spray is contained in droplets smaller than microns (Dv 0.9 < 80 um). The effects of flight speed, and for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. EQUIPMENT CALIBRATION: Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated." RELEASE HEIGHT: Fixed wing: "Apply using a nozzle height of no less than 100 feet above the ground or canopy."	

	Rotary wing: "Apply using a nozzle height of no less than 75 feet above the ground or canopy." BOOM LENGTH: "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter."	
End Use Products Intended for Residential Use		
Application Restrictions	"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	<u>For products applied as crack and crevice and surface sprays:</u> "Do not enter or allow other people (or pets) to enter the treated area until sprays have dried." <u>For products applied as space sprays or fogs:</u> "Close doors, windows and shut off all ventilation equipment before application. Leave treated area closed for at least 2 hours after application. Do not remain in treated area(s). Ventilate thoroughly for 20 minutes with fresh air before re-occupying treated area(s)."	Directions for use under General Precautions and Restrictions
Environmental Hazards .	<u>For products that have outdoor uses:</u> "This product is extremely toxic to fish, aquatic invertebrates, and oysters/shrimp. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements."	Precautionary Statements immediately following the User Safety Recommendations
Use-Specific Application Restrictions	<u>Labeling required on all products applied as sprays:</u> "Do not use in indoor metered spray systems." "Do not use in automatic misting systems." **APPLICATION RATE RESTRICTIONS:**	Directions for Use

	Products containing greater than 0.35% ai must not be labeled for use on pets. Note: Registrants must amend the label to reflect the below maximum allowable application rate per year. The rate must be listed as pounds or gallons of formulated product per acre or 1000 ft^2, not just as pounds active ingredient per acre or 1000 ft^2. For ready-to-use products, registrants must amend their labels to specify use rates that will result in the below maximum application rates. <u>Products labeled for use in Outdoor Sites (Backyard, patios, and ornamentals):</u> Maximum application rate 0.25 lb ai per acre. <u>Products labeled for Space Application (domestic dwellings):</u> Maximum application rate 0.001 lb ai per 1000 ft^2. "Do not use more than 3 times a year." <u>Products labeled for Surface Crack and Crevice Application (domestic dwellings):</u> Maximum application rate 0.242 lb ai per 1000 ft^2. **OTHER RESTRICTIONS:** <u>Products labeled for use in indoor use sites:</u> "Remove pets, birds, and cover aquariums and turn off air pumps before application." "In homes or any other location where food is prepared or served, do not apply this product while food is exposed or being processed. Cover or remove all exposed food and food contact surfaces. Do not apply directly to food, packaging material, or any food contact surfaces." "Remove or cover dishes, utensils, food processing equipment and food preparation surfaces before use of this product. All food processing surfaces and equipment in the treatment area should be covered or washed with an effective cleaning compound followed by a potable water rinse after use of this product." <u>Products labeled for use in outdoor use sites except for Ready to Use Formulations:</u>	

	"Do not apply directly to or near water, storm drains, or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) or apply when heavy rain is expected. Rinse application equipment over lawn or garden area only." <u>Ready to use products labeled for outdoor use sites:</u> "Do not apply directly to or near water, storm drains, or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) or apply when heavy rain is expected."	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Appendix A

