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Reregistration Eligibility Decision (RED) for Permethrin

Revised December 2007

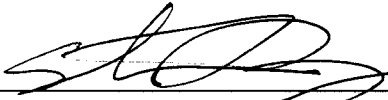
**REREGISTRATION ELIGIBILITY DECISION
(RED)**

For

Permethrin

CASE No. 2510

Revised December 2007

Approved by: 
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Special Review and
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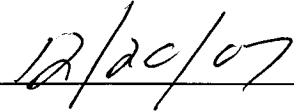
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Glossary of Terms and Abbreviations

ai	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}
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
IDFS	Incident Data System
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
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)
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
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

Permethrin Reregistration Eligibility Decision

The Reregistration Eligibility Decision document for Permethrin was signed on April 5, 2006. In accordance with the Agency's public participation process, a public comment period for the RED was conducted. This comment period opened July 28, 2006 and closed September 28, 2006. The risk assessments, benefit assessments, and public comments can be found on the Federal Docket Management System (FDMS), available at <http://www.regulations.gov> (docket # EPA-HQ-OPP-2004-0385). The Agency has reviewed the public comments submitted and has responded to those that related specifically to the Permethrin RED. These responses are also available for viewing on FDMS (docket # EPA-HQ-OPP-2004-0385). As a result of its review of the public comments, as well as post-RED activities such as meeting with the registrants regarding the development of mandatory label language for canine spot-on products and pre-construction termiticide application, and meetings with the Pyrethroid Working Group to revise spray drift language for agricultural products, the Agency has revised the Permethrin RED, where appropriate. These revisions are listed below.

- In Section IV, Other Residential Uses To be Addressed in RED, in order to address concerns regarding the residential use of outdoor pesticide misting systems, the following was added, “In addition, the Agency has developed a Outdoor Residential Misting System web-based fact sheet page aimed at helping consumers decide if these systems are appropriate for their home, understand safety precautions about using outdoor misting systems, find related information on Integrated Pest Management, and understand the role of the US EPA and state agencies in regulating misters (http://www.epa.gov/pesticides/factsheets/misting_systems.htm).”
- In Section V, Additional Product-Specific Data Requirements, the Agency included the following additional product-specific data requirements.
 - The Agency determined it does not have efficacy data for permethrin products registered for use in outdoor residential misting systems claiming to target public health pests. Efficacy data for this use pattern will be required on the product-specific data call-in (PDCI).
 - The Agency is requiring a companion animal study (870.7200) for permethrin products used on domestic animals. The study is to ensure that pesticide formulations for the treatment of external pests on domestic animals have an adequate margin of safety for the treated companion animal. In addition, data from companion animal safety studies also serve as a basis for product labeling. This data requirement will be included on the PDCI.
 - The Agency is requiring efficacy data for permethrin impregnated clothing applications claiming to target public health pests. This requirement will also be included on the PDCI.

A number of updates have also been made to the RED document, including the Labeling Changes Summary Table, Table 38 (Label Table), for purposes of clarification. Among the updates are the following:

- The incorrect maximum application rate for mushroom use was given in the Permethrin RED Appendix A. Appendix A has been revised to reflect the correct maximum application rate for mushroom, 2 -2.5 oz. per 30 oz water.
- For all wide area mosquito abatement products, the Agency received public comments that the droplet sizes indicated in the RED for aerial applications (Dv.05 <60 microns and Dv.09 <80 microns) were not feasible with current, standard application equipment. The Agency revised the droplet size as follows:
 - For aerial applications made at ≤ 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 60 microns (Dv 0.5 <60 μm) and that 90% of the spray is contained in droplets smaller than 100 microns (Dv 0.9 <100 microns); and
 - For aerial applications made at > 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 70 microns (Dv 0.5 <70 μm) and that 90% of the spray is contained in droplets smaller than 145 microns (Dv 0.9 <145 microns).
- The Agency omitted a reference to the Residential Exposure Joint Venture National Pesticide Use Survey data in the RED Bibliography, Appendix D. The citation has been added in the Bibliography, Appendix D.
- The Agency determined the following data is not needed; they will not be included on the Generic Data Call-In and have been deleted in the revised Permethrin RED:
 - 850.1735: Whole sediment acute toxicity for freshwater invertebrates
 - 850.1740: Whole sediment acute toxicity for estuarine/marine invertebrates
 - 860.1200: Directions for Use
 - 860.1340: Enforcement Analytical Method-Animals
- The Use Profile section of the RED has been revised to clarify that permethrin use is only permitted in non-food/feed areas of food handling establishments. A prohibitory statement has also been added to the label table.

The Whole sediment acute toxicity for freshwater invertebrates (850.1735) and Whole sediment acute toxicity for estuarine/marine invertebrates (850.1740) studies are considered unnecessary because the primary risk to estuarine/marine invertebrates has been determined to be chronic, reproductive risk. These aspects will be addressed by the

chronic studies that remain in the Generic Data Call-In: Chronic Freshwater Sediment Testing and Chronic Estuarine/Marine Sediment Testing.

Existing data is sufficient so that the residue chemistry studies stipulated in the RED, Directions for Use (860.1200) and Enforcement Analytical Method-Animals (860.1340) are unnecessary.

Additionally, a permethrin dermal absorption study is being conducted by the technical registrant to determine whether the 15% dermal absorption factor used in the Permethrin RED was appropriate. This study is expected to be submitted to the Agency for review in early 2008. The Agency will review the study and, if necessary, further amend the Permethrin RED.

A number of updates have also been made to the Label Table based on public comments and conversations with permethrin registrants and other external stakeholders following the RED. This updated table is included with the revised RED. Among the updates are the following:

- Revised spray drift and buffer zone language for agricultural products to reduce permethrin off-target movement.
- Inclusion of pre-construction termiticide language for residential products.
- Mandatory precautionary statements for canine 45/65% concentrate spot-on products.
- Additional directions for use for all products registered for outdoor use to reduce permethrin off-target movement.
- Clarifying that permethrin use is only permitted in non-food/feed areas of food handling establishments.

If you have questions on the Permethrin RED or any of the revisions listed above, please contact the Chemical Review Manager, Jacqueline Guerry at (215) 814-2184. For questions about product reregistration and/or the Product Data Call-In that will follow this document, please contact Bonnie Adler at (703) 308-8523.

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for permethrin and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of permethrin that pose risks of concern. As a result of this review, EPA has determined that permethrin-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Permethrin is part of the pyrethroid class of pesticides and was first registered in 1979. It is a broad spectrum, non-systemic, synthetic pyrethroid insecticide, and is registered for use on numerous food/feed crops, livestock and livestock housing, modes of transportation, structures, buildings, Public Health Mosquito abatement programs, numerous indoor and outdoor residential spaces, pets, and clothing. Initial risk assessments indicated some occupational and residential handler and post-application risks of concern. Risk estimates were revised based on refinements to the assessments and in some cases agreed to mitigation measures, and the Agency will be requiring additional data for some exposure scenarios. Occupational risks have been mitigated through personal protective equipment or engineering controls requirements on the labels; residential risks to homeowners have been mitigated by discontinuing or restricting certain application methods and reducing some application rates; and ecological risks have been addressed through adding buffer zone requirements and product stewardship statements to the labels, and amending use patterns for many uses.

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 a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). 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 hazards 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 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. 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 of infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are below the Agency’s LOC and the Agency 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.

As mentioned above, FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. Permethrin 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 interact with sodium channels, there are multiple types of sodium channels and it is currently unknown whether they the pyrethroids have similar effects on all channels. Nor do we 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 the EPA’s Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk. For information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>. For additional information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations

and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for permethrin. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical and 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 decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The revised risk assessments for permethrin and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (<http://www.regulations.gov>) under docket number EPA-HQ-OPP-2004-0385 and are available on the Agency's web page at <http://www.epa.gov/oppsrrd1/reregistration/permethrin/>.

II. Chemical Overview

A. Regulatory History

Permethrin was first registered and tolerances established in the United States in 1979 for use on cotton (April 29, 1979 44FR 24287). The registration was made conditional due to the need for additional toxicology data to fully evaluate carcinogenicity and the need for additional ecological effects data to fully evaluate aquatic risk. Laboratory studies indicated that permethrin was highly toxic to fish and aquatic invertebrates and the use on cotton was classified as Restricted Use pesticide (RUP). In making its decision to conditionally register the product, EPA considered the beneficial role of this compound in cotton pest management, the reduction of use of other cotton insecticides with known carcinogenic potentials, and the absence of suitable and sufficient supplies of alternatives for control of resistant insect strains.

From 1979 to 1982, there was considerable scientific debate over the interpretation of the carcinogenicity database, which considerably delayed the establishment of new crop tolerances and non-food registrations. After additional toxicity data were reviewed, EPA concluded that permethrin was a weak carcinogen. From 1982 to 1989, 55 + crop tolerances were approved for a wide variety of crops, including vegetables (i.e., broccoli, celery, lettuce, potatoes, etc.), alfalfa, pears, meat, milk and eggs. During this time, EPA regulated new crop uses on the basis of average daily intake (ADI) and not by quantitative cancer risk assessment.

In 1985 a Data Call-In (DCI) for ecological effects data for permethrin was issued, which include a full complement of ecological effects data. The additional data required were estuarine mollusc acute tests, estuarine invertebrate life cycle and fish life cycle tests. After evaluation of this data EPA concluded that the current RUP classification be maintained for all products for wide area agricultural uses (except livestock and premises uses) and outdoor wide area non-crop uses because of the possible adverse effects on aquatic organisms from spray drift and runoff.

In 1988 a comprehensive DCI was issued requiring additional residue chemistry,

environmental fate and toxicological data. This DCI was issued so that data required by 40 CFR Part 158 would be available to EPA for reregistration.

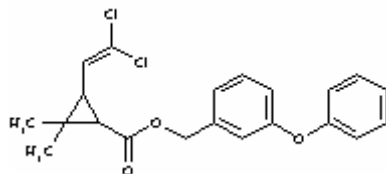
In 1990 EPA issued conditional registrations with product expiration dates for various synthetic pyrethroids prescribed specifically for use on cotton. The reason for time-limited tolerances/registrations was aquatic toxicity concerns. EPA required interim risk mitigation measures, i.e. buffer zones around water, an education program to inform growers on reducing off target spray deposition and additional data requirements. Since permethrin was registered for use on cotton, it was subject to these conditions and product expiration dates. However in 1994 the producers of products containing permethrin for use on cotton requested voluntary cancellation of this use and were no longer subject to the conditions of registration.

From 1994 thru 2000 permethrin was subject to specific DCIs requesting data to assess agricultural and residential exposure, agricultural re-entry, and mosquito ULV products. In 2000 the Agency notified the producers of concentrated (40 – 65%) permethrin “Spot-On” products for use on dogs of concerns about the potential misuse, of these products on cats. The Agency was made aware of instances of consumers using these dog products accidentally on their pet cats and/or not being aware of the danger of allowing cats to interact with newly treated dogs. The producers of these products voluntarily agreed to make a number of label changes to reduce this potential misuse such as adding in large bold type “Do Not Use On Cats” and the icon of a cat in a circle with a slash through it and a statement indicating the cats which actively groom or engage in physical contact with treated dogs may be at risk of harmful effect.

B. Chemical Identification - Permethrin

Permethrin [(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate] is a synthetic pyrethroid insecticide. Permethrin is a racemic mixture of the cis and trans isomers. Permethrin is a colorless crystal to a pale yellow viscous liquid with a melting point of 35EC and a boiling point of 220EC (0.05 mm Hg). Permethrin is soluble in water at less than 1 ppm, and is miscible in most organic solvents except ethylene glycol. Permethrin is soluble in acetone, ethanol, ether, and xylene.

Chemical Structure:



Common Name:	Permethrin
Chemical Name:	(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate
Chemical Family:	Synthetic Pyrethroids

Case Number:	2510
CAS Number:	52645-53-1
PC Code:	109701
Molecular Weight:	391.3
Empirical Formula:	C ₂₁ H ₂₀ CL ₂ O ₃
Technical Registrants:	Bayer Environmental Science Clark Mosquito Control Control Solutions Incorporated FMC Corporation Gharda Chemicals LTD LG Life Sciences LTD McLaughlin Gormley King Company Meghamani Organics Limited Micro Flo Company Syngenta Crop Protection, Incorporated United Phosphorus, Incorporated Valent BioSciences Corporation

C. Use Profile

The following is information on the currently registered uses of permethrin, including an overview of use sites and application methods. A detailed table of the uses of permethrin eligible for reregistration is available in Appendix A.

Type of Pesticide:	Insecticide
Target Pests:	Permethrin controls a broad spectrum of pests, including public health pests such as mosquitoes.
Mode of Action:	Permethrin is a type I pyrethroid (i.e., it lacks a cyano group at the α carbon position of the alcohol moiety) with the primary target organ being the nervous system of insects which then causes muscle spasms, paralysis and death.
Use Sites:	Permethrin is registered for use on/in numerous food/feed crops, livestock and livestock housing, modes of transportation, structures, buildings (including the non-food/feed areas of food handling establishments), Public Health Mosquito abatement programs, and numerous residential use sites including use in outdoor and indoor spaces, pets, and clothing (impregnated and ready to use formulations). Additionally, permethrin has non-FIFRA pharmaceutical uses as a pediculicide for the treatment of head lice and scabies. The Food and Drug Administration (FDA) approves use of the pesticide-containing pharmaceutical under FFDCA.

Use Classification:	Permethrin is a restricted use pesticide for crop and wide area applications (i.e. nurseries, sod farms) due to high toxicity to aquatic organisms. It is a general use pesticide for residential and industrial applications.
Formulation Types:	Permethrin formulations include emulsifiable concentrate, wettable powders, dusts, granular, and ready-to-use formulations.
Application Methods:	Permethrin application methods include broadcast or banded application using ground or aerial application; handheld equipment such as low and high pressure hand wand sprayers, handgun sprayers, backpack sprayers, hose-end sprayer, paint brush, foggers, and dip applications; automatic mister systems; and a number of ready-to-use methods such as shaker and aerosol cans, wipes, ear tags and flanges.
Application Rates:	Permethrin application rates vary depending on the use pattern. For most agriculture uses, maximum seasonal rates range from 0.1 to 0.4 pounds active ingredient per acre (lb ai/A), and depending on the crop, the maximum number of permethrin applications per season can range from 1 to 8. The maximum application rate for the public health use of permethrin is 0.018 lb ai/A, however, the typical application rate ranges from 0.0035 to 0.007 lb ai/A, and the number of applications depends on the need of the abatement district. Application rates vary for residential use products depending on indoor or outdoor use, and consumer or professional or commercial operator use. The maximum residential application rate is use on turf, 0.87 lb ai/A.
Application Timing:	Permethrin can be applied pre- or post-emergence, and most labels suggest "as needed."

D. Estimated Usage of Permethrin

According to Agency data, approximately 2 million pounds of permethrin are applied annually to agricultural, residential and public health uses sites. The majority of permethrin, approximately 70%, is used in non-agricultural settings, whereas approximately 30% is used on food/feed crops in agricultural settings. According to the Pyrethroid Issues and Reregistration Task Force (PIRTF), approximately 1,450,000 pounds of permethrin active ingredient is used on non-agricultural sites per year; 55% is applied by professionals, 41% is applied by homeowners on residential areas, and 4% is applied on mosquito abatement areas.

The Agency's screening-level usage analysis (SLUA) of permethrin from 1998 to 2004 indicates that approximately 605,000 pounds of permethrin are used annually on agricultural use sites in the United States. In terms of pounds applied, the greatest use is on corn (100,000 lbs ai per year);

however, annually this represents between <1 to 5 percent of corn acreage treated. In terms of percent crop treated (%CT), the greatest use is on celery, pistachios, spinach, hazelnuts, and Brussels sprouts, with on average, $\geq 50\%$ crop treated. Table 1 summarizes the best estimates of permethrin usage currently available to the Agency.

Table 1. Estimated Annual Permethrin Crop Usage Summary¹

Crop	Pounds of Active Ingredient Used on Annual Basis	% Crop Treated	
		Average	Maximum
Alfalfa	40,000	<1	<2.5
Almonds	20,000	20	30
Apples	3,000	5	5
Apricots	<500	5	5
Artichokes	1,000	30	65
Asparagus	2,000	10	20
Avocados	1,000	5	10
Beans, Green	1,000	<1	5
Broccoli	3,000	15	30
Brussels Sprouts	<500	50	50
Cabbage	4,000	15	20
Cantaloupe	3,000	10	20
Cauliflower	1,000	15	25
Celery	8,000	65	85
Cherries	3,000	10	20
Chicory	<500	ND*	ND
Collards	<500	5	5
Corn	100,000	<1	5
Cotton	5,000	<1	<2.5
Cucumbers	5,000	10	15
Eggplant	<500	5	5
Garlic	1,000	15	20
Grapes	1,000	<1	<2.5
Greens, Turnips	<500	10	10
Hazelnuts (Filberts)	1,000	50	70
Lettuce	50,000	50	70
Onions	5,000	10	20
Other Lettuces	10,000	35	35
Peaches	10,000	20	25

Crop	Pounds of Active Ingredient Used on Annual Basis	% Crop Treated	
		Average	Maximum
Pears	1,000	5	10
Peas, Green	<500	<1	<2.5
Pecans	<500	<1	<2.5
Peppers	3,000	5	15
Pistachios	20,000	55	70
Potatoes	20,000	5	10
Prunes & Plums	<500	<1	<2.5
Pumpkins	4,000	15	20
Sorghum	2,000	<1	<2.5
Soybeans	20,000	<1	<2.5
Spinach	9,000	50	70
Squash	3,000	10	15
Strawberries	<500	<1	<2.5
Sweet Corn	30,000	15	30
Swiss Chard (CA only)	1,000	ND	ND
Tobacco	<500	<1	<2.5
Tomatoes	8,000	5	10
Walnuts	5,000	5	10
Watermelon	5,000	10	15

*ND – Not Determined

¹ Based on EPA data from 1998-2004.

III. Summary of Permethrin Risk Assessments

The following is a summary of EPA's revised human health and ecological risk assessments for permethrin, as presented fully in the documents, *Permethrin: Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated April 4, 2006, 2006, and *The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III*, dated April 5, 2006. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for permthrin. While the risk assessments and related addenda are not included in this document, they are

available from the OPP Public Docket EPA-HQ-OPP-2004-0385 and may also be accessed on the Agency's website at <http://www.regulations.gov>. Hard copies of these documents may be found in the OPP public docket under this same docket number.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children.

The EPA released its preliminary risk assessments for permethrin for public comment on August 31, 2005 for a 90-day public comment period (Phase 3 of the public participation process). The preliminary risk assessments may be found in the OPP public docket at the address given above and in EPA's electronic docket under docket number EPA-HQ-OPP-2004-0385. In response to comments received and additional data submitted during Phase 3, the risk assessments were updated and refined. The revised risk assessments may be found in the OPP dockets under the same docket number identified above. Scenario specific revisions to the human health risk assessment occurred based on exposure or usage data provided by the registrants or PIRTF for several occupational and residential uses. Major revisions to the permethrin human health risk assessment include the following:

- Revised drinking water concentrations provided in the *Revised Tier II Estimated Drinking Water Concentrations of Permethrin*, dated December 27, 2005, which is also available in the public docket; and
- Inclusion of wash-off data for the impregnated clothing exposure scenarios (residential and occupational), which assumes clothing is usable for up to 30 washes and that the first wash results in a 33% permethrin loss, the second wash results in a 6% loss, washes 3 through 10 each result in a 3% loss, and washes 11 through 30 result in a total loss of 6.5% permethrin. For more detail, on the wash-off assumptions refer to the *Third Revision of the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated January 31, 2006.

For more information on the permethrin revised human health risk assessment, see: *Permethrin: Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated April 4, 2006.

1. Toxicity of Permethrin

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage, and lifetime or chronic effects such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for

permethrin and has determined that the toxicological database is sufficient for each exposure scenario, FQPA evaluation, and for important endpoints and dose-response evaluation. However, the Agency is requiring a confirmatory developmental neurotoxicity study (DNT) for additional assurance as to the dose-response in characterizing neurotoxic effects. For more details on the toxicity and carcinogenicity of permethrin, see *Permethrin: Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated April 4, 2006, which is available under docket number EPA-HQ-OPP-2004-0385.

a. Acute Toxicity Profile

Permethrin is classified as category III for acute oral and acute dermal toxicity. No acceptable data on acute inhalation toxicity for permethrin technical is available (Data Gap). Permethrin is classified as category III for eye irritation potential and category IV for dermal irritation potential. Permethrin technical is not considered a skin sensitizer based on a weight-of-evidence evaluation of available data. The acute toxicity profile for permethrin is summarized in Table 2 below.

Table 2. Acute Toxicity Profile for Permethrin				
Guideline	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute Oral Toxicity in Rats	242899	LD ₅₀ = 3580 mg/kg (M) 2280 mg/kg (F)	III
870.1200	Acute Dermal Toxicity in Rabbits	242899	LD ₅₀ > 2000 mg/kg	III
870.1300	Acute Inhalation Toxicity in Rats	Data Gap		ND*
870.2400	Primary Eye Irritation in Rabbits	242899	Irritation 24-48 hrs. All cleared by 72 hrs.	III
870.2500	Primary Dermal Irritation in Rabbits	242899	All irritation cleared by 48 hrs.	IV
870.2600	Skin Sensitization in Guinea Pigs	EPA Memo**	Non-sensitizer***	Not Applicable

* ND: No Data

** EPA Memorandum, June 13, 1995, "Permethrin: Review of a series 81-6 dermal sensitization study (guinea pig maximization test) and a series 85-2 dermal penetration study."