Use Patterns Subject for Reregistration of Resmethrin

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
DIRECT APPLICATION TO LIVESTOCK, FARM ANIMALS, AND PETS	RTU	0.35%	N/A	
OUTDOOR USE SITES (COMMERCIAL, RECREATIONAL, DOMESTIC OUTDOOR SITES, AGRICULTURAL STRUCTURES, AGRICULTURAL PREMISES, AND AGRICULTURAL EQUIPMENT)	EC, PRL, RTU, SC/L	0.25	lb/acre	For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.25 lb ai per acre.
SPACE APPLICATIONS (GREENHOUSES; INDOOR FOOD HANDLING/PROCESSING/ EATING ESTABLISHMENTS; COMMERCIAL STRUCTURE PREMISES AND EQUIPMENT; DOMESTIC STRUCTURE PREMISES AND EQUIPMENT)	EC, PRL, RTU	0.001	lb/1000ft^2	For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.001 lb ai per 1000ft^2.
SURFACE CRACK AND CREVICE APPLICATION (GREENHOUSES; INDOOR FOOD HANDLING/PROCESSING/ EATING ESTABLISHMENTS; COMMERCIAL STRUCTURE PREMISES AND EQUIPMENT; DOMESTIC STRUCTURE PREMISES AND EQUIPMENT)	EC, PRL, RTU	0.242	lb/1000ft^2	For ready-to-use products, registrants must amend their labels to specify use rates that result in no more than 0.242 lb ai per 1000ft^2.

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
END-USE PRODUCTS INTENDED FOR WIDE AREA MOSQUITO ABATEMENT PROGRAMS	EC, EC*RTU	0.007	lb/acre	"Restricted Use Pesticide. Due to Acute Fish Toxicity. For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Direct supervision for this product is defined as the certified applicator being physically present during mixing, loading, equipment repair and equipment cleaning. Certified applicators must ensure that all persons involved in these activities under their direct supervision are informed of the precautionary statements." "Do not apply more than 0.007 lb ai/acre per application." "Do not apply more than 0.2 lb ai/acre per year in any treated area. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal, or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort." "Products must comply with EPA PR Notice 2005-1."

Appendix B

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2510 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2510 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1550	**61-1**	**Product Identity and Composition**	**All**	42085701,43184901
830.1600 830.1620 830.1650	**61-2A**	**Start. Mat. & Mnfg. Process**	**All**	42085701,43184901,43392201,43090801
830.1670	**61-2B**	**Formation of Impurities**	**All**	42085701,43184901,4309081
830.1700	**62-1**	**Preliminary Analysis**	**All**	42085702
830.1750	**62-2**	**Certification of limits**	**All**	
830.1800	**62-3**	**Analytical Method**	**All**	42085702, 43184901,43090802
830.6302	**63-2**	**Color**	**All**	43241602, 42085703, 43259801,43184901,43435701,

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
				43330101,43090803
830.6303	**63-3**	**Physical State**	**All**	43241602, 42085703, 43259801, 43184901,43435701, 43330101, 43090803
830.6304	**63-4**	**Odor**	**All**	43241602, 42085703, 43259801, 43184901, 43435701, 43330101,43090803
830.6314	**63-14**	**Oxidation/reduction: chemical incompatability**		43241602, 42085703, 43259801, 43184901, 43435701, 43330101, 43090803
830.6315	**63-15**	**Flammability**		43241602, 43259801, 43184901, 43435701, 43330101, 43090803
830.6316	**63-16**	**Explodability**		43241602, 42085703, 43259801, 43184901, 43435701, 43330101, 43090803
830.6317	**63-17**	**Storage Stability**		42085703,43184901,43993701,43993601,43090803, 40766101
830.6319	**63-19**	**Miscibility**		43241602, 43259801,43184901, 43435701, 43330101, 43090803
830.6320	**63-20**	**Corrosion Characteristics**		42085703, 43259801, 43184901, 43993701, 43993601, 43090803
830.7100	**63-18**	**Viscosity**		43241602,43259801, 43184901, 43435701, 43330101, 43090803
830.7200	**63-5**	**Melting Point**	**All**	42085703
830.7300	**63-7**	**Density**	**All**	43241602,42085703,43259801,