*** Based on a weight of evidence evaluation of other sensitization study data do not indicate that permethrin should be regulated as a potential sensitizer.

b. FQPA Safety Factor Considerations

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA, directs the Agency to use an additional ten fold (10x) safety factor (SF) to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10x FQPA SF only if reliable data demonstrate that the resulting margin of safety would be safe for infants and children.

For permethrin, the database is adequate in terms of endpoint studies and dose response information to characterize any potential for prenatal or postnatal risk for infants and children. Developmental and reproductive toxicity studies demonstrated that there is no evidence (qualitatively

or quantitatively) for increased susceptibility to infants and children following *in utero* and/or pre/postnatal exposure to permethrin. Additionally, there is no evidence that permethrin induces any endocrine disruption.

There is, however, concern for developmental neurotoxicity based on evidence of neurotoxicity at high doses in a subchronic neurotoxicity study. The Agency is requiring a confirmatory developmental neurotoxicity study (DNT) for further characterization of neurotoxic effects. However, although a DNT is required, a dose-analysis with the existing reliable toxicity data for permethrin, that included an evaluation of the acute and subchronic neurotoxicity studies in addition to the 3-generation reproduction study, indicates that the results of the DNT would not have an impact on the risk assessment. Therefore, an FQPA database uncertainty factor (UF_{DB}) is not required for acute and chronic risk assessments or for residential (non-dietary) exposures. The Agency has determined that, based on the existing exposure and toxicity data for permethrin, the risk assessment, as conducted, indicates a reasonable certainty of no harm to infants and children. In addition, the dietary food exposure assessment demonstrates that acute and chronic exposures do not underestimate the risk and are not of concern, and the residential exposure assessment is based on reliable data and is unlikely to underestimate exposure and risk. Therefore, the FQPA SF is reduced to 1x.

c. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for permethrin are listed in Table 3 below. An estimated dermal absorption factor of 15% also is used in the risk assessment. The dermal absorption factor of 15% was estimated by comparing the Lowest Observed Adverse Effect Level (LOAEL) of the rat acute oral neurotoxicity study of 75 mg/kg/day and No Observed Adverse Effect Level (NOAEL) of the rat 21-day dermal study (because no LOAEL was established) of 500 mg/kg/day. The estimate is considered to be a conservative high-end estimate because the oral dose represents a LOAEL rather than a NOAEL. The uncertainty factors (UF) and safety factors used to account for interspecies extrapolation, intraspecies variability, and special susceptibility of infants and children (FQPA SF) are also described in Table 3.

Table 3. Toxicology Endpoints for Permethrin			
Exposure Scenario	Dose, Uncertainty Factors	FQPA Safety Factor and Level of Concern	Study and Endpoint for Risk Assessment
Acute Dietary (Females 13 to 49 years of age)	Acute RfD= not applicable	Since there is no developmental or reproductive toxicity of concern for permethrin, no appropriate endpoint or study was selected for the female (13-49) subgroup. The selected dose/endpoint for general population would provide adequate protection for females 13-49 years old.	

Table 3. Toxicology Endpoints for Permethrin			
Exposure Scenario	Dose, Uncertainty Factors	FQPA Safety Factor and Level of Concern	Study and Endpoint for Risk Assessment
Acute Dietary (General population including infants and children)	Oral NOAEL=25 mg/kg/day UF = 100X (10x interspecies and 10x intraspecies) Acute RfD= 0.25 mg/kg/day	FQPA SF = 1X aPAD= <u>Acute RfD</u> FQPA SF aPAD= 0.25 mg/kg/day	Acute Neurotoxicity Study in Rats LOAEL = 75 mg/kg/day based on observations of clinical signs (i.e. aggression, abnormal and/or decreased movement) and increased body temperature.
Chronic Dietary (All populations)	Oral NOAEL = 25 mg/kg/day UF = 100 Chronic RfD = 0.25 mg/kg/day	FQPA SF = 1X cPAD = <u>Chronic RfD</u> FQPA SF cPAD= 0.25 mg/kg/day	
Short- and Intermediate-Term Incidental Oral	Oral NOAEL = 25 mg/kg/day UF = 100	Residential LOC for MOE =100	
Short-, Intermediate-, and Long-Term Dermal	Dermal NOAEL = 500 mg/kg/day UF = 100	Residential LOC for MOE =100 Occupational LOC for MOE =100	21-Day Dermal Toxicity Study in Rats LOAEL was not established.
Short-, Intermediate-, and Long-Term Inhalation	Inhalation NOAEL = 0.042 mg/l (converts to oral equivalent of 11 mg/kg/day) UF = 100	Residential LOC for MOE =100 Occupational LOC for MOE =100	15-Day Inhalation Study in Rats LOAEL = 0.583 mg/l (converts to oral equivalent of 154 mg/kg/day) based on body tremors and hypersensitivity to noise.
Cancer (Oral, dermal, inhalation)	Classification: “Likely to be Carcinogenic to Humans” with a Q ₁ * (mg/kg/day) ⁻¹ = 9.6 x 10 ⁻³ (Dermal absorption rate=15% for dermal portion of the cancer equation)		
UF = uncertainty factor, FQPA SF = 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			

2. Carcinogenicity of Permethrin

As described in Table 3 above, the Agency classified permethrin as "Likely to be Carcinogenic to Humans" by the oral route. This classification was based on two reproducible

benign tumor types (lung and liver) in the mouse, equivocal evidence of carcinogenicity in Long-Evans rats, and supporting structural activity relationships (SAR) information. For the purpose of risk characterization, a low dose extrapolation model (Q_1^*) was used. The Q_1^* is 9.6×10^{-3} (mg/kg/day)⁻¹ and was derived from the female mouse lung (adenoma and/or carcinoma) tumors. For more information, see the document *Permethrin Report of the Cancer Assessment Review Committee (Third Evaluation)*, dated October 23, 2002.

3. Metabolites and Degradates

The Agency reviewed the metabolism of permethrin, and concluded that for tolerance expression and risk assessment, the parent (both *cis*- and *trans*-permethrin) is the only residue of concern for both plants and livestock, and drinking water exposure. For additional details refer to *Permethrin: Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, Dated April 4, 2006.

4. Permethrin Endocrine Effects

The EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including pesticides active and other ingredients) “may have an effect in humans similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” In the available toxicity studies on permethrin, there was no toxicologically significant evidence of endocrine disruptor effects. When additional appropriate screening and/or testing protocols being considered under the Agency’s Endocrine Screening Disruption Program have been developed, permethrin may be subject to further screening and/or testing to better characterize effects related to endocrine disruption.

5. Dietary Risk from Food and Drinking Water

EPA conducted acute, chronic, and cancer dietary (food and drinking water) risk assessments for permethrin using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA’s Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The acute and chronic non-cancer and cancer dietary risk assessments were conducted for all supported permethrin food uses. The estimated surface drinking water concentrations (EDWCs) for permethrin were calculated using the Tier II Pesticide Root Zone Modeling (PRZM) and Exposure Analysis Modeling System (EXAMS) and also includes the Index Reservoir (IR) and Percent Crop Area (PCA) factor requirements. The EDWCs from groundwater sources of drinking water were derived from the Tier I model SCI-GROW. The EDWCs were included in the DEEM-FCID analyses to estimate combined exposures from food and drinking water.

a. Dietary (Food and Drinking Water) Exposure Assumptions

As stated above, the acute dietary (food) risk assessment for permethrin was conducted using the DEEM-FCID™ computer model. Highly refined acute (probabilistic), chronic, and

cancer dietary exposure assessments were conducted to estimate the dietary risks associated with the reregistration of permethrin. Permethrin residue estimates used in these assessments include *cis*- and *trans*-permethrin, calculated as total permethrin, along with the Agency's percent crop treated data. The anticipated residue (AR) estimates are based primarily on the USDA Pesticide Data Program (PDP) food sampling data. Processing data was also used on a number of crops if available.

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or monitoring data, if available and of sufficient quality, to estimate those exposures. Permethrin is relatively persistent in the environment, and is stable to hydrolysis and photolysis. The parent compound has a very low mobility and has a high affinity to bind to soils/sediments and organic carbon; therefore, it is not expected to leach to groundwater. However, like several other chemicals in its class, it can reach surface waters by spray drift or in run-off events via erosion. Table 4 lists the EDWCs used to assess the exposure to permethrin in drinking water from surface water and groundwater sources. Based on screening-level model results, these values generally represent upper-bound estimates of the concentration that might be found in surface water and groundwater sources of drinking water. Because the surface water EDWCs from the screening-level PRZM-EXAMS model were higher than those predicted from the SCI-GROW model for groundwater sources, the relevant EDWC model value from surface water was used in the dietary exposure assessment conducted using the DEEM-FCID model to be protective.

Table 4. Permethrin Surface Water and Groundwater EDWC		
Drinking Water Source	Duration	EDWC (ppb)

*The surface water EDWCs are based on the Georgia onion use scenario – a maximum application rate of 0.285 lb ai/A and 7 applications per year.

**The groundwater EDWC is based on the California almond use scenario – a maximum application rate of 0.4 lb ai/A/year and 5 applications per year.

For more detail on the calculation of the EDWCs, refer to the *Second Revision Tier II Estimated Drinking Water Concentrations of Permethrin*, dated January 17, 2006 available in the public docket.

b. Population Adjusted Dose

The dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic dietary assessments, the risk is expressed as a percentage of a level of concern (i.e., the dose predicted to result in no unreasonable adverse health effects to any human

sub-population, including sensitive members of such sub-populations). This level of concern is referred to as the Population Adjusted Dose (PAD). Dietary risk is characterized in terms of the PAD, which reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA SF. For permethrin, the FQPA SF is 1x.

Estimated dietary risks less than 100% of the PAD, either acute (aPAD) or chronic (cPAD), are below the Agency's level of concern (LOC). The aPAD is the dose at which a person could be exposed at any given day with no adverse health effects expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime with no adverse health effects expected. Risk estimates from permethrin in food and drinking water are summarized in Table 5 below.

c. Acute and Chronic Dietary (Food and Drinking Water) Risk

Acute and chronic dietary risk estimates are provided for the general U.S. population and various population subgroups, with the major emphasis placed on the exposure estimated for infants and children. The Agency concluded that for all supported registered commodities, the acute and chronic (non-cancer) dietary (food and drinking water) risk estimates do not exceed the LOC (less than 100% of the aPAD and cPAD, respectively), with the highest exposed subgroup being infants (<1 year old) at 16% of the aPAD and <1% of the cPAD. Table 5 below summarizes the acute and chronic (non-cancer) risk estimates from dietary (combined food and drinking water) exposure to permethrin.

Table 5. Permethrin Dietary (Food + Drinking Water) Exposure Analysis Using DEEM FCID.				
Population Subgroup	Acute Exposure (mg/kg/day)*	% aPAD 99.9th Percentile	Chronic Exposure (mg/kg/day)*	% cPAD
U.S. Population	0.010971	4	0.000184	<1
Infants (<1 year old)	0.039416	16	0.000432	<1
Children 1-2 years	0.024494	10	0.000385	<1
*mg/kg/day = milligram per kilogram per day.				

d. Cancer Dietary (Food and Drinking Water) Risk

The cancer dietary assessment was conducted for the general U.S. population. To estimate cancer risk, the 70-year lifetime average daily exposure is multiplied by the cancer potency factor (Q_1^*) to yield a unitless number that represents the excess number of cancers potentially attributed to exposure to the pesticide over a lifetime. For the cancer dietary assessment, risk estimates within the range of an increased cancer risk of one in a million (1×10^{-6}) are generally below EPA's level of concern; however, the Agency generally considers risks up to 3×10^{-6} to be within the negligible risk range and below the Agency's LOC. A Q_1^* is an estimate of the upper bound on cancer risk.

The estimated lifetime average daily exposure of the general U.S. population to permethrin from food and drinking water is 0.000117 mg/kg/day. Applying the Q_1^* of 9.6×10^{-3} (mg/kg/day)⁻¹ to the exposure value results in a combined cancer risk estimate of 1.1×10^{-6} for food and drinking water, which is considered to be within the negligible risk range of 1×10^{-6} and does not exceed the Agency's LOC. See Table 6 below for cancer dietary risk estimates.

Table 6. Permethrin Cancer Dietary (Food + Drinking Water) Risk Estimates		
Dietary Exposures Assessed	Q_1^*	Cancer Risk Estimate
Food Alone	9.6×10^{-3} (mg/kg/day) ⁻¹	9.76×10^{-7}
Drinking Water Alone		1.52×10^{-7}
Food and Drinking Water Combined		1.1×10^{-6}

6. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in foods or in drinking water. Permethrin has a wide variety of residential uses, including use on pets, indoor and outdoor surfaces, turf and garden crops, and use of clothing (ready to use formulations or impregnation). Permethrin is also labeled as a mosquito adulticide, and can be used by Public Health Officials for mosquito abatement and other mosquito control programs. It can also be used for mosquito and general pest control in residential and commercial areas through outdoor automatic mister systems.

The Agency has determined that there is a potential for exposure to permethrin in residential settings for homeowners who handle (mix, load, and apply) products containing permethrin, as well as post-application exposure from entering permethrin-treated areas, such as lawns, home gardens, or indoor areas. Risk assessments have been completed for both residential handler and post-application scenarios.

To estimate residential non-cancer (dermal and inhalation) risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation), plus any additional FQPA SF retained due to concerns unique to the protection of infants and children. The FQPA SF for permethrin is reduced to 1x for reasons explained in section III.A.1.b.

To estimate the residential cancer risk, the lifetime average daily dose is calculated, which assumes the homeowner will be exposed to permethrin in the same manner for 50 years within a 70-year life span, and then multiplied by the Q_1^* value. Similarly, residential cancer risk estimates within the range of an increased cancer risk of one in a million (1×10^{-6}) are generally below EPA's level of concern; however, the Agency generally considers risks up to 3×10^{-6} to be within the negligible risk range and below the Agency's LOC. The cancer risk assessments also include the number of exposure events (handler and post-application) that could

occur per year before the estimated cancer risk reached the Agency's level of concern.

a. Residential Handler Risks

The Agency determined that exposure to homeowners handling a permethrin product is likely to occur via dermal (skin) and inhalation routes during the residential use of permethrin in a variety of indoor and outdoor environments, including use on lawns, gardens, ornamentals, indoor surfaces and spaces, and contact with pets. Permethrin is one of the most widely used pesticide active ingredients, and has an extraordinary number of use patterns. The risk assessment considered 25 major residential exposure scenarios, based on the types of equipment and techniques that can potentially be used to make permethrin applications; such as various handheld equipment, for example low pressure hand wand sprayers, backpack sprayers, hose-end sprayer, paint brush, and dip applications; automatic outdoor mister systems; and a number of ready-to-use (RTU) methods such as shaker and aerosol cans, wipes, ear tags and protective flanges. The use patterns assessed are considered to be representative scenarios that are believed to represent the vast majority of permethrin uses.

The Agency considered residential handler exposure scenarios to be short-term (1-30 days) only due to infrequency of use associated with homeowner products. According to the data submitted by the *Residential Exposure Joint Venture (REJV)*, which is a group of companies that conducted a survey of homeowners to ascertain how consumer pesticide products are used (e.g., rate, frequency, pests, etc), a permethrin product is used by homeowners on average 5 times a year. The residential risk assessment is also based on estimates of what and how much homeowners would typically treat, such as the size of the lawn or garden, based on the Agency's standard operating procedures for residential exposures and best professional judgment. For more information on the daily volume handled and the area treated used in each residential handler scenarios, refer to *Permethrin: Third Revision of the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006.

Non-cancer (dermal and inhalation) risks for homeowners handling permethrin products are below the Agency's LOC. The combined (dermal and inhalation) MOEs for all scenarios assessed are greater than 100 (ranging from 690 to 22 million) and are, therefore, not tabulated in this document, but are available in the document referenced above. For residential handler cancer risks, the Agency considered the REJV homeowner use pattern information discussed above, that homeowners use pesticide products on an average of 5 times a year, to assess whether homeowner use scenarios were above the Agency's LOC. Handler scenarios that result in a cancer risk estimate of $\leq 3 \times 10^{-6}$, which the Agency considers to be within the negligible cancer risk range, at 5 or more exposure events a year, are below the Agency's LOC and are similarly not tabulated in this document. All assessed residential handler cancer risk estimates are below the Agency's LOC at ≥ 5 exposure events per year, except for the eight use site scenarios listed in Table 7.

Table 7: Residential Cancer Handler Risk Estimates				
Exposure Scenario	Use Site	Application Rate	Area Treated Daily or Amount Applied per Day	# of Events per Year to Reach 3×10^{-6} LOC
Mixing/Loading/Applying				

Table 7: Residential Cancer Handler Risk Estimates				
Exposure Scenario	Use Site	Application Rate	Area Treated Daily or Amount Applied per Day	# of Events per Year to Reach 3×10^{-6} LOC
Emulsifiable Concentrates (EC) with Low Pressure Handwand	Outdoor surfaces	0.46 lb ai/gallon	5 gallons	3
	Ornamentals: outdoor trees	0.043 lb ai/gallon	5 gallons	3
	Perimeter treatment: outdoor wood surfaces	0.4 lb ai/gallon	5 gallons	3
EC with a Hose-End Sprayer	Ornamentals: outdoor tress	0.043 lb ai/gallon	100 gallons	<1
	Stored lumber, wood piles	0.04 lb ai/gallon	100 gallons	<1
	Ornamentals: outdoor	0.02 lb ai/gallon	100 gallons	3
EC via Sponge	Horses	0.005 lb ai/gallon	2 animals	2
Granulars via Belly Grinder	Turf	0.65 lb ai/acre	0.5 acres	2

For the complete residential handler assessment and risk estimates refer to the *Permethrin: Third Revision of the Occupational Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006. Additionally, refer to *Permethrin: Comparing Cancer Target Levels of Concern (1×10^{-6} vs 3×10^{-6})*, dated April 4, 2006, for refined residential cancer risk estimates.

The area treated daily used in the risk assessment for each scenario was based on the Agency's standard operating procedures for each application method. Additionally, the residential cancer risk assessment assumes a homeowner would be using a permethrin product in the manner assessed for 50 years of a 70-year lifetime. For most of these scenarios, the Agency does not believe they are feasible or likely to occur based on the frequency of application, amount of product handled, and the application method paired with the use patterns assessed above. For example, the Agency did not think it was likely that a homeowner would be applying 5 gallons of finished spray to outdoor surfaces, ornamentals, and perimeter treatments with a low pressure handwand more than three times a year, which would be a total of 15 gallons a year on these use sites. Further, the Agency does not believe it is likely that a homeowner would use a belly grinder to treat 0.5 acres of turf more than twice a year. Low pressure handwands and belly grinder are not conducive to handling a large amount of product (liquid or granular respectively) or treating a large area. The equipment would require multiple refills and would be labor intensive. Finally, the Agency does not believe a homeowner will be applying 100 gallons of finished spray in a day, as assumed above in the mixing/loading/applying EC formulated products with a hose-end sprayer scenario. Therefore, these scenarios are considered not to be of concern to the Agency. The Agency does not believe these scenarios are likely to occur in a year, and are highly unlikely to occur multiple times per year over 50 years.

The only handler scenario listed in Table 7 that the Agency considers to be of cancer risk concern is mixing/loading/applying the EC formulation via sponge to horses. The Agency believes that this use pattern is likely to occur as assessed. However, because the Agency lacked exposure data for this specific use pattern, data from a *Chemical Manufacturers Association*

(CMA) *Antimicrobial Exposure Assessment Study* was used to assess exposure to individuals who used wipes to apply antimicrobial pesticides. This study was judged to be the best available surrogate for this exposure scenario. While the wipe data from this study provides the best available information on handler exposure to sponge scenarios, there are some uncertainties associated with the data used, such as: good laboratory practices were not closely followed, extraction efficiencies were below the minimum level suggested in the guidelines, calibration of the air monitoring equipment resulted in much of the data being less than detection, and the limited number of replicates (the guidelines recommend 15 replicates). Therefore, although this scenario results in a risk estimate above the Agency's LOC, there are a number of uncertainties that may be addressed with better quality data.

b. Residential Post-Application Risks

The Agency refers to 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. Permethrin 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. Permethrin can also be used on companion animals, which can lead to exposure by contact with the treated animals. Further, permethrin is used in Public Health Abatement Programs as a mosquito adulticide, where it can be applied to wide areas through ultra-low volume (ULV) spraying, which can result in post-application exposure to the general population.

Permethrin is also used to treat clothing (ready to use formulations and impregnation), which can lead to exposure during use of the clothing. The Agency is aware that there are a variety of commercial application/impregnation methods currently being used to produce permethrin treated clothing, and that some of the new more technologically advanced application/impregnation methods will result in less exposure to individuals wearing this clothing. However, the Agency used the best available data collected from clothing treated with older and less technologically advanced application/impregnation methods when assessing post-application exposure to permethrin impregnated clothing. The Agency recently received a pilot exposure study based on a newer technologically advanced impregnation method currently being used by one permethrin registrant. This study is currently being reviewed by the Agency to determine the scientific viability and applicability of the study. However, based on a cursory review, the Agency has found that the "pilot study" (as it is referred to by the registrant) includes a very limited number of biomonitoring and patch replicates. Assuming a full review deems the study scientifically viable and applicable, it would appear that this pilot, product-specific exposure study suggests no risks in excess of those from the conservative assessment discussed above. Therefore, the Agency believes that the current assessment results in conservative and protective estimates of exposure and risk to permethrin impregnated clothing produced by any currently used application/impregnation method.

Unlike residential handler exposure, where the EPA assumed only adults will be handling and applying permethrin products, individuals of varying ages can potentially be exposed to permethrin when reentering or performing activities in areas that have been previously treated, wear permethrin treated-clothing, or have contact with treated companion animals. The

residential populations that were considered in the risk assessment include:

- **Residential adults engaged in:**
 - Mowing or exercising on a treated lawn,
 - Working in a treated garden,
 - Outdoor activities after a mosquito abatement public health ULV application (truck fogger and aerial spray),
 - Outdoor activities after the use of an outdoor residential mister system,
 - Playing/exercising on treated indoor surfaces, such as carpets and hard floors,
 - Pet contact activities, and
 - Wearing permethrin treated clothing.
- **Residential youth (representative age 10-12) engaged in:**
 - Working in a treated garden, and
 - Wearing permethrin treated clothing.
- **Residential toddlers (3 years) engaged in:**
 - Playing on a treated lawn,
 - Outdoor activities after a mosquito abatement public health ULV application (truck fogger and aerial spray),
 - Outdoor activities after the use of an outdoor residential mister system,
 - Wearing permethrin treated clothing,
 - Pet contact activities, and
 - Playing/exercising on treated indoor surfaces, such as carpets and hard floors.

Post-application exposures to permethrin for adults are most likely through the skin and inhalation routes (mosquito abatement scenarios), whereas children may also receive oral exposures from mouthing behaviors (i.e., hand-to-mouth, object-to-mouth, and soil ingestion).

Non-Cancer Risks

The non-cancer risks (dermal and inhalation) from post-application exposure to permethrin, for the scenarios listed above, including wearing impregnated clothing, are below the Agency's LOC for residential adults and youth (MOEs ranged from 120 to 500 billion) for adults and 3,700 to 48,000 for youth), and are, therefore, not tabulated in this document, but are available in *Permethrin: Third Revision of the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006. Additionally, most of the toddler risk estimates are also below the Agency's LOC (MOEs ranging from 140 to 250 billion); however, the incidental oral and dermal toddler post-application risk estimates for the indoor surface spray (carpet) scenario are of concern to the Agency (MOEs <100) and are listed in Table 8 below.

Table 8: Toddler Risk Estimates for Post-application Exposure to Permethrin			
Exposure Scenario	Route of Exposure	Application Rate	MOE on day of application

Table 8: Toddler Risk Estimates for Post-application Exposure to Permethrin			
Exposure Scenario	Route of Exposure	Application Rate	MOE on day of application
Hand to mouth activities on indoor surfaces - Spray (carpet)	Oral	0.0001 lb ai/sq. ft.	37
Indoor Surfaces (high contact activities)- Spray (carpet)	Dermal	0.0001 lb ai/sq. ft.	69

Both scenarios in Table 8 assume a 1% concentration of permethrin in a directed spray, a rate only used by professional applicators. Further, table 8 does not include aerosol sprays, which were assessed separately in the risk assessment referenced above, and are result in risk below the Agency's LOC (MOEs for oral and dermal exposure are 8,500 and 16,000, respectively).

The Agency also combines risk values from separate post-application exposure scenarios, when it is likely that they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. The non-cancer risk estimates for toddlers were combined since toddlers are the most sensitive population assessed, and are presented in Table 9 below.

Table 9: Permethrin Post-application Residential Scenarios for Combined Non-cancer Risk Estimates				
Post-application Exposure Scenario			Margins of Exposure (MOEs) (UF=100)	
			Individual Exposure	Combined (Total) Exposure
Toddler	Turf – Sprays (0.87 lb ai/A)	Dermal	12,000	6,400
		Hand to Mouth	15,000	
		Object to Mouth	250,000	
		Incidental Soil Ingestion	570,000	
Toddler	Indoor Carpet - Aerosols	Dermal	8,500	5,600
		Hand to Mouth	16,000	
Toddler	Indoor Carpet – Fogger	Dermal	410	270
		Hand to Mouth	770	
Toddler	Pet - Shampoo	Dermal	12,000	350
		Hand to Mouth	360	
Toddler	Pet- Dusts	Dermal	1,600	720
		Hand to Mouth	1,300	
Toddler	Impregnated Clothing: Long Sleeves/Long Pants	Dermal	2,700	2,400
		Object to Mouth	24,000	

The combined MOEs for the individual turf spray, indoor carpet-aerosol, indoor carpet-fogger, pet dust, pet shampoo, and impregnated clothing scenarios are all greater than 100, and therefore, do not exceed the Agency's LOC.

Cancer Risks

Similar to the residential handler cancer risk assessment, the post-application risk assessment includes the number of exposure events that could occur per year before the cancer

risk reached the negligible risk range ($\leq 3 \times 10^{-6}$) and assumes the same exposure occurring over a period of 50 years of a 70-year lifetime. Moreover, for indoor post-application exposure to toddlers, the Agency assumed 8 hours of exposure for carpet sprays, and 4 hours for vinyl flooring. Additionally, the post-application risk assessment assumed exposure to permethrin residues the same day the area was treated (i.e., day 0 residue), which are considered reasonably conservative assumptions, considering indoor residues are removed over time through cleaning and other indoor activities. Therefore, for example, 5 days of post-application exposure to day 0 residue, would assume 5 treatment event per year. Since the Agency assumed a residential handler would be applying a pesticide on average 5 times per year, the same assumption was used for post-application risk assessment, except for the impregnated clothing scenario. In general, the post-application risk estimates that reached the $\leq 3 \times 10^{-6}$ negligible risk range after 5 or more exposure events per year (over a period of 50 years of a 70-year lifetime) are considered to be below the Agency's LOC.

The same residential adult scenarios that were assessed for the non-cancer risk estimates were also assessed for the cancer risk estimates. All outdoor and pet contact scenarios assessed are below the Agency's LOC and are, therefore, not tabulated in this document. The number of exposure events per year (over a period of 50 years of a 70-year lifetime) to reach the cancer negligible risk level for these outdoor and pet contact scenarios are all > 5 (ranging from 18 to 365 days). However, two indoor scenarios are of concern to the Agency, and are presented in Table 10 below.

Table 10: Summary of Permethrin Post-application Residential Cancer Risks of Concern			
Exposure Scenario	Route of Exposure	Application Rate	# of Events/Year to Reach LOC
Indoor Surfaces (high Contact Activities) - Spray	Dermal	0.0001 lb ai/sq. ft.	<1
Indoor Surfaces (high contact activities)- Fogger	Dermal	0.0023 lb ai/s6 oz fogger	2

For the impregnated clothing scenario, the Agency estimated the number of days an article of clothing would typically be worn within a year's time. Unlike the other post-application scenarios, that considered each post-application exposure event to be day 0 residues, the Agency considered wash-off data to determine the potential exposure that would occur after each consecutive wear and wash of the garment. The Agency believes that consumers will primarily use permethrin treated clothing recreationally (i.e., weekends, outdoor activities, sporting events), as well as seasonally when mosquitoes are most active. Therefore, it is likely individuals will wear permethrin impregnated clothing more than 5 times per year, but highly unlikely that a consumer will wear a treated shirt 151 times per year, or treated pants and a long sleeve shirt 92 times per year, as presented in Table 11 below. Furthermore, the cancer risk assessment assumes that the consumer will wear the combination of permethrin treated clothing stated in Table 11 below each year for 50 years. Therefore, based on the use pattern discussed above, the cancer risk estimates for wearing impregnated clothing are below the Agency's LOC.

Table 11: Summary of Permethrin Post-application Impregnated Clothing Cancer Risks for Adults			
Exposure Scenario	Route of Exposure	Application Rate	# of Days/Year to Reach LOC
Impregnated Clothing: Long Sleeve	Dermal	0.125 mg ai/cm ²	151

Table 11: Summary of Permethrin Post-application Impregnated Clothing Cancer Risks for Adults			
Shirt			
Impregnated Clothing: Long Sleeve Shirt/Long Pants	Dermal	0.125 mg ai/cm ²	92

Permethrin is also used in outdoor residential misting systems. The Agency assessed the potential risks to both adults and toddlers exposed to permethrin during applications via outdoor residential misting systems. The MOE for adults by inhalation route is 160,000, and the MOE for toddlers is 69,000. The non-cancer risk estimates are below the Agency's LOC (MOE \geq 100). Further, it took 365 exposure events to reach the Agency's cancer LOC. The Agency does not believe an individual will be exposed to permethrin from an outdoor residential misting system application daily for 50 years. Therefore, the cancer risk estimate is below the Agency's LOC.

For the entire homeowner post-application assessment and risk estimates, refer to *Permethrin: Third Revision of the Occupational Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006. Additionally, refer to *Permethrin: Comparing Cancer Target Levels of Concern (1×10^{-6} vs 3×10^{-6})*, dated April 4, 2006, for refined residential cancer risk estimates.

7. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources or pathways: food, drinking water and, if applicable, residential or other non-occupational exposures. For permethrin, the Agency conducted a refined aggregate risk assessment that combines exposures across all pathways. The Agency included acute, chronic and cancer EDWCs directly in the dietary exposure assessments to calculate aggregate dietary (food + drinking water) risk. This was accomplished by using the relevant screening-level PRZM-EXAMS model value as a residue for drinking water (all sources) in the dietary exposure assessment conducted using the DEEM-FCIDTM model.

The short-term residential and other non-occupational exposure assessments consider all potential pesticide exposure, other than exposure due to residues in food and/or in drinking water. Each route of exposure (i.e., oral, dermal, inhalation) is assessed. Risk estimates from all relevant pathways (i.e., food, drinking water, and residential or non-occupational) for permethrin from all sources were calculated to assess aggregate risks. When aggregating exposure and risk from various sources, both the route and duration of exposure are considered. Exposure to multiple sources that are expected to co-occur are also considered in the aggregate risk estimate. In this case, preliminary results from the REJV survey were used to further refine the aggregate assessment. Again, the REJV survey is a 12-month longitudinal survey that examined pesticide use in a residential environment. The data evaluated by the Agency in this analysis were

information collected in 2001 and 2002.

The following scenarios were aggregated:

- Acute: food + drinking water
- Short-term
 - Food + drinking water + (lawn care and post-application vegetable garden)
 - Food + drinking water + (U.S. Population: handler lawn care and post-application indoor surface spray on carpet)
 - Food + drinking water + (U.S. population: handler lawn care and post-application vegetable garden)
 - Food + drinking water + (Females 13-49: handler lawn care and post-application indoor surface spray on carpet)
 - Food + drinking water + (Females 13-49: handler lawn care and post-application indoor surface spray on carpet)
 - Food + drinking water + (Toddler: post-application lawn and post-application indoor surface spray on carpet)
 - Food + drinking water + (Toddler: post-application lawn and post-application indoor surface spray on vinyl)
 - Food + drinking water + (Toddler: post-application lawn and post-application pet shampoo)
- Long-term (chronic): food + drinking water
- Cancer
 - Food + drinking water + (U.S. Population: handler lawn care and post-application vegetable garden)
 - Food + drinking water + (U.S. Population: handler lawn care and post-application indoor surface spray on carpet)

A technical registrant submitted an aggregate assessment for permethrin conducted with CARES (Cumulative and Aggregate Risk Evaluation System), a software program which performs single chemical, aggregate, and cumulative (multichemical) exposure and risk assessments. In the submission, exposures through food, drinking water, and residential pathways were assessed. The Agency reviewed and evaluated the CARES submission with respect to the internal guidelines and standard operating procedures for submission of probabilistic assessments. The Agency's review particularly focused on the residential pathways of exposure as these exposures were the main driver in the Agency's non-cancer deterministic aggregate assessment. Overall, the Agency concluded that the assessment submitted selected reasonable input parameters to estimate exposure to permethrin from the food and residential pathways. However, the CARES assessment does not reflect the revised EDWC developed in the *Second Revision Tier II Estimated Drinking Water Concentrations of Permethrin*, dated January 19, 2006, and instead relied on the EDWC developed from the State of Maine potato scenario in *Tier II Estimated Drinking Water Concentrations of Permethrin*, dated July 16, 2004. Both documents are available in the public docket. The CARES assessment only considered acute aggregate and short-term aggregate risks, and not cancer aggregate risks, and is discussed in more detail in the Acute Aggregate Risk and Short-Term Aggregate Risk sections below.

a. Acute Aggregate Risk

The acute aggregate risk estimate includes the contribution of risk from dietary (food + drinking water sources) only. Acute aggregate risk estimates from exposures to food and drinking water, associated with the use of permethrin, do not exceed the Agency's level of concern (<100% aPAD). The estimated acute dietary risk for the general U.S. population is 4% of the aPAD, and 16% of the aPAD for infants, the highest exposed population subgroup (see Table 5).

The CARES assessment reported dietary (food only) exposures (on a mg/kg per capita basis) and MOEs corresponding to the 99.9 percentile for both children 1-2 and adults 20-49. For children 1-2 years old, the CARES assessment reported food only exposures at the 99.9th percentile of 0.0269 mg/kg (equivalent to an MOE of 929). For adults 20-49, the food only exposures at the 99.9th percentile were 0.0107 mg/kg (equivalent to an MOE of 2,332). The CARES assessment also reported drinking water exposures (on a mg/kg per capita basis) and MOEs corresponding to the 99.9 percentile for both children 1-2 and adults 20-49. For children 1-2 years old, the drinking water exposures at the 99.9th percentile were 0.000749 mg/kg (equivalent to an MOE of 33,391). For adults 20-49, the CARES assessment reported drinking water exposures at the 99.9th percentile of 0.000447 mg/kg (equivalent to an MOE of 55,932). Again, these results do not reflect the results presented in the *Second Revision Tier II Estimated Drinking Water Concentrations of Permethrin*, dated January 19, 2006.

b. Short-Term Aggregate Risk

Aggregate short-term (1-30 days) risk estimates include the contribution of risk from chronic dietary sources (food + drinking water) and short-term residential sources. There are a number of exposure scenarios that could be aggregated. According to the preliminary results of the REJV survey, uses on lawns and on indoor crack and crevice sites account for the most use in the residential market place. For this assessment, the Agency used the REJV survey to determine the likelihood of a co-occurent application scenario.

For adult aggregate short-term risk, chronic food and drinking water exposures for the U.S. general population and for females 13-49 years of age were combined with residential handler and post-application exposures. Residential handler dermal and inhalation exposures for mixing/loading/applying EC formulated products with a low pressure handwand to lawns were combined with post-application exposures (dermal) for vegetable gardens. Residential handler dermal and inhalation exposures for mixing/loading/applying EC formulated products with a low pressure handwand to lawns were also combined with post-application exposures (dermal) for indoor carpet surface sprays.

To assess short-term aggregate risks for toddlers, chronic food and drinking water exposures for children 1-2 years of age were added to three separate combinations of post-application residential exposure scenarios that are likely to occur for toddlers, based on the REJV survey. These scenarios include 1) hand-to-mouth activity and dermal contact to lawns and indoor carpets; 2) hand-to-mouth activity and dermal contact to lawns and indoor vinyl floor sprays; and 3) hand-to-mouth activity and dermal contact to lawns and pets.

Table 12 summarizes the short-term aggregate risks to the general U.S. population, adult females (13-49), and toddlers. With the exception of post-application exposure of toddlers to treated lawns and indoor surfaces (carpets), the combined residues of permethrin from food, drinking water, and other potential residential exposures do not result in short-term aggregate risks of concern to population subgroups (MOEs >100).

Table 12: Estimated Short-Term Aggregate Risk for Permethrin [Dietary (food + drinking water) and Residential Exposures]							
Population	Residential Scenarios Included in the Aggregate	Short-Term Exposure					
		EPA's Aggregate LOC	MOE food + water	MOE incid. oral	MOE dermal	MOE inhalation	Aggregate MOE (dietary and residential)
U.S Pop	Lawn care, Postapp Vegetable	100	210,000	NA	4,200	1,000,000	4,100
	Lawn Care, Postapp Indoor Surface Spray on Carpet				120	1,000,000	120
Adult Female (13-49)	Lawn care, Postapp Vegetable	100	220,000	NA	4,200	1,000,000	4,100
	Lawn Care, Postapp Indoor Surface Spray on Carpet				120	1,000,000	120
Toddler (1-2)	Post-App Lawn Care, Post-App Indoor Surface Spray on Carpet	100	88,000	37	69	NA	24
	Post-App Lawn care, Post-App Indoor surface Spray on Vinyl	100	88,000	150	440	NA	110
	Post-App Lawn Care, Post-App Pet Shampoo	100	88,000	350	6,000	NA	330

The aggregate assessment considers the highest exposure, by route, from each scenario included. For example, for the aggregate assessment for toddlers, this considers post-application exposure from treated lawns and indoor surface sprays, the highest exposures result from the indoor surface sprays on carpet and vinyl. Therefore, the exposures from the indoor surface sprays are driving the aggregate risk estimates. For a detailed discussion of the short-term aggregate risk assessment and the REJV co-occurrence matrix, please refer to *Permethrin. Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document*, dated April 4, 2006.

The CARES assessment estimated residential exposures (on a mg/kg per capita basis) and MOEs corresponding to the 99.9th percentile for both children 1-2 and adults 20-49 based on the 11 residential scenarios reported in the REJV survey data, including indoor and outdoor use. For more detail on the input parameters used in the residential CARES assessment, refer to *Permethrin: Review of Valent BioSciences Corporation's CARES Aggregate Submission entitled "Preliminary Evaluation of Potential Aggregate Human Health Risks Associated with Agricultural and Consumer Uses of Permethrin"*, dated June 21, 2005, which is available in the

public docket.

The residential portion of the CARES assessment relied extensively upon the data from the REJV survey. Based on the information collected under the REJV and the scenarios used in the Agency's human health risk assessment, the CARES assessment included 15 residential uses [including lawn care operator/pest control operator (LCO/PCO) applications] for permethrin including lawn and vegetable garden care, wasp and hornet control, indoor crack and crevice treatments, termite treatments, pet care, indoor and outdoor fogger, indoor flying insect knockdown aerosols, impregnated clothing, indoor carpet aerosols, and public health mosquito control. The Agency verified that these scenarios are of most interest with respect to high-end exposures and most relevant for inclusion in the residential portion of an aggregate probabilistic risk assessment.

For children 1-2 years old, the CARES assessment reported exposures at the 99.9th percentile of 0.801 mg/kg (equivalent to an MOE of 624). For adults 20-49, the CARES assessment reported exposures at the 99.9th percentile of 0.337 mg/kg (equivalent to an MOE of 1484). These estimates are expressed on a *per capita* basis, i.e., all individuals (or all exposure-days) are considered and not just those individuals (or exposure days) on which an actual application occurs. This is a fundamental difference between the residential assessment calculations performed by the EPA in its assessment, in accordance with the Agency's standard operating procedures, and those performed in the CARES submission. The residential exposure estimates calculated by the Agency reflect exposure estimates to a user on the day of application, whereas those represented in the CARES assessment apply to all individuals (i.e., whether they are users or not, and on all days, and whether permethrin was used or not). The two methods of expressing risk cannot be considered directly comparable, but should rather be seen as two alternate ways in which exposures can be viewed. The Agency's short-term aggregate assessment is more conservative and is, therefore, relied upon in this document.

c. Intermediate-Term & Long-Term Aggregate Risk

All residential/recreational exposures are expected to be short-term (1-30 days) in duration. Therefore, no intermediate-term (1-6 months) aggregate risk was assessed. Moreover, because labeled uses indicate no long-term (>6 months) or chronic residential or other non-occupational exposures, chronic aggregate risk estimates include exposures from food and drinking water sources only. As indicated in Table 5, chronic aggregate risk, associated with the use of permethrin, do not exceed the Agency's level of concern for the U.S. population and all population subgroups (all populations were less than 1% of the cPAD).

d. Cancer Risk

Cancer food and drinking water exposures for the U.S. general population were combined with residential handler and post-application exposures similar to the short-term aggregate risk assessment. Residential handler dermal and inhalation exposures for mixing/loading/applying EC formulated products with a low pressure wand to lawns were combined, by exposure route, with post-application exposures (dermal) for vegetable gardens. Residential handler dermal and inhalation exposures for mixing/loading/applying EC formulated products with a low

pressure handwand to lawns was also combined, by exposure route with post-application exposures (dermal) for indoor carpet surface sprays.

Table 13 summarizes the cancer aggregate risk estimates associated with the use of permethrin. With the exception of exposure to indoor carpet sprays, the Agency can conclude that combined exposures to residues of permethrin from food, drinking water, and other potential residential use scenarios are within the negligible risk range of $\leq 3 \times 10^{-6}$ and do not result in cancer aggregate risks of concern.

Table 13: Estimated Permethrin Cancer Aggregate Risk				
Population	Residential Scenarios Included in Aggregate	Cancer Risk from Dietary	Cancer Risk from Residential	Aggregate Cancer Risk (Dietary and Residential)
U.S. Pop	Lawn Care, Postapp Vegetable	1.1×10^{-6}	4.3×10^{-7}	1.5×10^{-6}
	Lawn Care, Postapp Indoor Surface Spray on Carpet		1.4×10^{-5}	1.5×10^{-5}

Similar to the short-term aggregate risk assessment, the aggregate cancer assessment considers the highest exposure from each scenario included. For a detailed discussion of the aggregate cancer risk assessment and the REJV co-occurrence matrix, please refer to *Permethrin. Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document*, dated April 4, 2006.

e. Permethrin Pesticide and Pharmaceutical Use Co-Exposure Assessment

As indicated above, in determining the risk to human health, the Agency examines more than just dietary exposures. Section 408 of FFDCA requires EPA to consider potential sources of exposure to a pesticide in addition to the dietary sources expected to result from a pesticide use subject to the tolerance. In order to determine whether to maintain a pesticide tolerance, EPA must “determine that there is a reasonable certainty of no harm. . . .” Under FFDCA section 505, the Federal Drug Administration reviews human drugs for safety and effectiveness and may approve a drug notwithstanding the possibility that some patients may experience adverse side effects. EPA does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical patient the same as a non-patient, or to assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the patient constitutes “harm” under the meaning of section 408 of the FFDCA.