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
				43184901,43435701, 43330101
830.7840 830.7860	**63-8**	**Solubility**	**All**	42085703
830.7950	**63-9**	**Vapor Pressure**	**All**	42085703
830.7370	**63-10**	**Dissociation Constant**	**All**	42085703,42143701
830.7550	**63-11**	**Octanol/Water Partition Coefficient**	**All**	
830.7000	**63-12**	**pH**	**All**	43241602, 42085703, 43184901, 43435701, 43330101, 43090803
830.6313	**63-13**	**Stability**	**All**	42085703
	ECOLOGICAL EFFECTS			
850.2100	**71-1A**	**Avian Acute Oral Toxicity - Quail**	**ABCIKM**	
850.2200	**71-2A**	**Avian Dietary Toxicity - Quail**	**ABCIKM**	
850.2200	**71-2B**	**Avian Dietary Toxicity - Duck**	**ABCK**	
850.1075	**72-1A**	**Fish Acute Toxicity Bluegill**	**ABCK**	
850.1075	**72-1C**	**Fish Acute Toxicity Rainbow Trout**	**ABCIKM**	
850.1010	**72-2**	**Invertebrate Toxicity**	**ABCIKM**	
None	**72-3A**	**Estuarine/Marine Toxicity - Fish**	**ABCK**	

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
None	**72-3C**	**Estuarine/Marine Toxicity - Shrimp**	**ABCK**	
None	**72-4B**	**Estuarine/Marine Invertebrate Life Cycle**	**ABCK**	
	122-2	**Aquatic plant growth**		
850.4225	**123-1A**	**Seed germ/seedling emergence**	**ABCK**	
850.4250	**123-1B**	**Vegetative vigor**	**ABCK**	
850.4400	**123-2B**	**Aquatic Plant Growth, Tier 2**	**ABCK**	
TOXICOLOGY				
870.1100	**81-1**	**Acute Oral Toxicity-Rat**	**ABCIKM**	42076201
870.1200	**81-2**	**Acute Dermal Toxicity-Rabbit**	**ABCIKM**	42076202
870.1300	**81-3**	**Acute Inhalation Toxicity-Rat**	**ABCIKM**	42153701
870.2400	**81-4**	**Primary Eye Irritation-Rabbit**	**ABCIKM**	42076203
870.2500	**81-5**	**Primary Skin Irritation**	**ABCIKM**	42076204
870.2600	**81-6**	**Dermal Sensitization**	**ABCIKM**	42153702
870.3100	**82-1A**	**90-Day Feeding - Rodent**	**ABCIKM**	43338601, 43838101
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	**ABCHIK**	42066901
870.3465	**82-4**	**90-Day Inhalation**		00158476

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
870.4100	**83-1A**	**Chronic Feeding Toxicity - Rodent**	**ABCIKM**	00157961,43601601
870.4100	**83-1B**	**Chronic Feeding Toxicity - Non-Rodent**	**ABCIKM**	43062601
870.4200	**83-2A**	**Oncogenicity - Rat**	**ABCIKM**	0083319
870.4200	**83-2B**	**Oncogenicity - Mouse**	**ABCIKM**	43052101
870.4300	**83-5**	**Chronic/Oncogenicity**		00041402,00085870,00108628,43271701, 43601601,00041402,00108828
870.3700	**83-3A**	**Developmental Toxicity - Rat**	**ABCIKM**	00028453,
870.3700	**83-3B**	**Developmental Toxicity- Non Rodent**		46582601,00029002
870.3800	**83-4A**	**2-Generation Reproduction - Rat**	**ABCIKM**	43189101,
870.3800	**83-4B**	**Reproduction**		00081276, 124308
870.5140	**84-2A**	**Gene Mutation (Ames Test)**	**ABCIKM**	
870.5265				41068010
870.5375	**84-2B**	**Structural Chromosomal Aberration**	**ABCIKM**	41068011,
870.5550	**84-2**			
870.6200	**82-7A**	**Acute Neurotox. Screening Battery (rat)**		00025552,00025553,00025554
870.6200	**82-7B**	**90 Day Neuro. Screening Battery (rat)**		