Rather, EPA believes the appropriate way to consider the pharmaceutical use of permethrin in its risk assessment is to examine the impact that the additional non-occupational pesticide exposures would have to a pharmaceutical patient exposed to a related (or, in some cases, the same) compound. Where the additional pesticide exposure has not more than a minimal impact on the pharmaceutical patient, EPA could make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA. If the potential impact on the pharmaceutical user as a result of co-exposure from pesticide use is more than minimal, then EPA and FDA could discuss appropriate measures to reduce exposure

from one or both sources. The Agency provided its findings with respect to permethrin to FDA in a letter dated August 10, 2005, which is available on the public docket (EPA-HQ-OPP-2004-0385).

The exposure estimates used in the determination of permethrin pharmaceutical and pesticide co-exposure assessment, attachments A and B to the August 10, 2005 letter referenced above, reflect the external dermal dose of permethrin a patient treated with a pharmaceutical permethrin product would receive in a reasonable worst-case scenario. EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with exposure to the pharmaceutical use of permethrin. Using the permethrin 1% and 5% registered pharmaceutical labels, EPA estimated exposure from a typical treatment of both products, and compared those to the potential exposure an individual would receive from the pesticide uses of permethrin. Because the permethrin 1% and 5% creams are used over a 10 minute period and an 8 - 14 hour period, respectively, EPA considers the pharmaceutical use as a short-term exposure. To estimate combined pesticide exposure for a short-term scenario, EPA integrated average dietary exposure estimates (food + drinking water) with one of the non-occupational exposure scenarios (i.e. post-application to permethrin treated residential lawns). EPA chose the treated residential lawn exposure scenario because this application is a reasonable high-end scenario, and the REJV survey data showed this use to be among the most frequent exposure scenarios.

EPA estimates that the permethrin exposure a patient is expected to receive from a typical single application of Nix (1%) and Elimate (5%) creams, respectively, is 450 to 2300 times greater than the combined exposure from the dietary and other non-occupational sources of permethrin. FDA has reviewed these estimates and determined that pesticide exposure in patients receiving treatment with a pharmaceutical permethrin drug product would fall within the expected range of exposure following treatment with permethrin drug product alone, and would not present an increased safety risk.

8. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying the pesticide, or re-entering a treated site. For dermal and inhalation exposures, worker risk is estimated by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the No Observed Adverse Effect Level (NOAEL) selected from animal studies. Please see Table 3 for the toxicological endpoints used in the permethrin occupational assessment. The risk assessment for short-term (1-30 days) and intermediate-term (1-6 months) occupational exposures are similar because the toxicity endpoints (NOAELs) are numerically the same, and the target MOE of 100 is the same for both durations. Based on the registered use patterns of permethrin, long-term (> 6 months) handler exposure is not expected to occur for permethrin. The dermal and inhalation risks were combined for all scenarios assessed because the adverse effects for the dermal and inhalation routes of exposure were the same (neurotoxicity). Since permethrin is currently classified as a "likely to be carcinogenic to humans," the Agency assessed both cancer and non-cancer risks for occupational handlers and post-application workers. A dermal absorption factor of 15% was used for the dermal component of the cancer equation for the cancer risk assessment.

For permethrin, MOEs that are greater than 100 and cancer risks within the range of an increased cancer risk of 1×10^{-6} generally do not exceed the Agency's level of concern. However, when occupational MOEs are less than 100 or occupational cancer risks exceed 1×10^{-6} , EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls. The Agency generally considers occupational cancer risks within the range of 1 to 3×10^{-6} (approximately 1-3 in 1 million persons) or less to be negligible, but will consider risks as high as 1×10^{-4} (1 in 10,000 persons) when all mitigation measures that are practical and feasible have been applied and when there are critical pest management needs associated with the use of the pesticide.

a. Occupational Handler Exposure and Risk

Exposure to permethrin by pesticide handlers (mixers, loaders, applicators and flaggers) is likely during the use of permethrin based on the type of equipment and techniques that can potentially be used. Thirty-nine occupational exposure scenarios were assessed based on registered labels, equipment, and techniques that could be used for permethrin applicators. Due to the scope of the various permethrin occupational uses (there are over 900 registered permethrin products), it would be difficult to assess each individual exposure scenario. Therefore, the following selected scenarios are representative of the worse-case exposure scenarios to represent the major ways permethrin can be handled in the occupational environment. The scenario numbers correspond to the non-cancer and cancer risk estimate tables presented in the *Permethrin: Third Revision of the Occupation and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006. Scenarios denoted with a "*" could not be evaluated quantitatively because applicable unit exposure data are not available; however, the Agency believes other assessed scenarios are protective of these specific, and specialized, uses.

Mixer/Loaders:

- 1a Liquids for Aerial Applications;
- 1b Liquids for Groundboom Applications;
- 1c Liquids for Airblast Applications;
- 1d Liquids for Truck Mounted ULV Applications;
- 1e Liquids for Dip Applications;
- 1f Liquids for Residential Mister Systems;
- 2a Wettable Powder for Aerial Applications;
- 2b Wettable Powder for Groundboom Applications;
- 2c Wettable Powder for Airblast Applications;
- 2d Dusts for Mechanical Duster Applications (using PHED WP mixer/loader data);
- 2e Dusts for Dust Bag Applications (using PHED WP mixer/loader data);
- 3a Granulars for Aerial Applications;
- 3b Granulars for Tractor Drawn Spreader Applications

Applicators:

- 4 Aerial Applications (Sprays);
- 5 Groundboom Applications;

- 6 Airblast Applications;
- 7 Truck Mounted ULV Applications;
- 8 Dip Applications*;
- 9 Aerial Applications;
- 10 Tractor Drawn Spreader Applications (Granulars);
- 11 Mechanical Duster Applications*;
- 12 Dust Bag Applications*;

Flaggers:

- 13 Flagging for Aerial-Sprays;
- 14 Flagging for Aerial-Granulars;

Mixing/Loading/Applicators:

- 15 Liquid: Low Pressure Handwand Sprayer;
- 16 Liquid: Handgun Sprayer;
- 17 Liquids: High Pressure Handwand Sprayer;
- 18 Liquid: Termite Injector;
- 19 Liquid: Foam Applicator Equipment (using ORETF low pressure handwand data);
- 20 Liquid: Watering Can (using ORETF residential hose end sprayer data);
- 21 Liquid: Backpack ULV Sprayer (using ORETF low pressure handwand data);
- 22 Liquid: Paint Brush;
- 23 Liquid: Cold Fogger*;
- 24 Wettable Powder: Low Pressure Handwand Sprayer;
- 25 Wettable Powder: Handgun Sprayer;
- 26 Wettable Powder: High Pressure Handwand Sprayers*;
- 27 Water Soluable Bag: Handgun Sprayer;
- 28 Wettable Powder: Cold Fogger*;
- 29 Dusts: Shaker Cans;
- 30 Liquid: Fogger/Mister Generator*;
- 31 RTU: Liquid: Pour On Applications (using PHED mixing/loading liquid data);
- 32 RTU: Ear Tag Applications*;
- 33 RTU: Hand Applications (Shampoos)*;
- 34 RTU: Wipe Applications*;
- 35 RTU: Trigger Pump Sprayer Applications;
- 36 RTU: Aerosol Cans;
- 37 RTU: Fogger (using PHED aerosol can data);
- 38 RTU: Protective Flanges*;
- 39 RTU: Vapor Recovery Systems Tubes*.

The level of personal protective equipment (PPE) varies on the numerous permethrin labels. Some labels only require the minimum level of PPE, while others require additional PPE, such as chemical-resistant gloves, respirators, etc., depending on the labeled handler activity. Therefore, the Agency considered the following levels of PPE or engineering controls in the occupational non-cancer and cancer exposure assessments:

- Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator. (Baseline)
- Baseline plus chemical-resistant gloves, and no respirator. (PPE-G-NR)
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator. (PPE-G-DL-NR)
- Baseline plus chemical-resistant gloves and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-80%R)
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-DL-80%R)
- Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit. (EC)

No chemical-specific information was available for permethrin handler exposure assessments. Therefore, the Agency used the Pesticide Handler Exposure Database (PHED, Version 1.1, 1998) data, as well as acceptable surrogate exposure data, to calculate unit exposure values to estimate occupational handler exposures to permethrin for each scenario assessed.

For each of the 39 handler scenarios above, the Agency considered numerous crops or target use sites with various application rates and area treated daily to reflect the way in which permethrin can be applied (approximately 200 various use patterns were assessed). Additionally, due to the broad spectrum use of permethrin, the Agency believes that occupational exposure can occur over a single day or up to a week's time for many use-patterns, and intermittent exposure over several weeks are also anticipated. Therefore, the non-cancer risk assessment considers both short- (1-30 days) and intermediate-term (1-6 months) exposure to permethrin, and dermal and inhalation exposures are combined.

Non-Cancer Risks

The majority of the non-cancer risk estimates were below the Agency's level of concern, MOEs ranged from 120 to 200 million, when baseline PPE and chemical-resistant gloves were applied and are, therefore, not tabulated in this document; however, six of the approximately 200 use patterns assessed required additional PPE before the risk estimates were below the Agency's LOC and are listed in Table 14. The number next to each scenario corresponds to the handler scenarios listed above, and the non-cancer risk estimate tables and calculations in the *Permethrin: Third Revision of the Occupation and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006, which is available in the public docket.

Table 14. Summary of Permethrin Non-Cancer Handler Risk Estimates Requiring PPE greater than Baseline and Gloves									
Exposure Scenario	Crop or Use	Max. Application Rate	Max. Area Treated Daily	Baseline	PPE-G-NR	PPE-G-DL-NR	PPE-G-80%R	PPE-G-DL-80%R	EC
Mixer/Loader (M/L)									
M/L Wettable Powder (WP) for Aerial	Corn: Sweet (FL only)	0.25 lb ai/A	1200 acres	21	55	56	650	840	ND

Table 14. Summary of Permethrin Non-Cancer Handler Risk Estimates Requiring PPE greater than Baseline and Gloves									
Exposure Scenario	Crop or Use	Max. Application Rate	Max. Area Treated Daily	Base-line	PPE-G-NR	PPE-G-DL-NR	PPE-G-80%R	PPE-G-DL-80%R	EC
Mixer/Loader (M/L)									
Application (2a)	Alfalfa, corn (field, pop, seed, sweet), corn: field (preplant), range grasses, soybeans	0.2 lb ai/A	1200 acres	26	69	70	820	1100	ND
Loading Dusts via Mechanical Duster (2d)	Animal: poultry	0.0025 lb ai/animal	100000 animals	25	66	67	780	1000	ND
Mixer/Loader/Applicator (M/L/A)									
M/L/A WP via Low Pressure Handwand (24)	Conifer: field grown	0.2 lb ai/gal	40 gal	ND	75	78	500	680	NF
M/L/A Emulsifiable Concentrates via Cold Fogger (23)	Mushroom Houses	0.0078 lb ai/sq ft	40000 sq ft (8000 sq ft per house)	ND	ND	4000*	ND	ND	ND
	Indoor Spaces	0.00036 lb ai/cu ft	200000 cu ft	ND	35000*	ND	ND	ND	ND

Four of the scenarios, wettable powder and dust formulations, in Table 14 require baseline PPE with chemical-resistant gloves and respirator (PPE-G-80%R) to be worn by workers before the estimated MOEs are >100 and are, therefore, below the Agency's LOC at this level of PPE. The two emulsifiable concentration scenarios with a ULV cold fogger applicator are below the Agency's LOC with double layer PPE.

Cancer Risks

The occupational handler cancer risk assessment considered the same use patterns (approximately 200) for each handler activity listed above. Based on EPA information, it is assumed that all handlers (small, medium, and large scale growers, as well as commercial applicators) would handle permethrin approximately 10 days per year. In addition, a 35-year career and a 70-year life span were considered in the cancer risk estimate calculations. PPE and engineering controls were also evaluated in the assessment.

The estimated cancer risks for the majority of grower scenarios are also within the negligible risk range ($\leq 3 \times 10^{-6}$) or less with baseline PPE and gloves and were, therefore, below the Agency's LOC and not tabulated in this document. However, 45 of the approximately 200 use patterns assessed results in risk in the 10^{-5} to 10^{-6} range at this level of PPE, and either require additional PPE before the cancer risk estimates are below the negligible risk range of $\leq 3 \times 10^{-6}$, have no data available to estimate risk, or further mitigation measures are not feasible. Table 15 below presents the predicted cancer risk estimates for these scenarios at the baseline PPE and gloves, and lists the required level of PPE at which the cancer risk estimate reaches the

negligible risk range. The handler scenarios are grouped by formulation, and, again, the number next to each scenario corresponds with handler scenarios listed in the section above.

Table 15: Permethrin Occupational Handler Cancer Risk Estimates Between 10 ⁻⁴ and 10 ⁻⁶					
Exposure Scenario	Use Site	Application Rate	Area Treated Daily or Amount Applied per Day	Baseline PPE & Gloves	PPE to Reach LOC
Wettable Powders					
Mixing/loading Wettable Powder for Aerial Applications (2a)	Pine seed orchard	1.2 lb ai/A	100 acres	1.50x10 ⁻⁵	EC
	almonds, apples, filberts, pears (dormant & pre-bloom combo), pistachios, walnuts	0.4 lb ai/A	350 acres	1.80x10 ⁻⁵	EC
	artichokes, garlic, nectarines, onion: dry: bulb, peaches	0.3 lb ai/A	350 acres	1.30x10 ⁻⁵	EC
	Corn: sweet (FL only)	0.25 lb ai/A	1200 acres	3.80x10 ⁻⁵	EC
	Corn: sweet (FL only)	0.25 lb ai/A	350 acres	1.10x10 ⁻⁵	EC
	alfalfa, corn (pop, field, seed, sweet), corn: field (preplant), range grasses, soybeans	0.2 lb ai/A	1200 acres	3.10x10 ⁻⁵	EC
	Cabbage, Chinese cabbage, corn (pop, seed, sweet), cucurbits, eggplant, leafy vegetables, peppers: bell, potatoes, tomatoes, tomatillos	0.2 lb ai/A	350 acres	9.00x10 ⁻⁶	EC
	asparagus, broccoli, Brussels sprouts, cauliflower, Chinese broccoli, collards	0.1 lb ai/A	350 acres	4.50x10 ⁻⁶	PPE-G-80%R
Mixing/loading Wettable Powder for Groundboom (2b)	corn: sweet (FL only)	0.25 lb ai/A	200 acres	6.40x10 ⁻⁶	PPE-G-DL-80%R
	alfalfa, corn (pop, field, seed, sweet), corn: field (preplant), range grasses, soybeans	0.2 lb ai/A	200 acres	5.1x10 ⁻⁶	PPE-G-80%R
Mixing/loading/applying Wettable Powder with Low Pressure Handwand (24)	Conifers (field grown)	0.2 lb ai/gallon	40 gallons	3.60x10 ⁻⁵	PPE-G-DL
Mixing/loader/applying Wettable Powder with a Handgun Sprayer (25)	confier (field grown)	0.2 lb ai/gallon	40 gallons	6.40x10 ⁻⁵	PPE-G-DL
	rose: field grown	0.02 lb ai/gallon	40 gallons	6.40x10 ⁻⁶	PPE-G-DL
Mixing/loading/applying Water Soluable Bags with Handgun Sprayer (27)	Chrysanthemum	0.005 lb ai/gallon	1000 gallons	4.10x10 ⁻⁶	PPE-G-DL
	rose: greenhouse, ornamental nursery stock (non-bearing)	0.002 lb ai/gallon	1000 gallons	4.10x10 ⁻⁵	PPE-G-DL
Mixing/loader/applying Wettable Powder with a High Pressure Handwand (26)	rose: field grown	0.02 lb ai/gallon	1000 gallons	ND	ND
	Chrysanthemum	0.005 lb ai/gallon	1000 gallons	ND	ND
	rose: greenhouse	0.002 lb ai/gallon	1000 gallons	ND	ND

Table 15: Permethrin Occupational Handler Cancer Risk Estimates Between 10^{-4} and 10^{-6}

Exposure Scenario	Use Site	Application Rate	Area Treated Daily or Amount Applied per Day	Baseline PPE & Gloves	PPE to Reach LOC
Mixing/loader/applying Wettable Powder with via Cold Fogger (28)	mushroom houses	0.0078 lb ai/sq ft	40000 sq ft (8000 sq ft per house)	1.2×10^{-6}	PPE-G-DL
	Indoor surfaces	0.00036 lb ai/cu ft	200000 cu ft	2.8×10^{-7}	PPE-G-DL
Emulsifiable Concentrate (EC)					
Applying EC via dip (8)	animal: livestock (beef and dairy cattle), horses, swine	0.0023 lb ai/animal	400 animals	ND	ND
	animal: dogs	0.005 lb ai/dog	10 gallons	ND	ND
	Military battle dress	0.0000011 lb ai/cm ² of fabric		ND	ND
Mixing/loading/applying EC with a handgun sprayer (16)	Conifers (field grown)	0.2 lb ai/gallon	1000 gallons	2.80×10^{-5}	NF
	perimeter treatment	0.08 lb ai/gallon	500 gallons	5.5×10^{-6}	PPE-G-DL
	ornamental: outdoor	0.046 lb ai/gallon	1000 gallons	6.30×10^{-6}	PPE-G-DL-80%R
Mixing/loading/applying EC with low pressure handwand (15)	Termites	33.2 lb ai/1000 linear feet	1000 linear feet	5.90×10^{-6}	PPE-G-DL-90%R
Mixing/loading/applying EC with a high pressure handwand (17)	rose: field grown	0.02 lb ai/gallon	1000 gallons	1.90×10^{-5}	PPE-G-DL
	agricultural premises	0.012 lb ai/gallon	1000 gallons	1.10×10^{-5}	PPE-G-DL
	Chrysanthemum	0.005 lb ai/gallon	1000 gallons	4.60×10^{-6}	PPE-G-DL
	animal: poultry	0.00027 lb ai/animal	4000 gallons	2.50×10^{-5}	PPE-G-DL
Mixing/loading/applying EC Liquids via Fogger/Mist Generator (30)	Animal premises	0.012 lb ai/1000 sq ft.	1000 sq ft	ND	ND
	indoor spaces	0.00036 lb ai/1000 cu ft.	1000 cu ft	ND	ND
Mixing/loading/applying EC with an injector (18)	Termites	0.08 lb ai/gallon	2000 gallons	1.70×10^{-5}	PPE-G-DL
Dust Formulation					
Applying Dusts via Mechanical Duster (11)	animal : dairy and beef cattle, horses	0.000031 lb ai/animal	400 animals	ND	ND
	animal : poultry	0.0025 lb ai/animal	100,000 animals	ND	ND
	animal: swine	.00016 lb ai/animal	400 animals	ND	ND
Applying Dusts via Dust Bag (12)	animal : dairy and beef cattle, horses	0.000031 lb ai/animal	400 animals	ND	ND

Table 15: Permethrin Occupational Handler Cancer Risk Estimates Between 10^{-4} and 10^{-6}

Exposure Scenario	Use Site	Application Rate	Area Treated Daily or Amount Applied per Day	Baseline PPE & Gloves	PPE to Reach LOC
	animal: swine	.00016 lb ai/animal	400 animals	ND	ND
Loading Dusts via Mechanical Duster (2d) - using PHED data for WP	animal: poultry	0.0025 lb ai/animal	100000 animals	3.20×10^{-5}	NF
Applying ready to use formulations via RTU Ear Tag (32)	Animal	0.0044 lb ai/2 ear tags	400 cattle (2 tags/cattle)	ND	ND
Applying RTU formulations via hands (33)	animal: dogs	0.0062 lb ai/animal	8 animals	ND	ND
Applying RTU formulations via wipes (34)	animal: dogs, horses	0.0062 lb ai/animal	8 animals	ND	ND
Applying RTU formulations via Protective Flanges (38)	Ants	ND	ND	ND	ND
Applying RTU Vapor Recovery Systems (39)	Engines	0.000189 lb ai/tube	ND	ND	ND

ND= No Data
 NF= Not feasible to reach 10^{-6} range with highest level of PPE.

None of the occupational handler scenarios assessed in Table 15, for which there is available exposure data, have non-cancer MOEs <100 or cancer risks estimates greater than 1×10^{-4} at some level of PPE. Further, most cancer risk estimates are less than 1×10^{-6} with some level of PPE. However, there are several occupational scenarios that the Agency was unable to assess due to lack of data. The Agency believes that other scenarios assessed are appropriate surrogates for some of these uses. In other cases, where the use is specialized and/or the Agency does not believe other scenarios assessed are an appropriate surrogate for the use, the Agency will require additional data.

b. Occupational Post-Application Exposure and Risk

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 (also referred to as reentry exposure). There are distinct job functions or tasks related to the kinds of activities that occur in previously treated areas. Job requirements (e.g., the kinds of jobs to cultivate a crop), the nature of the crop or target that was treated, and the degradation of residues in the environment can cause exposure levels to differ over time. Each factor has been considered in this assessment. Additionally, the EPA considered post-application risks for both agricultural scenarios and impregnated clothing scenarios.

i. Agricultural Scenarios

To assess post-application exposures and risks, the Agency estimates the amount of contact with a treated surface a worker likely would have while doing a specific post-application task or activity, such as hand harvesting, conducting scouting activities, crop maintenance tasks

(e.g., irrigating, hoeing and weeding), and turf maintenance. To determine the amount of post-application exposure for each crop and post-application activity, the EPA used dislodgeable foliar residue (DFR) and turf transferable residue (TTR) data in the post-application risk assessment. The Agency's standard transfer coefficients were also used to assess worker reentry exposures. EPA has received permethrin-specific post-application DFR data on cotton and peaches, as well as TTR data from treated turf. DFR data do not cover all crops treated with permethrin; therefore, the existing DFR data were extrapolated to the remaining crops by considering the effects of application method, crop type, and climate.