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
None	**84-4**	**Other Genotoxic Effects**	**ABCIKM**	
870.7485	**85-1**	**General Metabolism**	**ABCIKM**	42133801,42136101
870.7600	**85-3**	**Dermal Penetration**		46382501
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	**132-1A**	**Foliar Residue Dissipation**	**ABCIK**	
ENVIRONMENTAL FATE				
835.2120	**161-1**	**Hydrolysis**	**ABCIK**	470077046
835.2240	**161-2**	**Photodegradation - Water**	**ABCK**	00153059,
835.2410	**161-3**	**Photodegradation - Soil**	**ABC**	
	161-4			
835.4100	**162-1**	**Aerobic Soil Metabolism**	**ABCIK**	41913601, 41913601
	162-2	**Anaerobic soil Metabolism**		
835.4400	**162-3**	**Anaerobic Aquatic Metabolism**	**ABC**	42298401
	162-4	**Aerobic Aquatic Metabolism**		42043003
835.1240	**163-1**	**Leaching/Adsorption/Desorption**	**ABCIK**	
	163-2			
	163-3			

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
835.6100	164-1	Terrestrial Field Dissipation	ABCK	
	164-2			
	164-3			
	165-4			
	165-5			
	166-1			
	166-2			
	201-1			
	202-1			
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	ABK	
860.1300	171-4B	Nature of Residue - Livestock	AB	
860.1340	171-4C	Residue Analytical Method - Plants/Animals	ABK	
860.1340	171-4D	Residue Analytical Method- Animal		
860.1360	171-4M	Multiresidue Method		
860.1380	171-4E	Storage Stability	ABK	

Data Supporting Guideline Requirements for the Reregistration of Resmethrin

REQUIREMENT			USE PATTERN	CITATION(S)
860.1480	**171-4J**	**Magnitude of Residues - Meat/Milk/Poultry /Egg**	**ABK**	
860.1500	**171-4K**	**Crop Field Trials (Potatoes)**	**ABK**	
OTHER				
860.1850	**165-1**	**Confined Accumulation in Rotational**	**ABC**	
810.1900	**165-2**	**Field Accumulation in Rotational**	**ABC**	
840.1200	**202-1**	**Drift field evaluation**		

a- TGAI is a solid at room temperature.
b- Data used to support carbendazim.
c- Additional data is needed. The registrant has proposed two HPLC/UV methods for enforcing tolerances of thiophenate-methyl in plant (Method BR-93-28) and animal (Method KP-100-04) commodities. Prior to validation by the Agency, the method should be radiovalidated using samples from animal and plant metabolism studies.
d- Multiresidue method (MRM) recovery data are required for thiophenate-methyl and MBC through FDA protocols A through G.
e- Data are required depicting the frozen storage stability of thiophenate-methyl and MBC in representative raw and processed plant commodities held in frozen storage for up to five years.
f- Additional field trial in CA is required (see residue chemistry chapter).
g- Data are required depicting residues of thiophenate-methyl and MBC in/on green onions harvested at the minimum interval following a broadcast application at planting of thiophenate-methyl (WP/WDG/FIC) at 1.4 lb ai/A. A minimum of three field trials should be conducted; two in Region 10 and one in Region 6.
h- If the registrant intends to support a use on dry peas and lentils, additional residue data for dried peas need to be submitted.

i- To support this group crop tolerance, the registrant has submitted representative field trials for the following representative crops: cucumbers, melon, pumpkin and squash.
j- The available residue data are inadequate because of deficiencies in analytical method.
N/A not applicable.

Appendix C

TECHNICAL SUPPORT DOCUMENTS

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The preliminary risk assessments for permethrin are available in the public docket and in e-dockets under docket number OPP-2004-0385. This contains risk assessments and related documents as of August 2005. During the comment period, the registrant submitted additional data for permethrin. EPA reviewed these data and incorporated them into the revised risk assessments for permethrin. These revised risk assessments form the basis of the regulatory decision described in this RED. These risk assessment and related documents are available under docket number OPP-2004-0385.