Post-application exposures are calculated by multiplying the DFR or TTR concentrations and transfer coefficients factors by an 8 hour work day. Exposures are then normalized by body weight and adjusted for dermal absorption (if necessary) to calculate absorbed doses. Risk estimates were then calculated. Post-application risks diminish over time because permethrin residues eventually dissipate in the environment. As a result, risk values were calculated over time based on the specified retreatment interval and the changing residue levels over that time. Permethrin labels specify retreatment intervals as needed or 7 days, except for conifers grown for seed where the retreatment interval is 28 days. The risk assessment assumed the average foliar residue between 1 to 7 days for all crop scenarios, except conifer seed cone harvesting, which assumed an average foliar residue value between 1 to 28 days.

The use of personal protective equipment or other types of equipment to reduce exposures for post-application workers is not considered a viable alternative for the regulatory process. This is described in some detail in EPA's Worker Protection Standard (40CFR170). However, the Restricted-Entry Interval (REI) is an approach to reduce the risks. The REI is the required time period following a pesticide application during which entry into the treated area is restricted. The REI on current permethrin labels is 12 hours.

EPA assessed the post-application exposure to permethrin to both hired hand and migrant agricultural workers. The Agency assumed growers and hired hands would perform post-application activities 10 days per year and migrant workers would perform post-application activities 30 days per year. Inhalation exposures are thought to be negligible in outdoor post-application scenarios, because of the low vapor pressure and due to the infinite dilution expected outdoors. As such, inhalation post-application exposures are not considered in this assessment. The Agency assessed 20 post-application crop scenarios, with various post-application activities or tasks associated with each crop scenario.

For short- and intermediate-term post-application exposure, the target MOE is 100. For all agricultural post-application scenarios assessed, the non-cancer risks do not exceed the level of concern (MOEs > 100) on the day of application, approximately 12 hours following application. The MOEs range from 1,900 to 130,000 and are, therefore, not tabulated in this document. A summary of the results for each post-application crop/activity combination considered is detailed in the *Permethrin: Third Revision of the Occupation and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006.

As stated in the section above, the Agency generally considers occupational cancer risks within the range of 1 to 3×10^{-6} (approximately 1-3 in 1 million persons) or less to be negligible,

but will consider risks as high as 1×10^{-4} (1 in 10,000 persons) when all mitigation measures that are practical and feasible have been applied and when there are critical pest management needs associated with the use of the pesticide. Most of the post-application cancer risk estimated for both hired hands and commercial/migratory farm workers are in the 10^{-5} to 10^{-7} range. The highest risk estimates, in the 10^{-4} range, are for conifer seed cone harvesting and thinning of certain fruit trees. Table 16 below summarizes the post-application scenarios for migratory workers that result in cancer risk estimates between 10^{-4} and 10^{-6} . These present the worst case cancer risk estimates since the Agency assumed migratory workers are exposed to post-application residues of permethrin for 30 days per year for 35 years.

Table 16: Permethrin Occupational Post-Application Cancer Risk Estimates for Migrant Workers Between 10^{-4} and 10^{-6}		
Crop	Activity	Cancer Risk Estimate (30 days/yr for 35 yr)
conifer seed orchard	seed cone harvesting	1.90×10^{-4}
apples, pears	thinning	9.60×10^{-5}
	hand-weeding, irrigation, scouting	4.80×10^{-5}
almonds, filberts, pistachios, walnuts	hand-harvesting, hand-pruning, propping, training	4.80×10^{-5}
	hand-weeding, irrigation, scouting	3.20×10^{-5}
cherries: sweet and sour, nectarines, peaches	thinning	7.20×10^{-5}
	hand-harvesting, hand-pruning	3.50×10^{-5}
	hand-weeding, irrigation, scouting	2.40×10^{-5}
avocados, conifer (field grown-christmas trees), papayas	thinning	4.80×10^{-5}
	hand-pruning	2.40×10^{-5}
	hand-weeding, scouting	1.60×10^{-5}
ornamentals	hand-pruning	6.40×10^{-6}
alfalfa, soybeans	hand-harvesting	9.10×10^{-6}
	irrigating, scouting (full development)	5.40×10^{-6}
corn	detasseling, hand-harvesting	6.20×10^{-5}
curbits	hand-harvesting, hand-pruning	9.10×10^{-6}
	irrigating, scouting	5.40×10^{-6}
onions: dry bulb, garlic	hand-harvesting	1.20×10^{-5}
	hand-weeding, irrigating, scouting, thinning (min development)	8.20×10^{-6}
potatoes	hand-harvesting	9.10×10^{-6}

Table 16: Permethrin Occupational Post-Application Cancer Risk Estimates for Migrant Workers Between 10^{-4} and 10^{-6}

Crop	Activity	Cancer Risk Estimate (30 days/yr for 35 yr)
	hand-weeding, irrigating, scouting, thinning (full development)	5.40×10^{-6}
turnips	hand-harvesting	4.50×10^{-6}
cabbage	hand-harvesting, hand-pruning, irrigating	1.80×10^{-5}
	scouting	1.50×10^{-5}
	hand-weeding	7.20×10^{-6}
broccoli, Brussels sprouts, cauliflower, Chinese broccoli	hand-harvesting, hand-pruning, irrigating	9.10×10^{-6}
	scouting	7.20×10^{-6}
	hand-weeding	3.60×10^{-6}
collards	hand-harvesting	4.50×10^{-6}
Chinese cabbage, leafy vegetables	hand-harvesting	9.10×10^{-6}
	irrigating, scouting, thinning (all at medium development)	5.40×10^{-6}
artichokes	hand-harvesting, hand-pruning	5.40×10^{-6}
cut flowers	cut roses	1.40×10^{-5}

ii. Impregnated Clothing Scenarios

The Agency considered two different types of occupational post-application exposures to permethrin treated clothing: military personnel who wear battle dress impregnated with permethrin on a daily basis (i.e., approximately 250 days/year) and factory workers who work with fabric or clothing after impregnation during making of garments or packaging of clothing on a work-day basis (i.e., 250 days/year).

Since both post-application occupational exposures are more than 180 days per year, the duration of exposure considered for this non-cancer assessment is long-term. The cancer assessment assumed that these populations would be exposed to permethrin from post-application activities involving impregnated clothing 250 days per year. These assumptions are conservative in nature and were selected based on best professional judgment. Inhalation exposures are thought to be negligible for post-application scenarios involving exposure to permethrin-impregnated clothing, and as such, inhalation post-application exposures are not considered in this assessment.

When assessing post-application exposures to impregnated clothing, EPA used the latest approaches to estimate the post-application exposures. The data required for estimating post-

application potential doses include the clothing residue concentration (assumed to be equivalent to the application rate on a mass per area basis, as determined from the label), surface area of the skin that is in contact with the fabric, the transfer factor, and the body weight. EPA estimated exposures to permethrin-impregnated clothing by considering exposure frequency and duration, as well as degree of contact.

Dermal exposures to military personnel are based on the clothing contact surface area of adults exposed to permethrin-impregnated clothing (0.85 m^2). This number is based on the assumption that military personnel wear briefs and undershirts underneath the battle dress and, therefore, the surface area of arms and legs (but not the torso) for an adult are used. Dermal exposures to garment workers are based on the contact surface area of adults exposed to permethrin impregnated clothing in a factory after the impregnation process (0.22 m^2). This number is based on the hands and forearms of an adult garment worker.

For the cancer assessment, risks were calculated for wearing impregnated military clothing calculated to have an average exposure level of $0.038 \text{ mg permethrin/cm}^2$. This average was calculated by assuming the uniform is usable for up to 30 washes and that the first wash results in a 33% permethrin loss, the second wash results in a 6% permethrin loss, washes 3 through 10 each result in a 3% permethrin loss, and washes 11 through 30 result in a total loss of 6.5% permethrin (MRID 457519-02). It was also assumed that each individual would wear a uniform for 7 days before a washing event took place to take into account military personnel being in the field for extended periods of time. Further, the exposure durations for military personnel and garment workers were assumed to 10 and 35 years, respectively.

All non-cancer post-application exposure scenarios for permethrin-impregnated clothing do not exceed the Agency's level of concern. The MOEs are 6,700 and 26,000 for military personnel and garment workers, respectively. Further, all of the post-application cancer risk estimates for both populations are in the 10^{-6} range. The cancer risk estimates are 3.2×10^{-6} and 9.5×10^{-6} for military personnel and garment workers, respectively.

c. Incident Reports

The Agency evaluated reports of human permethrin poisonings and adverse reactions associated with its use from the following sources: OPP Incident Data System (IDS); Poison Control Center Data; California Pesticide Illness Surveillance Program; National Pesticide Information Center (NPIC); the National Institute of Occupational Safety and Health; and scientific literature. Review of these data sources concluded that it is likely that most poisonings from permethrin resulted from misuse or inadvertent exposures. The large majority of cases resulted in minor effects to the skin (primarily rash, irritation, itching), eyes (redness, pain, burning), headache, dizziness, nausea, vomiting, and shortness of breath or difficulty breathing. Loss of consciousness appears to occur only in cases of ingestion involving 700 mg/kg body weight or more. Persons handling permethrin directly are the most likely to experience symptoms. Permethrin does not appear to pose significant risks from exposure to residues or drift, based upon a relatively small number of documented cases.

Compared to other pesticides, permethrin is much less likely to result in serious or persistent medical outcome/condition. Even ingestion of suicidal or potentially lethal doses can be resolved within a few days with medical treatment. The only death reported was due to pneumonitis, and was likely due to xylene solvent rather than permethrin. Although it is a relatively safe product, it can aggravate asthma or lead to asthma like symptoms.

The EPA performed a review of animal incidents reported between April 1, 1998 to March 31, 2002. For permethrin containing products, there were 18,343 incidents involving domestic animals. The products were either used directly on the animals or for other uses, such as household ant or roach killer. There have also been severe adverse reactions, including deaths, in cats exposed directly to concentrated permethrin products or secondarily exposed to treated dogs. As such, the registrants voluntarily included a warning statement on permethrin concentrated spot-on products indicating they are highly toxic to cats.

B. Environmental Fate and Effects Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. For detailed discussion of all aspects of the environmental risk assessment, please see *the Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III*, dated April 5, 2006, which is available on the internet and in the public docket. This risk assessment was refined and updated to incorporate comments and additional studies submitted by the registrant. Major changes to the risk assessment include the following:

- Consideration of 150 and 25 foot buffer zone for aerial and ground agricultural applications consistent with the buffer zones required for all pyrethroids;
- Clarification of agricultural use patterns, such as typical application rates and number of applications;
- Revisions to the public health use parameters based on the provisions of the PR Notice 2005-1, which aims to standardize the use of public health use pesticides.
- Modification to the down-the-drain residential assessment to include revised production numbers of permethrin used in pharmaceuticals provided by the US Food and Drug Administration (FDA).

1. Environmental Fate and Transport

Permethrin is a persistent pyrethroid in the environment, and was immobile in several soils tested, both sterile and viable ($K_{oc} > 5000$). It is also slow to hydrolyze and biodegrade. It is relatively stable to hydrolysis at pHs ranging from 3 to 7 when stored in the dark at 25°C. At pH 9, permethrin degraded very slowly with a half-life of 125–350 days. The half-life reported for permethrin in an anaerobic aquatic study ranged from 113 days to 175 days, which indicates that the degradation in soil and water is slower as the oxygen levels are reduced. The relatively low water solubility and hydrophobic nature of permethrin leads to strong soil adsorption and a tendency to partition to sediment in aquatic systems. The high octanol/water partition coefficient suggests that permethrin will bioconcentrate in aquatic organisms. Permethrin has a vapor pressure of 2.15×10^{-8} mm Hg, water solubility of 0.0055 mg/L, and an estimated Henry's law constant of 1.4×10^{-6} atm-m³/mol. Based upon its Henry's law constant and vapor pressure,

permethrin is expected to have a relatively low potential for volatilization from soil and water surfaces. Permethrin's potential for volatilization is also reduced significantly because it adsorbs strongly to soils and suspended solids or sediment in the water column.

Based on laboratory and field studies that were submitted to the Agency, permethrin has very low mobility, is moderately persistent and has a high affinity to bind to soils/sediments and organic carbon. This compound binds readily to particulate matter and organic carbon in a lake or stream, thus possibly reducing its bioavailability in this medium after 48 hours. However, as the particulate-bound permethrin settles out of the water column and onto the benthos, there is an increase in permethrin sediment concentrations that could result in toxic exposure to benthic and epibenthic aquatic organisms (e.g., early life stage of many invertebrates and fish, as well as crabs and shrimp).

Additionally, like several other chemicals in its class, permethrin can reach surface waters by spray drift or in runoff events via erosion. However, as opposed to many other synthetic pyrethroids, permethrin labels currently do not have a required buffer zone to protect bodies of water against spray drift. In addition to drift and runoff from agricultural areas, permethrin residues can also be transported to aquatic systems via release of water from wastewater treatment plants. The Agency assessed the occurrence of permethrin residues being found in wastewater as a result of laundering permethrin treated clothing and the disposal wastewater from of other household uses (e.g., pet shampoo and pharmaceutical shampoo rinsate).

2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic estimated environmental concentrations (EECs), based on environmental fate characteristics and pesticide use data, by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs), and when the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern to that category. In general, the higher the RQ, the greater the potential risk (see Table 17 below for the Agency's LOCs). Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to non-target organisms.

Table 17. EPA's Levels of Concern (LOCs) and Risk Presumptions			
If a calculated RQ is greater than the LOC presented, then the Agency presumes that...	LOC terrestrial animals	LOC aquatic animals	LOC plants
Acute Risk ...there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification	0.5	0.5	1.0
Acute Restricted Use ...there is potential for acute risk, but may be mitigated through restricted use classification	0.2	0.1	NA

Table 17. EPA's Levels of Concern (LOCs) and Risk Presumptions			
If a calculated RQ is greater than the LOC presented, then the Agency presumes that...	LOC terrestrial animals	LOC aquatic animals	LOC plants
Acute Endangered Species ...endangered species may be adversely affected	0.1	0.05	1.0
Chronic Risk ...there is potential for chronic risk	1	1	NA

For permethrin, the Agency modeled EECs for six crop scenarios, which are listed in Table 18 below. The scenarios were selected to represent a variety of crops among the major uses, and a variety of sites in the U.S.

Table 18: Input parameters for permethrin used in PRZM/EXAMS			
Crop	Modeled Location	Max. App. Rate* (lb ai/A) [Typical App. Rate**]	Maximum # of Apps.* [Typical #**]
Alfalfa	California	0.2 [0.1]	5 [1]
Corn	North Dakota	0.2 [0.8]	3 [1]
Potatoes	Maine	0.2 [0.11]	8 [1]
Sweet Corn	Oregon	0.2 [0.15]	6 [2]
Apples	Pennsylvania	0.3 [0.13]	2 [1]
Tomatoes	Florida	0.2 [0.13]	6 [7]
*The maximum application rates and number of applications were derived from currently registered labels. **The data for the typical application rates and number of applications are from EPA and USDA National Agricultural Statistics Service (NASS) databases for the years 2002-2004, and reflect the annual number of applications, and maximum annual application rate for the selected crops for the US. The annual averages are straight averages. The National Potato Council provided typical use information, which was corroborated by the Agency and used in the assessment.			

a. Terrestrial Organisms

Birds and Mammals

The Agency terrestrial exposure model (ELL-FATE, Version 1.4, dated April 7, 2004) was used to estimate exposures and risks to avian and mammalian species. Input values on avian and mammalian toxicity, as well as chemical application and foliar dissipation half-time data, are required to run the model. The model provides estimates of both exposure concentrations and RQs. Specifically, the model provides estimates of concentrations (maximum and average) of chemical residues on the surface of different types of foliage that may be sources of exposure to avian, mammalian, reptilian, or terrestrial phase amphibian receptors. The surface residue concentration (ppm) is estimated by multiplying the application rate (pounds active ingredient per acre) by a value specific to each food item.

ELL-FATE was run for permethrin for use on potato crops using the inputs provided in Table 19 below. In the absence of foliar dissipation half-life data for permethrin the Agency's

default half-life value of 35 days because the Agency did not have half-life data for the crops used in the assessment.

Table 19: Input Parameters for Permethrin Used in ELL-FATE.	
Parameter	Value
Application rate (lbs ai/A)	0.2
Foliar half-life (days)	35
Retreatment interval (days)	4
Maximum applications per year	8

Effects characterization describes the potential effects a pesticide can produce in a terrestrial organism, and is based on registrant-submitted studies that describe acute and chronic effects toxicity information for various terrestrial animals. Table 20 summarizes the toxicity effects and reference values used to assess risks for permethrin to mammals and birds.

Table 20. Toxicity Reference Values for Mammals and Birds for Permethrin.				
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value	Toxicity Category/ Effect
Mammals				
Acute	Rat	Single dose	LD ₅₀ = 8,900 mg/kg /day	Practically non-toxic
Chronic	Rat	Developmental Toxicity	NOAEC = 1,000 ppm (50 mg/kg/day) LOAEC = 3,000 ppm (150 mg/kg/day)	Decreased mean fetal bodyweight
Birds				
Acute	Mallard duck	5-day dietary	LC ₅₀ > 10,000 ppm	Practically non-toxic
Chronic	Mallard duck	Reproduction study	NOAEC = 500 ppm	Slight decrease in egg production

As presented in Table 21 below, avian acute RQs are below the acute, restricted use, and endangered species LOCs and the chronic RQs are below the chronic LOC at registered maximum application rates for permethrin for all forage items.

Table 21. Acute and Chronic Risk Quotients for Birds Exposed to Permethrin			
Food Item	Maximum EEC (ppm)	Bird Acute RQs	Bird Chronic RQs
Short grass	295.8	0.03	0.59
Tall grass	135.6	0.01	0.27

Table 21. Acute and Chronic Risk Quotients for Birds Exposed to Permethrin			
Food Item	Maximum EEC (ppm)	Bird Acute RQs	Bird Chronic RQs
Broadleaf plants small insects	166.4	0.02	0.33
Fruits, pods, large insects, seeds	18.5	<0.01	0.04

Table 22 below presents the acute RQs for small mammalian species that forage on plants and insects containing permethrin residues. All acute RQs were below the acute LOC for each environmental scenario and therefore not of concern.

Table 22. Acute Risk Quotients for Terrestrial Mammals Exposed to Permethrin				
Food Item	Maximum EEC (ppm)	Mammal Acute RQs by Body Weight		
		15g	35 g	1000 g
Short grass	295.8			
Tall grass	135.6			
Broadleaf plants small insects	166.4			
Fruits, pods, large insects, seeds	18.5			

Chronic RQs for mammals were calculated using the results of a developmental toxicity study performed with rats. Dose based RQs based on the Maine Potatoe scenario, which is the most conservative of the crop scenarios assessed, range from 0.02 to 2.57. This study was conducted via oral gavage and represents a more intense dosing regime than that of the 3-generation rat reproduction studies (dietary exposure) which the Agency typically relies on to estimate chronic effects and risk to mammals. Therefore, given the questionable toxicological response and the intense dosing regime, it should be noted that this NOAEC represents a conservative estimate of toxicity and its use may result in the overestimation of chronic risk to mammals. Thus, the results are not tabulated in this document. The Agency is not requiring additional data at this time. For more details, refer to the *Addendum to Revised Draft EFED RED Chapter for Permethrin*, dated April 5, 2006.

Non-Target Insects

EPA currently does not estimate RQs for terrestrial non-target insects. However, permethrin toxicity data show that the compound is highly toxic to honeybees, as well as beneficial insects. A hazard assessment shows that permethrin exposure can result in acute toxicity to honeybees and is considered to be highly toxic on both a contact and an oral basis (contact LD₅₀ = 0.13 ug/bee; oral LD₅₀ = 0.024 ug/bee). Permethrin was also found to be highly toxic to honeybees exposed to foliage that had been sprayed with a permethrin formulation. Several field studies were submitted that showed the effects of permethrin formulations on non-target insects. These studies show that applications of formulations of permethrin are likely to reduce the numbers and possibly eliminate populations of beneficial insects.

Non-Target Plants

Toxicity data are not available for terrestrial plants. Therefore, the potential for risk to terrestrial plants from exposure to permethrin cannot be assessed, and remains an uncertainty. However, any toxicity to plants would occur for reasons other than permethrin's insecticidal mode of action, because permethrin works in insects as a neural toxin. Unlike insects, plants do not have neural networks that could be affected.

b. Aquatic Organisms

i. Agricultural Use of Permethrin

Freshwater and Estuarine/Marine Fish and Invertebrates

To assess potential risks to aquatic animals, the Agency considers predicted EECs in surface water using the Tier II model PRZM/EXAMS. Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment do not include the Index Reservoir (IR) and Percent Cropped Area (PCA) factor refinements. These factors represent a drinking water reservoir, not the variety of aquatic habitats relevant to a risk assessment for aquatic animals, such as ponds adjacent to treated fields. Therefore, the EEC values used to assess potential exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

Peak EECs were compared to acute toxicity endpoints to derive acute RQs. The highest EECs were observed for the Maine potatoes scenario followed by Pennsylvania apples. These results are summarized in *The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III*, dated April 5, 2006.

Effects characterization describes the potential effects a pesticide can produce in an aquatic organism, and is based on registrant-submitted studies that describe acute and chronic effects toxicity information for various aquatic animals. Table 23 summarizes the toxicity effects and reference values used to assess risks for permethrin to aquatic organisms.

Table 23. Permethrin Toxicity Reference Values for Aquatic Organisms				
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (ppb)	Toxicity Category/Effect
Freshwater Fish				
Acute	Bluegill sunfish	96 hours	LC ₅₀ = 0.79 ppb	Very highly toxic
Chronic	Fathead minnow	Full life cycle	NOAEC = 0.30 ppb LOAEC = 0.41 ppb	Reduced survival
Freshwater Invertebrates				
Acute	<i>Hexagenia bilineata</i>	48 hours	EC ₅₀ = 0.1 ppb	Very highly toxic

Table 23. Permethrin Toxicity Reference Values for Aquatic Organisms				
Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (ppb)	Toxicity Category/ Effect
Chronic	<i>Daphnia magna</i>	Life cycle	NOAEC = 0.039 ppb LOAEC = 0.084 ppb	Reproduction and growth
Estuarine/Marine Fish				
Acute	Atlantic silverside	96 hours	LC ₅₀ = 2.2 ppb	Very highly toxic
Chronic	Sheepshead minnow	28 day early life stage	NOAEC 0.83 ppb ¹ LOAEC 10 ppb	Reduced survival
Estuarine/Marine Invertebrates				
Acute	Mysid shrimp	96 hours	LC ₅₀ = 0.019 ppb	Very highly toxic
Chronic	Mysid shrimp	30 day life cycle	NOAEC = 0.011 ppb LOAEC = 0.024 ppb	Mortality

As noted in Table 18, the Agency considered the maximum labeled application rate, as well as the typical use scenario in order to evaluate the potential for permethrin to cause acute and chronic toxic risk to fish and aquatic invertebrates (freshwater and estuarine/marine). As presented in Table 34, at the maximum application rates, most acute RQs for both freshwater and estuarine/marine fish and invertebrates exceed the Agency's acute LOC (0.5), and all exceed the Agency's endangered species LOC (0.05).

Table 24. Acute Risk Quotients for Aquatic Organisms Exposed to Permethrin (no buffer zone; Maximum application rate and number of applications)					
Crop Scenario	Peak EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish 96 hr. LC ₅₀ = 0.79 ppb	Invertebrates 96 hr. EC ₅₀ = 0.10 ppb	Fish 96 hr. LC ₅₀ = 2.2 ppb	Invertebrates EC ₅₀ = 0.019 ppb
California Alfalfa	.54	0.68	5.4	0.25	28.4
Maine Potatoes	5.32	6.73	53.2	2.42	280.0
North Dakota Corn	0.55	0.7	5.5	0.25	29.0
Oregon Sweet Corn	0.96	1.22	9.6	0.44	50.5
Pennsylvania Apples	1.83	2.32	18.3	0.83	96.3
Florida Tomatoes	1.11	1.41	11.1	0.50	58.4

As presented in Table 25, at the maximum application rates, RQs for both freshwater and estuarine/marine invertebrates exceed the Agency's chronic LOC (1.0). The RQs for freshwater and estuarine/marine fish exceed the chronic LOC only for the Maine potato scenario.

Table 25. Chronic Risk Quotients for Aquatic Organisms Exposed to Permethrin [no buffer zone; Maximum application rate and number of applications]

Crop Scenario	21-d/60-d EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish NOAEC= 0.30 ppb	Invertebrates NOAEC = 0.039 ppb	Fish NOAEC = 0.83 ppb	Invertebrates NOAEC = 0.011 ppb
California Alfalfa	0.1/0.09	0.3	2.6	0.1	9.1
Maine Potatoes	1.3/1.0	3.4	33.9	1.23	120
North Dakota Corn	0.16/0.11	0.4	4.1	0.1	14.6
Oregon Sweet Corn	0.35/0.24	0.8	9.0	0.3	31.8
Pennsylvania Apples	0.29/0.24	0.8	7.4	0.3	26.4
Florida Tomatoes	0.24/0.18	0.6	6.2	0.2	21.8

If typical application rates and numbers of applications are considered, all resulting RQs are reduced from the maximum rate and are listed in Table 26. However, the resulting freshwater and estuarine/marine invertebrate RQs still exceed the acute and endangered species LOCs for all crops simulated. All of the freshwater and estuarine/marine fish RQs exceed the endangered species LOC, and most exceed the acute LOC.

Table 26. Acute Risk Quotients for Aquatic Organisms Exposed to Permethrin (no buffer zone; typical application rate and number of applications)

Crop Scenario	Peak EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish 96 hr. LC ₅₀ = 0.79 ppb	Invertebrates 96 hr. EC ₅₀ = 0.10 ppb	Fish 96 hr. LC ₅₀ = 2.2 ppb	Invertebrates EC ₅₀ = 0.019 ppb
California Alfalfa	0.24	0.30	2.4	0.11	12.6
Maine Potatoes	0.61	0.77	6.1	0.28	32.1
North Dakota Corn	0.20	0.25	2.0	0.09	10.5
Oregon Sweet Corn	0.43	0.54	4.3	0.20	22.6
Pennsylvania Apples	0.38	0.48	3.8	0.17	20.0
Florida Tomatoes	0.74	0.93	7.4	0.34	39.0

For typical use scenarios, RQs for both freshwater and estuarine/marine invertebrates exceed the Agency's chronic LOC (1.0) in most cases, and are presented in Table 27. The RQs for freshwater and estuarine/marine fish calculated for typical use scenarios do not exceed the chronic LOC.

Table 27. Chronic Risk Quotients for Aquatic Organisms Exposed to Permethrin [no buffer zone; typical application rate and number of applications]

Crop Scenario	21-d/60-d EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish NOAEC= 0.30 ppb	Invertebrates NOAEC = 0.039 ppb	Fish NOAEC = 0.83 ppb	Invertebrates NOAEC = 0.011 ppb
California Alfalfa	0.1/0.09	0.03	0.5	0.01	1.8
Maine Potatoes	1.3/1.0	0.3	3.1	0.1	10.9
North Dakota Corn	0.16/0.11	0.03	0.5	0.01	1.8
Oregon Sweet Corn	0.35/0.24	0.23	2.3	0.08	8.2
Pennsylvania Apples	0.29/0.24	0.17	1.5	0.06	5.5
Florida Tomatoes	0.24/0.18	0.43	4.4	0.16	15.5

Effect of Spray Buffers

In addition to considering typical application rates and numbers of applications, the Agency considered buffer zones proposed by the registrant of 150 ft for aerial applications that do not involve Ultra Low Volume (ULV) and 25 feet for ground applications. The effects of spray drift and the use of buffer zones in reducing exposure to bodies of water adjacent to treated areas were investigated using the AgDRIFT model.

Table 28 and 29 below present the acute and chronic RQs to aquatic organisms, respectively, exposed to permethrin at the maximum labeled application rates, and with a 150 foot buffer zone for aerial applications, and 25 feet for ground application (PA Apples).

Table 28. Acute Risk Quotients for Aquatic Organisms Exposed to Permethrin (Buffer Zone 150 ft, 25 ft for PA apples; Maximum application rate and number of applications)

Crop Scenario	Peak EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish 96 hr. LC ₅₀ = 0.79 ppb	Invertebrates 96 hr. EC ₅₀ = 0.10 ppb	Fish 96 hr. LC ₅₀ = 2.2 ppb	Invertebrates EC ₅₀ = 0.019 ppb
California Alfalfa	0.42	0.53	4.20	0.19	22.11
Maine Potatoes	5.27	6.67	52.70	2.40	277.37
North Dakota Corn	0.43	0.54	4.30	0.20	22.63
Oregon Sweet Corn	0.83	1.05	8.30	0.38	43.68
Pennsylvania Apples	1.83	2.32	18.30	0.83	96.32
Florida Tomatoes	1.00	1.27	10.00	0.45	52.63

At the maximum application rates, most acute RQs for both freshwater and estuarine/marine fish, invertebrates, and sediment organisms exceed the Agency's acute LOC (0.5), and all exceed the

Agency's acute LOC for restricted use risk (0.1) and endangered species (0.05).

Table 29. Chronic Risk Quotients for Aquatic Organisms Exposed to Permethrin [Buffer Zone 150 ft, 25 ft. for PA apples; Maximum application rate and number of applications]

Crop Scenario	21-d/60-d EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish NOAEC= 0.30 ppb	Invertebrates NOAEC = 0.039 ppb	Fish NOAEC = 0.83 ppb	Invertebrates NOAEC = 0.011 ppb
California Alfalfa	0.08/0.07	0.23	2.05	0.08	7.27
Maine Potatoes	1.28/0.98	3.27	32.82	1.18	116.36
North Dakota Corn	0.13/0.09	0.30	3.33	0.11	11.82
Oregon Sweet Corn	0.29/0.20	0.67	7.44	0.24	26.36
Pennsylvania Apples	0.28/0.24	0.80	7.18	0.24	25.45
Florida Tomatoes	0.20/0.15	0.50	5.13	0.18	18.18

In contrast to the acute risk estimate, most of the freshwater and estuarine/marine chronic risks to fish are below the Agency's chronic LOC (1). However, the chronic RQs for freshwater and estuarine/marine invertebrates and sediment organisms exceed the LOC (1) in all scenarios.

The effect of a spray buffer on potential exposure may be underestimated by the risk quotients shown above. AgDrift was used to evaluate the effect of spray buffers on the amount of permethrin reaching the standard pond via spray drift. However, the PRZM model is an edge-of-field model which cannot simulate an untreated area between the field and the receiving water body. Therefore, the RQs for the scenario with the 150-foot buffer reflect the same amount of loading from runoff/erosion as the RQs with no buffer at all. Presumably, the mass of permethrin that would be applied to that portion the field within an untreated spray buffer zone would be less than that applied to the rest of the crop, and would decline with distance, but the resulting reduction in the loading from runoff and erosion cannot currently be quantified.

All of the risk quotients reflect the same predicted reduction in spray drift for any particular spray buffer, but different contributions from runoff/erosion. This is important because while the EEC from PRZM/EXAMS used in the screening model represents a 1-in-10-year exposure from combined runoff/erosion and spray drift, the typical drift fractions calculated by AgDrift used for the buffer-analysis RQs above represent the amount of exposure from spray drift that could occur any time a pesticide is applied. Therefore, while the buffer may not reduce exposure below LOCs when permethrin exposure from spray drift coincides with heavy rain events, it will reduce exposure from spray drift even when runoff does not occur. Comparison of the results from PRZM/EXAMS runs in the risk assessment performed with varying amounts of spray drift with those from the hypothetical "no drift" scenario suggests that exposure from drift alone might be enough to exceed some acute aquatic LOCs.

Risk to Sediment Dwelling Organisms

The ecological risk assessment also considers the potential for risk to epibenthic and sediment-dwelling invertebrates from exposure to permethrin in sediment pore water. The risk assessment estimates pore water exposure to sediment organisms through the use of equilibrium-partitioning predicted porewater concentrations of permethrin normalized to the organic carbon (OC) in sediment. Since aquatic invertebrates living in the water column are no less sensitive to toxic compounds than those invertebrates living in the benthos, and toxicity data were not available for sediment-dwelling invertebrates, the assessment uses standard water-column toxicity values with the model-generated porewater exposure values for RQ calculations. As presented in Table 30, the resulting RQs indicate a potential for acute and chronic risk to epibenthic and sediment-dwelling invertebrates from exposure to permethrin in sediment pore water, based on maximum application rates and no buffer zone restrictions.

Table 30. Acute and Chronic Risk Quotients for Aquatic Organisms Exposed to Permethrin in Sediment Pore Water [no buffer zone; Maximum application rate and number of applications]					
Crop Scenario	Acute/Chronic pore water EECs (ppb)	Acute RQs		Chronic RQs	
		Freshwater Invertebrates EC ₅₀ = 0.1 ppb	Estuarine/Marine EC ₅₀ = 0.019 ug/L	Freshwater Invertebrates NOEC = 0.039 ppb	Estuarine/Marine Invertebrates NOEC = 0.011 ug/L
California Alfalfa	0.05/0.05	0.5	2.6	1.3	4.6
Maine Potatoes	0.56/0.55	5.6	29.5	14.1	50
North Dakota Corn	0.05/0.05	0.5	2.6	1.3	4.6
Oregon Sweet Corn	0.12/0.12	12.0	6.3	3.1	10.9
Pennsylvania Apples	0.12/0.12	12.0	6.3	3.1	10.9
Florida Tomatoes	0.08/0.07	0.80	4.2	1.8	6.4

Non-Target Plants

Toxicity data are not available for aquatic plants. Therefore, the potential for risk to aquatic plants from exposure to permethrin cannot be assessed, and remains an uncertainty. However, any toxicity to plants would occur for reasons other than permethrin's insecticidal mode of action, because permethrin works in insects as a neural toxin. Unlike insects, plants do not have neural networks that could be affected.

a. Public Health Use of Permethrin

Permethrin is registered as a mosquito adulticide for use in Public Health Abatement Programs. Permethrin used in mosquito abatement programs to control adult mosquitoes in residential and recreational areas can lead to potential exposure to various types of water bodies. The Agency conducted aquatic exposure modeling for mosquito abatement to consider the risk to aquatic organisms from this use of permethrin.

Mosquito adulticides are more efficacious if they come into contact with insects in flight. For that reason, mosquito abatement using permethrin (as well as other mosquito adulticides) is typically applied via aerial spray methods with very fine mists to prevent immediate deposition of the pesticide. Therefore, the modeling approach for this type of use included calculations of spray drift using the Agricultural Dispersal (AGDISP) model. This model estimates the deposition of the pesticide to the treatment area and deposition assessment to the adjacent bodies of water (i.e. standard pond).

Most input parameters are standard for AGDISP; however, some are variable. For example, the temperature and relative humidity were selected to be similar to those conditions where mosquitoes grow, a wind speed of 10 miles per hour was selected, a low evaporation rate was assumed, and the volatile fraction was very small. The current permethrin labels vary in their specificity of application parameters (i.e. boom height, droplet size, application rate, and number of applications). Therefore, the Agency relied upon the guidelines and recommendations in the Pesticide Registration (PR) Notice 2005-1, which presents Agency guidance for pesticide products intended for wide-application to control adult mosquitoes. The specific label statements and label organization principles recommended in the Notice are intended to improve existing labels by clarifying language conveying environmental hazards posed by the products, as well as specific use direction and instructions to the applicators. The Agency also considered public comments submitted to the Agency by the American Mosquito Control Association (AMCA) during Phase 3 of the public process for reregistering pesticides.

Most labels specify a maximum boom height of 300 feet; however, most do not specify a minimum boom height. The Agency initially assumed a minimum boom height of 25 feet. However, following receipt of comments from the AMCA that most applications do not take place lower than 100 and 75 feet for fixed wing and helicopters, respectively, the Agency also assessed minimum boom heights of 75 and 100 feet. The current and proposed labels provide a range of droplet size ranging from 20 to 50 ug; however, the proposed labels recently submitted to the Agency in response to PR-2005-1 propose a droplet size of 60 ug. Larger droplets are expected to result in higher deposition and potential exposure in the spray area, but lower deposition outside the spray area. In order to be conservative in its assessment, the Agency considered the two larger sized droplets, 50 ug and 60 ug, in the risk assessment. Based on the Agency's assessment there was little difference in risk to aquatic organisms between 50 ug and 60 ug.

Currently, the maximum application rate registered for aerial application is 0.021 lb ai/A; however, according to the AMCA and technical registrant, this rate is hardly used. The "high-end" application rate used in mosquito abatement programs is 0.007 lb ai/A, and the "typical" application rate is 0.0035 lb ai/A. The Agency assessed both the proposed high-end and typical application rates in the risk assessment. Further, most permethrin labels do not specify the number of applications and application timing. The Agency assumed 26 applications per site per season in the risk assessment based on use data provided for another mosquito adulticide.

Finally, the current permethrin mosquito adulticide labels maintain a 100-foot buffer zone between the treated area and any body of water. However, according to PR-2005-1 the buffer zone may not be warranted, because it was added to labels out of concern for aquatic toxicity that might result due to runoff from agricultural sites, and not as a result of risks associated with the significantly lower concentration of the active ingredient involved in ULV mosquito control applications. Further,

the PR Notice contends that protecting human health from mosquito-borne diseases with pesticides now available often involves some degree of ecological risks, and that a buffer zone may require leaving potentially infested areas untreated. Therefore, to determine the extent of the ecological risk, and the need for a buffer zone on permethrin mosquito adulticide labels, the Agency considered a zero, 100, and 150 foot buffer zone in its assessment.

The Agency assessed a number of scenarios with different variables, such as boom height and application rate, with the various buffer zones (zero, 100 ft, and 150 ft). Based on the risk estimates, the Agency concluded for the public health use of permethrin, a buffer zone does not serve to reduce the potential risk to aquatic organisms. Further, a zero foot buffer zone and a minimum boom of 100 ft results in over a 50% reduction in acute and chronic exposure to aquatic fish and invertebrates as compared to a 75 ft. boom height. Additionally, as stated above, there was little difference in risk to aquatic organisms between 50 ug and 60 ug. For more detail on the various scenarios assessed, refer to *The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III*, dated April 5, 2006, available on the internet and in the public docket.

Based on the conclusions above, the tables below are provided to present the acute and chronic RQs to freshwater and estuarine/marine fish and invertebrates with a zero foot buffer, a boom height of 100 feet, and a droplet size of 50 ug. Table 31 presents the RQs when the high-end application rate is used, and Table 32 presents to RQs when the typical application rate is used.

Table 31. Comparison of the Freshwater and Estuarine/Marine Acute and Chronic RQs for Fish and Invertebrates (Application rate 0.007 lb ai/A, boom height 100 feet, Buffer Zone 0 ft., Droplet size 50 ug)								
Depth of Water	Fish				Invertebrates			
	Freshwater		Estuarine/Marine		Freshwater		Estuarine/Marine	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
6.6 feet	0.07	0.10	0.03	<0.00	1.46	0.76	3.00	2.73

The reduction in application rate to the typical rate of 0.0035 lb ai/A can further result in a reduction in potential permethrin exposure to freshwater and estuarine/marine fish and invertebrates. The RQs associated with this rate at a boom height of 100 feet and zero buffer zone do not exceed the Agency's acute and chronic LOC for all fish and the chronic LOC for freshwater invertebrates. However, although a reduction in rate reduced the overall risk to invertebrates, RQs exceed the acute LOC both freshwater and estuarine/marine invertebrates and the chronic LOC is exceeded for estuarine/marine invertebrates. See Table 32 below for more details.

Table 32. Comparison of the Freshwater and Estuarine/Marine Acute and Chronic RQs for Fish and Invertebrates (Application rate 0.0035 lb ai/A, boom height 100 feet, Buffer Zone 0 ft., Droplet size 50 ug)

Depth of Water	Fish				Invertebrates			
	Freshwater		Estuarine/Marine		Freshwater		Estuarine/Marine	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
6.6 feet	0.03	0.05	0.01	<0.00	0.71	0.38	1.47	1.36

b. Down-the-Drain Assessment

As part of its aquatic exposure assessment, the Agency also assessed the ecological impact of permethrin released into domestic wastewater, and eventually into Publicly Owned Treatment Works (POTWs). The Agency relied on the Office of Pollution Prevention and Toxics (OPPT) consumer exposure model, Exposure and Fate Assessment Screening Tool (E-FAST). The Down-the-Drain module of E-FAST is specifically designed to address all sources of permethrin that could potentially be disposed to domestic wastewater from a down-the-drain application. This model provides screening-level estimate of chemical residues in surface water that may result from household uses and the disposal of consumer products into wastewater. The model uses input parameters that include annual production volume of the pesticide and takes into account the fraction of the chemical removed during wastewater treatment. The assumptions of the model state that in a given year, the entire production volume of permethrin is parceled out on a daily per capita basis to the entire US population and converted to a mass release per capita. This mass is diluted into the average daily volume of wastewater released per person per day to arrive at an estimated concentration of target permethrin in wastewater prior to entering a treatment facility. The concentration of permethrin in untreated wastewater is then reduced by the fraction removed during the wastewater treatment process before release into a river or stream. The remaining chemical is discharged into surface water, where it is assumed that it is instantaneously diluted, with no further removal. A stream Dilution Factor is the volume of the receiving stream flow divided by the volume of the wastewater released from the POTW. The resulting EEC values are then used to assess potential ecological risks resulting from this exposure scenario.

The Agency included permethrin pesticide products (pre-treated clothing and pets products), as well as permethrin pediculicide pharmaceutical products, both over the counter (OTC) and prescription, in the down-the-drain assessment. Production volume of permethrin for these specific uses was based on unpublished market data, from the U.S. Food and Drug Administration, the technical registrants, and by Agency sources. A total of approximately 252,000 kg ai of permethrin are used per year for pet products, products to treat clothes, impregnated clothing, and OTC and prescribed drugs.

Information on the degree of removal of permethrin from wastewater at POTWs is limited. Agency data shows the removal of permethrin in pretreatment systems employing granular activated carbon and resin adsorption to be 52, 75 and 94%. For permethrin, granular carbon and resin adsorption is considered the best available technology economically achievable. Although the values of removal varied widely, the Agency considers this the best available data and relied on it for the down-the-drain assessment.

Table 33 summarizes the risk estimates for aquatic organisms' exposure to permethrin from surface waters containing permethrin after varying levels of removal at POTWs. Acute and chronic RQs were below the LOCs at the three removal levels for freshwater and estuarine/marine fish. However, aquatic invertebrates appear to be at acute risk from exposure to surface waters containing permethrin from wastewater. Acute RQs exceeded some LOCs for freshwater and estuarine/marine invertebrates at most treatment levels of removal. Additionally, chronic RQs were below the LOC for all aquatic invertebrates. See Table 33 below.