Technical support documents for the Permethrin RED include the following:

Human Health Risk Assessment Documents;

1. *Resmethrin HED Revised Risk Assessment for Reregistration Eligibility Document (RED) PC Code 097801; DP Barcode 326088,* dated February 23, 2006.
2. *Resmethrin: Response to Public Comments on the HED Risk Assessment for Resmethrin RED Chapter; PC Code 097801; DP Barcode 291445,* dated February 23, 2006.
3. *Resmethrin and Bioresmethrin. Revised Product and Residue Chemistry Considerations for Reregistration Eligibility Decisions,* dated February 16, 2006.
4. *Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision (RED) for Resmethrin,* dated February 23, 2006.
5. *Resmethrin Revised Chronic and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision PC Code 097801 DP Barcode 326090,* dated February 22, 2006.

Environmental Fate and Effects Documents;

1. EFED RED Chapter for Resmethrin, Revision Phase 3, dated March 8, 2006.
2. Response to Comments of the Phase 3 Period for the Revised Draft EFED RED Chapter for Resmethrin, dated March 8, 2006.
3. Revised Tier II Estimated Drinking Water Concentrations for Resmethrin, dated February 13, 2006.
4. Preliminary Environmental Fate and Effects Division Risk Assessment Chapter for the Reregistration Eligibility Decision (RED) Document for: Resmethrin, dated March 8, 2006.

5. Appendicies to the EFED Risk Assessment Chapter for the RED Document for Resmethrin, dated March 8, 2006

Appendix D

Bibilography

MRID	Citation Reference
Human Health Studies	
43338601	Kangas, L. (1989) A 4-Week Dietary Toxicity Study of SBP-1382 in the Albino Mouse: Lab Project Number: 83753. Unpublished study prepared by Bio-Research Lab. Ltd. 241 p.
42066901	Meyers, L. (1991) 21-Day Percutaneous Toxicity Study of Resmethrin in Rabbits: Lab Project Number: HWA 2623-100: RBT-90-217. Un- published study prepared by Hazleton Washington, Inc. 312 p.
00025552	Schwartz, C.S.; Becci, P.J.; Parent, R.A.; et al. (1979) Report: Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats--Phase 1: FDRL Study # 6067. Includes method dated Jul 2, 1979. (Unpublished study including letter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten devries, received Dec 19, 1979 under 432-487; prepared by Food and Drug Research Laboratories, Inc., submitted by Penick Corp., Lyndhurst, N.J.; CDL:241501-B)
00025553	Cox, G.E.; Becci, P.J.; Parent, R.A.; et al. (1979) Supplementary Report for Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats--Phase I: FDRL Study # 6362. (Unpublished study in- cluding letter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten L. derVies, prepared by Food and Drug Research Laboratories, Inc., received Dec 19, 1979 under 432-487; submit- ted by Penick Corp., Lyndhurst, N.J.; CDL:241502-B)
00025554	Schwartz, C.S.; Becci, P.J.; Parent, R.A.; et al. (1979) Report: Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats: Phase II: FDRL Study # 6068. (Unpublished study including let- ter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten L. deVries, received Dec 19, 1979 under 432-487; pre- pared by Food and Drug Research Laboratories, Inc., submitted by Penick Corp., Lyndhurst, N.J.; CDL:241503-B)
00157961	Gephart, L.; Johnson, W.; Becci, P.; et al. (1980) 180-Day Sub- chronic Oral Dosing Study with Resmethrin (SBP-1382) in Beagle Dogs: Laboratory No. 6289. Unpublished study prepared by Food and Drug Research Laboratories, Inc. 553 p.
43062601	Dalgard, D. (1993) 52-Week oral Toxicity Study of SBP-1382 (Resmethrin) Technical in Dogs: Final Report: Lab Project Number: HWA 2623-105: RBT-92-100. Unpublished study prepared by Hazleton Washington, Inc. 375 p.
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