Table 33. Estimated risks to aquatic organisms from permethrin consumer products released into domestic wastewater after different levels of removal a POTWs								
Level of Removal	Fish				Invertebrates			
	Freshwater		Estuarine/Marine		Freshwater		Estuarine/Marine	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
52%	0.06	0.01	0.02	<0.01	0.44	0.09	2.33	0.09
75%	0.03	0.01	0.01	<0.01	0.23	0.05	1.21	0.16
94%	0.01	0.01	<0.00	<0.01	0.06	0.01	1.29	0.04

iii. Other Non-Agricultural Use

The other non-agricultural applications of permethrin that include perimeter treatments in and around buildings, lawn care, outdoor surfaces, etc., may result in exposure to aquatic organisms in adjacent water bodies because of irrigation that can result in runoff and/or erosion. Even though permethrin has a strong affinity to bind to soils and surfaces, residue monitoring in non-agricultural areas, such as in certain areas of California, have shown that residues toxic to aquatic organisms are occurring in aquatic areas that receive runoff from suburban developments. A recent monitoring study conducted in an urban area of California found residues of permethrin and other pyrethroids in adjacent water bodies from these residential areas and suggested that these areas are unlikely to be unique with similar profiles occurring in other suburban areas, particularly in dry regions where landscape irrigation can dominate seasonal flow in some water bodies. The Agency recognizes the potential of aquatic toxicity from non-agricultural uses, but was not able to assess the risks associated with these uses at this time due to lack of available data. The Agency's plan to consider aquatic exposure from non-agricultural uses of permethrin is further discussed in Section IV.

c. Endangered Species

Based on a screening-level assessment, permethrin will have no direct acute or chronic effect on listed terrestrial mammal, avian, and plants species, or aquatic plants species. The screening level assessment, however, indicates there is a potential concern for direct effects to a variety of aquatic organisms, should exposure actually occur at the modeled level. These are as follows:

- Freshwater Fish and Aquatic-phase Amphibians- The acute endangered LOC (RQ >0.05) for direct effects were exceeded for all maximum application rates for

corn, sweet corn, potatoes, alfalfa, orchards, tomatoes, and mosquito abatement modeled scenarios. Estimated concentrations in surface water due to waste water containing permethrin were also used to calculate RQ values and show acute endangered species LOC exceedance. Potential chronic exposure for fish was limited to the corn modeled scenario. (In the ecological risk assessment for permethrin, freshwater fish toxicity data are used as surrogates for aquatic-phase amphibians).

- Freshwater Invertebrates- The acute and chronic LOC was exceeded for the maximum application rate for all crops relative to aquatic macroinvertebrate exposure. Permethrin is expected to reach surface water concentrations high enough to exceed the acute endangered LOC (acute RQ > 0.05) for aquatic invertebrates.
- Estuarine/Marine Fish- The acute endangered LOC (acute RQ > 0.05) is exceeded for all maximum application rates. The Agency also calculated estimated concentrations of permethrin in surface water due to waste water and noted the potential for acute endangered species exceedances. However, maximum application rates only showed that the potential for chronic exposure to fish was limited to the corn modeled scenario.
- Estuarine/Marine Invertebrates- The endangered species acute LOC and chronic LOC is exceeded for all modeled use sites and maximum label rates. However, currently there are no listed estuarine/marine invertebrates.

Although a hazard assessment shows that permethrin exposure can result in acute toxicity to honey bees and is considered to be highly toxic on both a contact and an oral basis (contact LD₅₀ = 0.13 ug/bee; oral LD₅₀ = 0.024 ug/bee), an assessment method for estimating the risk to bees is not yet available; therefore, we cannot preclude the possibility of potential effects to listed insect species. Additionally, the Agency currently does not have toxicity data to quantify risks for permethrin at the screening-level for terrestrial and aquatic plants and, therefore, can not preclude potential direct effects to plants. However, a review of permethrin's mode of action (neural toxin) suggests that direct toxicity to plants should not be an issue of concern. Finally, the agency cannot preclude the potential for indirect effects to listed species that may be dependent upon taxa that experience direct effects from the use of permethrin. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species. 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 result in the need to modify use of the pesticide in specific geographic areas, those changes to the pesticide's registration will take through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

3. Ecological Incidents

The incident reports reported to the Agency since 1994 support the conclusions of the risk assessment that exposure to permethrin has a low acute toxicity to terrestrial animal and plants, but is highly toxic to aquatic species and beneficial insects. According to the Ecological Incident Data System (EIDS), terrestrial risks from exposure to permethrin appear to be low. Three incidents resulting in seven bird kills and one dog incapacitation have been reported. Six occurrences of damage to plants have been reported, the largest reported damage occurring on 142 acres of soybeans in Wisconsin. The majority of incidents (21) reported are fish kills, ranging from 50 to 3000. Finally, three beneficial insect, bees and butterflies, kills were also reported.

Incidents entered into EIIS are usually categorized into one of several certainty levels: highly probable, probable, possible, unlikely, or unrelated. Additionally, incidents entered into the EIIS are also categorized as to use/misuse. Unless specifically confirmed by a state or federal agency to be misuse, or there was very clear misuse, such as intentional baiting to kill wildlife, incidents would not typically be considered misuse. The permethrin incidents data available in the EIIS is inconclusive of the probability and if the incidents were a result of misuse or registered use.

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

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 (i.e., active ingredient-specific) data required to support reregistration of products containing permethrin as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing permethrin.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient permethrin. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient permethrin, the Agency has sufficient information on the human health and ecological effects 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 permethrin-containing products are eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted and (ii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of permethrin that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of permethrin, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of permethrin, the Agency has determined that permethrin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of permethrin. If all changes outlined in this document are incorporated into the product labels, then all current risks for permethrin will be adequately mitigated for the purposes of this determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III. B.2.c. of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for permethrin. EPA released its permethrin preliminary risk assessments for public comment on August 31, 2005, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on October 31, 2005, the Agency received comments from the technical registrants, the PIRTF, stakeholder groups, such as the American Mosquito Control Association, the American Mushroom Institute, and the National Association of Clean Water Agencies, State and Local government entities in California, California Water Boards, Publicly Owned Treatment Works, Mosquito and Vector Control Districts, and several private citizens. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (OPP-2004-0385) at the address given above and in the EPA's electronic docket at <http://www.regulations.gov>.

C. 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 this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to permethrin are within acceptable levels. In other words, EPA has concluded that the tolerances for permethrin 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 exposures to permethrin from all possible sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for permethrin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of permethrin. In reaching this conclusion, the Agency has considered all available information on

the toxicity, use practices and exposure scenarios, and the environmental behavior of permethrin. As discussed in Section III, the acute, chronic, and cancer dietary (food and drinking water) risks from permethrin are below the Agency's acute and chronic LOC.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for permethrin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, 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 permethrin residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of permethrin, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA SF has been reduced to 1X for permethrin. The rationale for the decisions on the FQPA SF can be found in Section III and the following document: *Permethrin: Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated April 4, 2006.

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 such endocrine effects as the Administrator may designate.*” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. In the available toxicity studies on permethrin, there was no significant toxicological evidence of endocrine disruptor effects. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, permethrin may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Cumulative Risks

Permethrin 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 interact with sodium channels, there are multiple types of sodium channels and it is currently unknown whether they

the pyrethroids have similar effects on all channels. Nor do we 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 the EPA's Office of Research and Development and pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When available, the Agency will consider this research and make a determination of common mechanism as a basis for assessing cumulative risk.

4. Endangered Species

The Endangered Species Act required 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 federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of permethrin "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

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 the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment 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 permethrin result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program. Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will help to reduce the likelihood that endangered and threatened species may be exposed to permethrin at levels of concern.

D. Tolerance Reassessment Summary

Tolerances for residues of permethrin in/on plant RACs are currently expressed in terms

of permethrin and the sum of its metabolites, DCVA and MPBA [40 CFR §180.378 (b), and (d)]. Tolerances for residues of permethrin in/on cottonseed expired on November 15, 1997. Tolerances for permethrin residues in/on animal RACs are currently expressed in terms of permethrin and the sum of its metabolites, DCVA, MPBA, and 3-PBA [40 CFR §180.378 (c)].

The Codex Alimentarius Commission, Canada, and Mexico have established maximum residue limits (MRLs) for permethrin residues in/on various plant and animal commodities. U.S. tolerances are not currently compatible with Codex, Canadian, and Mexican MRLs, because the U.S. tolerance expression includes the parent permethrin and its DCVA and MPBA metabolites (also 3-PBA in animal commodities). The Agency concluded that for purposes of tolerance assessment, the regulated residues of permethrin would include only the *cis*- and *trans*-isomers of permethrin. Accordingly, the tolerance definition for permethrin should be amended to include only isomers of the parent, permethrin. In addition, the tolerances currently listed under 40 CFR §180.378 (b) and (c) for plant and animal commodities should be reassigned to §180.378(a) under general tolerances. Once the U.S. tolerance definition is amended, it will be compatible with the Codex, Canadian, and Mexican MRL definitions.

Table 34 summarizes the reassessment of the permethrin tolerances. 40 CFR must be reorganized to reflect the tolerance reassessment values in the table below. The tolerances listed in 40 CFR must be reorganized in order to: (i) incorporate the recommendations made by the Agency concerning the permethrin residues of concern that need to be regulated for plant and animal commodities; (ii) include tolerances that are needed to cover permethrin residues of concern in/on the raw agricultural commodities and processed commodities of rotational crops; and (iii) conform with the requirements of FQPA.

Table 34. Tolerance Reassessment Summary for Permethrin.				
Commodity	Current Tolerance (ppm)	Range of Residues (ppm) ¹	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tolerances listed under 40 CFR §180.378 (b):				
Alfalfa, fresh ²	25.0	0.1 lb ai/A (0 DAT): 2.1-15.2 0.2 lb ai/A (14 DAT): 0.51-12.6	20.0	Residue data support lower tolerances.
Alfalfa, hay ²	55.0	0.1 lb ai/A (0 DAT): 0.7-44.5 0.2 lb ai/A (14 DAT) <1.0-31.4	45.0	
Almond	0.05	0.01-0.05	0.05	
Almond, hulls	20.0	0.043-18.1	20.0	
Apple	0.05	<0.02 (2x)	Reassign	Residue data support establishing a 0.05 ppm tolerance on pome fruits. Concomitant with establishing a 0.05 ppm tolerance on fruit, pome, group 11, the tolerance on apples should be deleted.
Artichoke, globe	10.0	0.28-4.00	5.0	Residue data support a lower tolerance.

Table 34. Tolerance Reassessment Summary for Permethrin.

Commodity	Current Tolerance (ppm)	Range of Residues (ppm) ¹	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Asparagus	1.0	0.11-1.24	2.0	Residue data indicate that a higher tolerance is required.
Avocado	1.0	0.10-0.80	1.0	
Broccoli	1.0	0.03-1.76 (0.8-1.2x)	2.0	Residue data indicate that a higher tolerance is required.
Brussels sprouts	1.0	0.04-1.0 (0.9-1.4x)	1.0	
Cabbage	6.0	<0.01-18.5	TBD ³	The majority of the available data reflect 1x the maximum seasonal rate, but only 0.5x the maximum single use rate, therefore EPA is requiring additional cabbage field trial data (860.1500) to determine the appropriate tolerance level.
Cauliflower	1.0	<0.05-0.32	0.50	Residue data support a lower tolerance.
Celery	5.0	0.47-4.02	1.0 Reassign	The tolerance should be deleted once a tolerance is established for <i>Leaf petioles</i> , subgroup 4B.
Cherry	3.0	0.47-3.94	4.0	Residue data indicate that a higher tolerance is required.
Corn, forage	60.0	0.21-42.6 (1x-1.3x)	50.0	Residue data support a lower tolerance. Separate tolerances should be established for <i>Corn, field, forage</i> and <i>Corn, sweet, forage</i> each at 50 ppm.
Corn, grain	0.05	<0.01-0.02	0.05	Separate tolerances should be established for <i>Corn, field, grain</i> and <i>Corn, pop, grain</i> each at 0.05 ppm.
Corn, stover	60.0	field corn: <0.02-16.97 sweet corn: 1.40-27.1	30.0	Residue data support a lower tolerance. Higher residues on sweet corn fodder reflect the shorter PHI for sweet corn (1 day) than field or pop corn (30 days) Separate tolerances should be established for <i>Corn, field, stover</i> and <i>Corn, sweet, stover</i> , and <i>Corn, pop, stover</i> each at 30 ppm.
Corn, sweet, kernel plus cob with husks removed	0.1	<0.01-0.08	0.10	
Eggplant	1.0	0.008-0.26	0.50	Residue data support a lower tolerance.
Filbert	0.05	<0.02	0.05	
Garlic	0.1	no data	0.10	

Table 34. Tolerance Reassessment Summary for Permethrin.

Commodity	Current Tolerance (ppm)	Range of Residues (ppm) ¹	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Grass, range	15.0	1.79, 2.13 ⁴	TBD Reassign	Residue data are required. This tolerance should also be listed with other tolerances having regional restrictions.
Horseradish	1.0	<0.01-0.48	0.50	Residue data support a lower tolerance.
Kiwifruit	2.0	no data	Revoke	No registered uses.
Leafy Vegetables (except Brassica)	20.0	Celery: <0.01-1.0 Head Lettuce: 0.01-16.8 Leaf lettuce: 4.98-10.7 Spinach: 9.04-18.2	TBD	No data are available supporting the use on leaf lettuce. Depending on the results from the requested leaf lettuce field trials, a tolerance on <i>Leafy greens, subgroup 4A</i> may be appropriate. The available celery field trial data will support a separate tolerance on <i>Leaf petioles, subgroup 4B</i> .
Lettuce, head	20.0	0.17-10.7	Reassign	If supported by the requested leaf lettuce data, the separate tolerance for head lettuce should be deleted and a tolerance should be established for <i>Leafy greens, subgroup 4A</i> .
Mushroom	6.0	<0.02-4.9	5.0	Residue data support a lower tolerance.
Onion, dry bulb	0.1	<0.01-0.09 (1.2x, 0 DAT)	0.10	
Peach	5.0	0.20-0.92	1.0	Residue data support a lower tolerance with a 14-day PHI.
Pear	3.0	#0.02 (1x-2x)	Reassign	Residue data support establishing a 0.05 ppm tolerance on pome fruits. Concomitant with establishing a 0.05 ppm tolerance on <i>Fruit, pome</i> , group 11, and the separate tolerance on pears should be deleted.
Pepper, bell	1.0	0.10-0.47	0.50	Residue data support a lower tolerance.
Pistachio	0.1	<0.008-0.093	0.10	
Potato	0.05	<0.01-0.04	0.05	
Soybean	0.05	<0.01-0.05	0.05	<i>Soybean, seed.</i>
Spinach	20.0	9.04-18.2	20.0	If supported by the requested leaf lettuce data, the separate tolerance for head lettuce should be deleted and a tolerance should be established for <i>Leafy greens, subgroup 4A</i> .

Table 34. Tolerance Reassessment Summary for Permethrin.

Commodity	Current Tolerance (ppm)	Range of Residues (ppm) ¹	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Tomato	2.0	0.08-1.3 (0.7x-1.8x)	TBD	The majority of the available data reflect 0.5x the maximum single use rate. Only limited data (6 samples) are available supporting the current use rate. New tomato field trial data are required.
Vegetable, curcubit, group 9	3.0	Cucumbers: <0.036-0.52 Melons: <0.01-1.2 Squash: 0.11-1.27	1.50	Current use pattern and residue data support a lower tolerance.
Watercress	5.0	<6.4-15.5	Revoke	No registered uses.
Tolerances currently listed under 40 CFR §180.378 (c):				
Cattle, fat	3.0	0.88 ⁵	1.50	Residue data support lower tolerances. Eggs were lowered to only 0.1 ppm to harmonize with the Codex MRL.
Cattle, meat	0.25	0.064	0.10	
Cattle, meat byproducts	2.0	0.048	0.10	
Egg	1.0	0.023	0.10	
Goat, fat	3.0	0.88	1.50	Residue data support lower tolerances.
Goat, meat	0.25	0.064	0.10	Residue data support lower tolerances.
Goat, meat byproducts	2.0	0.048	0.10	
Hog, fat	3.0	<0.01	0.05	
Hog, meat	0.25	<0.01	0.05	
Hog, meat byproducts	3.0	<0.01	0.05	
Horse, fat	3.0	0.88	1.50	Residue data support a lower tolerance.
Horse, meat	0.25	0.064	0.10	Residue data support lower tolerances.
Horse, meat byproducts	2.0	0.048	0.10	
Milk, fat	6.25	0.088 whole milk –2.20 milk, fat	3.0	Residue data support a lower tolerance. <i>Milk fat</i> (reflecting 0.0.88 ppm in whole milk)
Poultry, fat	0.15	0.11	0.15	Maximum excepted residue in poultry meat and fat were estimated using data from the oral poultry metabolism study.
Poultry, meat	0.05	<0.01	0.05	
Poultry, meat byproducts	0.25	<0.01	0.05	Residue data support a lower tolerance.
Sheep, fat	3.0	0.88	1.50	Residue data support a lower tolerance.
Sheep, meat	0.25	0.064	0.10	Residue data support lower tolerances.
Sheep, meat byproducts	2.0	0.048	0.10	
Tolerances currently listed under 40 CFR §180.378 (d):				

Table 34. Tolerance Reassessment Summary for Permethrin.

Commodity	Current Tolerance (ppm)	Range of Residues (ppm) ¹	Tolerance Reassessment (ppm)	Comment/ <i>Correct Commodity Definition</i>
Collards	20.0	1.48-11.27	15.0	Residue data support a lower tolerance
Papaya	1.0	0.610-0.697	1.0	
Turnip, greens	20.0	0.30-8.25	10.0	Residue data support a lower tolerance.
Turnip, roots	1.0	0.02-0.12	0.20	Residue data support a lower tolerance.
Tolerances needed under 40 CFR §180.378(a):				
grain, aspirated fractions	None	0.386 ⁶	0.50	Residue data from a corn grain processing study indicate that a tolerance is required on aspirated grain fractions.

- ¹ Unless otherwise indicated, the reported range of residues for permethrin are from commodities treated at 1x the maximum specified use rate and harvested at the minimum specified PHI. Rates other than 1x are reported in parentheses.
- ² Residue ranges reflect residues in/on forage and hay harvested at a 0-day PHI following applications up to 0.1 lb ai/A or at a 14 day PHI for applications at 0.2 lb ai/A.
- ³ TBD = To be determined. Tolerance level cannot be determined at this time because additional data are required.
- ⁴ Results for the two samples of rangeland grass were originally reported on a dry weight basis (3.33, 4.42 ppm), but have been converted to a fresh weight basis.
- ⁵ For animal commodities, the residues are the estimated maximum residues for the 1x MTDB using data from the feeding studies or metabolism studies.
- ⁶ Calculated residue value bases on 19.3x concentration factor in aspirated grain fractions from corn and HAFT residues of 0.02 ppm from field corn grain.

a. Tolerances Listed Under 40 CFR §180.378(a)

The temporary tolerance for residues of permethrin in/on cottonseed expired on November 15, 1997, and therefore 40 CFR §180.378(a) should be removed.

b. Tolerances Listed Under 40 CFR §180.378(b)

The tolerance expression and tolerances in 40 CFR §180.378(b) should be recodified as 40 CFR §180.378(a)(1). Based on available residue data, the existing tolerances are adequate on almond, almond hulls, apple, avocado, Brussels sprouts, corn grain, filbert, garlic, dry bulb onion, pistachio, potato, soybean seeds, spinach and walnuts. Tolerances can be lowered for residues in/on alfalfa fresh and hay, artichoke (globe), cauliflower, celery, corn forage, stover and sweet, cucurbit vegetables, eggplant, horseradish, mushroom, peach, pear, and pepper (bell); the recommended tolerances are listed in Table 34. Tolerances for permethrin should be increased to 2.0 ppm in/on asparagus and broccoli and to 4.0 ppm in/on cherry.

Tolerances on kiwifruit and watercress should be revoked as there are no registered uses for permethrin on these commodities, and these tolerances are no longer needed.

Additional residue data are required to support the existing tolerances on cabbage, grass (rangeland), tomato, and leafy vegetables (excluding Brassica). The existing residue data on cabbage are incomplete, but indicate that the current 6 ppm tolerance may be too low. The

existing residue data on tomatoes are also incomplete, but indicate that the current 2.0 ppm tolerance is likely to be adequate. The available rangeland grass data indicate that the current 15 ppm tolerance may be too high. In addition, the tolerance for grass (rangeland) should be reassigned to §180.378 (d), as this is a regionally restricted use.

The current crop group tolerance for leafy vegetables (excluding Brassica) is supported by adequate field trial data on celery, head lettuce, and spinach. However, no residue data are available on the representative commodity leaf lettuce, which is likely to incur the highest residues based its growth habit and the current use pattern. Although incomplete, the available data indicate that separate tolerances should be established for the leafy greens (4A) and leaf petiole (4B) subgroups of the leafy vegetable crop group, as residues in/on celery are substantially lower than on head lettuce and spinach. The existing celery data would support a general tolerance of 1.0 ppm for the Vegetable, leaf petiole, subgroup 4B. Once the requested leaf lettuce data are available, a separate tolerance should be established for the Vegetable, leafy greens, subgroup 4A.

The apple and pear field trial data also indicate that a single tolerance of 0.05 ppm would be appropriate for Fruit, pome, group 11. Concomitant with establishing this crop group tolerance, the separate tolerances of apple and pear should be removed.

c. Tolerances Listed Under 40 CFR §180.378(c)

The tolerance expression and tolerances in 40 CFR §180.378(c) should be recodified as 40 CFR §180.378(a)(2). Part 180.378(b) should be established for Section 18 emergency exemptions as is current Agency practice, and reserved. Sufficient data are available to ascertain the adequacy of the established tolerances on animal commodities provided that adequate data depicting the stability of permethrin in frozen animal matrices are submitted.

Data from the ruminant and poultry feeding studies were used as the basis for reassessing tolerances. Based upon residue data from feeding studies and studies involving direct applications to livestock and their housing, dietary exposure to permethrin residues is the route that results in the highest potential residues in animal commodities. As feeding studies are not available for swine, the ruminant feeding studies were used to reassess tolerances for hogs.

For tolerances on commodities of cattle, goats, horses, and sheep, the available data indicate that the tolerances for fat, meat, meat byproducts, and milk fat should be lowered to 1.50 ppm, 0.10, 0.10 ppm, and 3.0, respectively. The tolerance for fat of hogs, hog meat and meat byproducts can be lowered to 0.05 ppm.

For poultry commodities, the 0.15 ppm tolerance for fat is adequate. Tolerances for poultry meat and meat byproducts should be lowered to 0.05 ppm, and the tolerance for eggs should be lowered to 0.10 ppm.

d. Tolerances Listed Under 40 CFR §180.378(d)

The tolerance expression and tolerances in 40 CFR §180.378(d) should be recodified as 40 CFR §180.378(c) for regional registrations as is current Agency practice. Part 180.378(d) should be established for indirect or inadvertent residues, as is current Agency practice, and reserved. Sufficient data are available to ascertain the adequacy of the established tolerances with regional registration for papayas and turnip roots and tops. The current 1.0 ppm tolerance in/on papaya is adequate and the available turnip data indicate that tolerances for turnip roots and tops can be lowered to 0.20 and 10.0 ppm, respectively.

Additional data are required on collards before the tolerance level can be determined, but the currently available data would support lowering the tolerance to 15.0 ppm.

e. New Tolerances Needed Under 40 CFR §180.378(a)(1)

The available corn grain processing study indicates that a tolerance is required on aspirated grain fractions (grain dust). Based on the HAFT residues for field corn grain of 0.02 ppm and the observed processing factor of 19.3x for grain dust, the maximum expected residues in corn grain dust would be 0.386 ppm. These data would support establishing a tolerance of 0.50 ppm for residues of permethrin in grain, aspirated fractions.

As indicated above, the available celery, apple and pear field trial data support establishing crop group tolerances for the leaf petiole vegetables subgroup 4B and the pome fruits group 11.

E. Regulatory Rationale

The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of permethrin for permethrin products to be eligible for reregistration. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

1. Human Health Risk Management

a. Dietary (Food and Drinking Water) Risk Mitigation

Acute dietary (food and drinking water) risk is below the Agency's level of concern; acute dietary risk estimates are 4% of the aPAD for the general U.S. population, and 16% for infants, the subgroup most exposed. Additionally, the chronic dietary (food and drinking water) risk is below the Agency's level of concern; risk estimates are <1% cPAD for the general U.S. population and all population subgroups. The estimated cancer dietary (food and drinking water) risk, 1.1×10^{-6} , is within the negligible risk range of up to 3×10^{-6} , and is also below the Agency's LOC. No mitigation is required to address dietary risks.

b. Residential Risk Mitigation

A dermal absorption factor was used for the dermal part of the cancer equation for residential. The Agency calculated the dermal absorption factor from an oral to dermal toxicity ratio (oral exposures LOAEL of 75/dermal NOAEL of 500), and concluded 15% is appropriate for the dermal part of the cancer equation for cancer risk assessment.

The permethrin registrants and the PIRTF believe that 15% is still a highly conservative factor, and requested that the Agency employ a weight-of-the-evidence approach to determine the human dermal absorption factor for permethrin from existing peer-reviewed published studies and registrant-submitted data which, in this view, supports a 2-5% dermal absorption factor. The Agency previously concluded that the dermal penetration study submitted by the registrants to support a 2-5% dermal absorption factor does not satisfy the basic criteria for an in vivo survival primate study, and therefore, was determined to be scientifically unacceptable. Further, the Agency contends that after consideration of other data available for permethrin, a weight-of-evidence approach was utilized to reduce the dermal absorption factor to 15%. Again, this value is considered to be a conservative high-end estimate because the oral dose represents a LOAEL rather than a NOAEL.

Although the Agency recognizes that the 15% dermal absorption factor used for residential risk assessment is a conservative high-end factor, without an additional guideline dermal absorption study, the Agency does not have the confidence to further reduce the dermal absorption factor. However, if a guideline dermal absorption study were voluntarily submitted, the Agency would review the data and consider the results with the risk assessments and risk mitigation measures for this RED.

i. Residential Handler

The Agency assessed the potential non-cancer (dermal and inhalation) and cancer risks to homeowners handling (mixing, loading, and applying) permethrin products in residential settings (indoor and outdoor). All handler scenarios assessed were below the Agency's non-cancer LOC (MOEs ≥ 100). However, the Agency is concerned with the potential cancer risks associated with exposure a homeowner could receive when mixing, loading, and applying emulsifiable concentrate (EC) formulation of permethrin to horses via sponge (see Table 7).

Mitigation for Sponge Application of EC formulation

This scenario reached the Agency's cancer LOC ($\leq 3 \times 10^{-6}$) after 2 exposure events (2 days) per year. Current registered labels recommend this application for use on horses, foals, dogs, cats and kittens to treat numerous pests, such as face flies, stable flies, deer flies, fleas, ticks, mosquitoes, gnats, mites, chiggers, and lice. Additionally, the labels recommend for initial treatment to apply to the animal daily, and as the infestation subsides, reapply every 2-3 days as needed. Given the broad range of target pests, coupled with the re-treatment instructions, the Agency believes an individual using a permethrin product for this purpose will be exposed more than 2 times per year.

To determine the potential exposure a homeowner could receive for this scenario, the Agency relied on Chemical Manufacturers Association antimicrobial wipe exposure data, which is the best available data for the sponge application scenario. However, as stated in Section III, the Agency has concerns regarding the quality of the data and believes exposure data specific to this scenario would be more reliable, and potentially result in a reduced risk estimate. However, neither the technical registrants nor any member of the PIRTF have volunteered to conduct exposure data to support this application method.

Therefore, to mitigate the risks associated with this use, the registrants have agreed to discontinue the use of sponge application for products applied as a liquid, and amend their respective labels appropriately (see Section V, Table 35). Other application methods are available for this use, such as RTU wipes, RTU pour-on, and RTU trigger pump sprays. The Agency assessed these alternative application methods in the residential handler risk assessment and both non-cancer and cancer risk estimates for all scenarios were below the Agency's non-cancer and cancer LOCs, respectively.

ii. Residential Post-Application

The non-cancer dermal, inhalation and oral risks from post-application exposure to permethrin are below the Agency's LOC for residential adults and youth aged children (MOEs ranged from 120 to 500 billion). Additionally, most of the toddler non-cancer risk estimates are also below the Agency's LOC (MOEs ranged from 140 to 250 billion); however, the incidental oral and dermal risk estimates for toddlers exposed to post-application of permethrin on carpets by directed surface sprays were above the Agency's non-cancer LOC (MOEs <100). The MOEs are 37 and 69 for oral and dermal exposures respectively.

Additionally, all post-application outdoor and pet contact activities were below the Agency's cancer LOC. Based on the REJV survey data, a typical homeowner uses permethrin products approximately 5 times per year. The number of exposure events per year for these scenarios to reach the Agency's cancer LOC ranged from 18 to 365 days. However, two indoor scenarios assessed were of concern to the Agency; 1) post-application exposure treated with permethrin products by directed carpet sprays (broadcast and crack and crevice) and 2) total release foggers. These scenarios reached the Agency's cancer LOC in <1 and 2 events per year, respectively. Moreover, the Agency assumed 8 hours of exposure for carpet sprays, and 4 hours for vinyl flooring. Additionally, the post-application risk assessment assumed exposure to permethrin residues the same day the area was treated (i.e., day 0 residue), which are considered reasonably conservative assumptions, considering indoor residues are removed over time through cleaning and other indoor activities.

To address the non-cancer and cancer risks associated with these post-application scenarios, the following mitigation measures are to be implemented.

Mitigation for Indoor Directed Surface Sprays:

The permethrin registrants and PIRTF members suggested that 1% ai was a high-end concentration, and a large majority of indoor products for either PCO or consumer use contains

0.5% ai or less. The Agency's Standard Operating Procedure, which is based on a number of indoor deposition studies, identifies the ISR for 0.5% broadcast sprays as $15 \mu\text{g}/\text{cm}^2$, and $7.5 \mu\text{g}/\text{cm}^2$ for crack and crevice treatment. The Agency calculated comparison cancer risk estimates for 0.5% ai broadcast products using a 15% dermal absorption factor. As a result, these products also reached the Agency's cancer LOC in <1 event/year. Additionally, the 0.5% crack and crevice sprays reached the Agency's cancer LOC in approximately 2 events/year. Based on these comparison risk assessments, a reduced application rate would not mitigate the cancer risks of concern.

The registrants also pointed to the conservative dermal absorption factor used in the cancer risk assessment. To determine if a reduced dermal absorption factor would significantly reduce the risks, the Agency calculated potential risk estimates using a hypothetical 10% and 5% dermal absorption factor for 0.5% ai concentrated products. The Agency determined that for both broadcast and crack and crevice applications, neither a 10% nor a 5% reduced dermal absorption factor would significantly increase the number of exposure events to a level that would be below the Agency's cancer LOC. However, if a guideline dermal absorption study was voluntarily submitted, which supported a dermal absorption factor less than 5%, the Agency may consider the results following this RED determination.

According to the PIRTF, the majority of RTU sprays contain 0.5% ai permethrin or less. Therefore, the Agency assessed a 0.5% ai spray, based on a pyrethrin and piperonyl butoxide deposition study following the use of an aerosol spray submitted by the Non-Dietary Exposure Task Force, with an ISR of $0.21 \mu\text{g}/\text{cm}^2$. The Agency believes aerosol sprays and trigger pump sprays will result in similar deposition. These application methods are used on indoor surfaces, but unlike the indoor broadcast and crack and crevice applications used by PCOs, they are mostly consumer products used more as spot treatments, thus, the deposition is considerably less than the directed sprays intended to treat larger areas. Both the non-cancer and cancer risk estimates for application of aerosol sprays on indoor surfaces (hard and carpet) were below the Agency's LOC. For carpet and vinyl floors, the post-application MOEs for toddlers, the most sensitive sub-population, are 8,500 and 35,000 (oral route) and 16,000 and 84,000 (dermal route), respectively. Also, for the US general population, the number of events per year it takes the cancer LOC to reach the negligible risk range are 57 and 114, respectively, which is significantly greater than the average number of times per year permethrin products are used in the home in this manner, according to the REJV survey.

Therefore, in order to mitigate the non-cancer and cancer risks, the registrants have agreed to discontinue all directed spray application methods (i.e., low pressure handwands, ULV cold foggers, and backpack sprayers) for use on indoor surfaces, and amend their respective labels as appropriate (see Section V, Table 38). RTU consumer sprays, such as aerosol and trigger pump sprays, will be the only application methods for use on indoor surfaces. Based on its risk assessment, the Agency is limiting RTU sprays to concentrations of 0.5% ai or less. However, the Agency acknowledges that there are specialized sprays with higher concentrations, up to 3% ai, which are intended to be injected directly into cracks and crevices and behind walls or spaces, and therefore, result in little to no potential exposure. The Agency will consider these products if the registrants for these products are able to provide justification or data to the Agency which demonstrate that little to no exposure will occur due to the specialized use of the

product. The registrants have agreed to limit use of all aerosol sprays with a concentration of no more than 0.5% ai of permethrin, and amend their respective labels as appropriate (see Section V, Table 38).

Mitigation for Indoor Total Release Foggers

The Agency assessed a 0.58% ai concentrated indoor total release fogger (TRF) with a maximum application rate of 0.0023 lb ai/6 oz fogger, which is labeled to treat 6000 cubic feet (ft³) or less. A permethrin specific deposition study was available to the Agency, which determined the ISR for a 0.5% ai concentrated 6 oz TRF to be 4.8 µg/cm² when treating a space approximately 2000 ft³. Therefore, the Agency used an ISR of 4.8 µg/cm² in both its non-cancer and cancer risk assessments.

The non-cancer risk estimates on both hard surfaces and carpets were below the Agency's LOC for both adults and toddlers. However, the cancer risk estimate for total release foggers reached the Agency's cancer LOC in 2 exposure events/year for carpet, and 5 exposure events/year for vinyl surfaces. This estimate assumes that an individual is exposed to permethrin residues the day of treatment, and is engaged in high contact activities, such as exercising or playing, for 8 hours on carpet and 4 hours on vinyl. According to the registrants, a single permethrin active ingredient fogger loses efficacy below approximately 0.48% ai. However, there are combination products registered that contain permethrin with other chemicals, often other pyrethroids, and a synergist, such as PBO. These combination products contain approximately 0.25% of permethrin or less. The Agency calculated the potential cancer risk estimate from a TRF with a 0.25% ai concentration (ISR of 2.4 µg/cm²). The risk estimates reached the Agency's LOC after 5 exposure events and 33 exposure events for carpet and vinyl surfaces, respectively. According to the REJV survey data, a typical homeowner will use a TRF approximately 3 times per year. Therefore, the Agency believes the use of permethrin TRF products with 0.25% ai concentration or less are below the Agency's LOC, and are eligible for reregistration.

In order to mitigate the cancer risks associated with this use, the registrants have agreed to limit all TRF products to no more than 0.25% ai permethrin. The Agency will consider products with higher concentrations if the registrants of the products can provide justification or data to the Agency which demonstrates that an equivalent ISR of 2.4 µg/cm², or less, will result in a room size of 2000 ft³ or less.

Further, unlike the indoor surface sprays, a reduced dermal absorption factor does significantly decrease the risk associated with post-application exposure to a 0.5% ai concentrated permethrin TRF. Using a hypothetical 10% dermal absorption factor, the risk estimates reach the Agency's LOC in 4 and 8 exposure events for carpet and vinyl, respectively; and using a hypothetical 5% dermal absorption factor, the risk estimates reach the Agency's LOC in 8 and 16 exposure events, respectively. As stated in the discussion of the dermal absorption study above, the Agency may consider the results of a guideline dermal absorption study, which is proposed to be voluntarily conducted and submitted by the registrants, following this RED determination.

iii. Other Residential Uses To be Addressed in RED

Outdoor Residential Misting Systems

As stated in Section III, the Agency considered post-application exposure to adults and toddlers who are exposed to permethrin from an outdoor residential misting system pesticide application. These systems are fairly new to the pesticide market, and vary in their system design. Based on outreach to the permethrin registrants and review of labels currently registered for use in these systems, the Agency used the following assumptions in the permethrin risk assessment:

- The breathing rates utilized were:
 - adult breathing rate for moderate activity is 1.6 m³/hour, and
 - toddler breathing rate for light activity is 0.8 m³/hour.
- Cubic feet treated is based on the assumption that nozzles are placed at 10 feet from the ground (e.g., on eaves) creating a ceiling of 10 feet in height;
- The emission is to be treated as an “instant release” scenario where all active ingredient is assumed to be released in the air immediately (this is assumed to represent a conservative approach); and
- It was assumed that in an individual (toddler or adult) was exposed to one nozzle that released 1.5 fl. oz. in a one minute period of time.

As stated in section III, based on these assumptions, the Agency has no risk concerns associated with post-application exposure to permethrin from outdoor residential misting systems. However, the Agency recognizes that due to the variation in the systems’ design and the way in which the systems are installed, these assumptions may not be inclusive of all systems available in the market. However, the Agency did not receive any comments on the assumptions used in the permethrin risk assessment during the Phase 3 public comment period.

Statutory Requirements

Further, the distribution or sale, and use of pesticides in outdoor residential misting systems are subject to several statutory requirements. At this time, permethrin, pyrethrins, and piperonyl butoxide (PBO) appear to be the only chemicals used in outdoor residential misting systems; however, it is possible that other pesticides registered for residential outdoor use might also be used in a similar systems. Section 2(ee)(3) of FIFRA permits the use of any application methods that are not prohibited by the pesticide’s labeling; however, the application must only be to target sites specified by the labeling and at no more than the maximum dosage rates specified by the labeling. Since most pesticide labels do not explicitly prohibit use in outdoor residential misting systems, other chemicals that target similar pests could be used in these misting systems. The Agency is not aware of other pesticides being used in outdoor residential misting systems, and therefore, has not assessed the potential risks to homeowners associated with use of pesticides in these systems from pesticides other than permethrin, pyrethrins, and PBO.

All permethrin, pyrethrins, and PBO registrants that do not support outdoor residential misting systems use for their products, will be expected to amend their Manufacturing Use Product label to state the following, “This product must not be formulated into an end use product for use in outdoor misting systems.” Additionally, all registrants of permethrin, pyrethrins, and PBO wettable powder or EC formulated EPs, with outdoor residential use, will be expected to include a statement prohibiting use in an outdoor residential misting system or include separate and specific instructions for use in outdoor residential misting systems, including the maximum application rate per day, use directions, and restrictions specified in Section V, Table 38. Although this action will only address permethrin, pyrethrins, and PBO products, the Agency plans to issue broader guidance pertaining to use of outdoor misting systems, and the pesticides which can be used in these systems, as part of its on-going effort to standardize the way in which these systems are used.

Finally, in accordance with FIFRA Section 2(e)(1) and (gg), leaving unapplied pesticide at a use site constitutes the distribution or sale of a pesticide. In order to be in compliance with FIFRA, companies which sell, install, and service outdoor residential misting systems must ensure that one of the following transactions occur when providing these services:

- the unopened registered pesticide is distributed or sold to the use site owner prior to mixing and loading into the equipment; or
- the diluted registered pesticide is distributed or sold as a custom blend in accordance with EPA’s custom blending policies at 3.4 and 7.1 of the Enforcement Policy Compendium; or
- the diluted pesticide is registered and is distributed or sold to the use site owner prior to loading into the equipment.

Although the Agency’s post-application assessment for adult and toddler exposure to permethrin via outdoor residential misting systems indicates exposures below the Agency’s LOC, several issues, in addition to those discussed above, have been raised to the Agency through State FIFRA Issues Research and Evaluation Group issue papers, stakeholder forums and comments, and other sources regarding the use of these systems. These issues include, but are not limited to, the potential for inadvertent exposure and risks to residents, misuse of the systems and pesticide products, offsite drift and potential exposure to non-target organisms, and resistance issues. The Agency is aware of a cooperative effort lead by the National Pest Management Association involving state and industry stakeholders, and pest management professionals to standardize these systems and address the issues raised above, and intends to continue to address these on-going issues through continued involvement and discussions with the States, industry and stakeholder groups. In addition, the Agency has developed a Outdoor Residential Misting System web-based fact sheet page aimed at helping consumers decide if these systems are appropriate for their home, understand safety precautions about using outdoor misting systems, find related information on Integrated Pest Management, and understand the role of the US EPA and state agencies in regulating misters (http://www.epa.gov/pesticides/factsheets/misting_systems.htm). Finally, the Agency is requiring efficacy data be submitted for all products registered for use in outdoor residential

misting systems claiming to target public health pests. Refer to the product-specific data call-in PDCI) for more detail regarding the required data.

The Agency provided a 60-day comment period after the publication of the RED to solicit feedback on the assumptions used in the permethrin risk assessment, the required label language in Section V, Table 38, and the statutory requirements addressed above.

Permethrin Impregnated Fabrics

The Agency has approved methods for impregnating fabric with permethrin when treating bulk fabric (prior to being cut and constructed) and treating the finished fabric (after being cut and constructed into an article of clothing, tents, netting, etc.). The issue has been raised to the Agency that several different finishing processes i.e., pre-washing, dying, permanent press etc. can occur, before a fabric is finished which may compromise the efficacy of the permethrin treatment.

Further, the labeling of current impregnated fabric products claim to retain a level of permethrin that is efficacious up to 25 washings. The Agency has received comment that depending on the manufacturing method, the claims may not be accurate and that the product may lose efficacy in less than 25 washings.

To address these uncertainties, the Agency is requiring product specific efficacy data for all permethrin impregnated fabric products, and wash-off data to support the efficacy claims. Refer to the PDCI for more detail regarding the required data.

c. Aggregate Risk Mitigation

Acute Aggregate Risk

For permethrin, the acute aggregate risk estimates are the same as those presented in the acute dietary (combined food and drinking water) risk section of this document. Since acute aggregate risks are below the Agency's LOC, no mitigation is necessary.

Short-Term Aggregate

This section describes the aggregate (combined) risk from food, drinking water, and short-term residential exposures, as well as risk refinements and the mitigation measures that need to be implemented to manage risks of concern. As noted above in Section III of this document, short-term aggregate risks for the U.S. general population and adult females were below the Agency's LOC. However, the short-term aggregate risk for toddlers exceeded the Agency's LOC for one scenario, with an aggregate MOE of 24, due to the incidental oral and dermal risks associated with post-application exposure to indoor carpets treated with directed sprays (see Table 12). In order to mitigate these risks, the registrants agreed to discontinue use of directed spray applications on indoor surfaces. As a result, aerosol cans will be the only remaining application method. This measure reduces the toddler non-cancer incidental oral and dermal exposures, thus increasing the MOEs to 8,500 and 16,000, respectively. Provided these

mitigation measures are implemented, the short-term aggregate risks are below the Agency's LOC and no further mitigation measures are necessary. Moreover, the Agency believes it is still appropriate to include this post-application scenario in the short-term aggregate risk assessment because, according to the preliminary results of the REJV survey, permethrin use on lawns and on indoor crack and crevice sites account for the most use in the residential market place, and are likely to co-occur. Thus, Table 35 summarizes the short-term aggregate scenarios that previously were of concern and the new risk results based on mitigation measures detailed above.

Table 35: Short-Term Aggregate Risk with Mitigation		
Population	Short-Term Scenario	
	Previous Short-Term Aggregate MOE [Food, Drinking Water and Residential (Lawn Care and Indoor Surface Spray on Carpet)]	Revised Short-Term Aggregate MOE [Food, Drinking Water and Residential (Lawn Care and Indoor Aerosol Spray on Carpet)]
Toddler	24	4709

Cancer Risk

Similar to the short-term aggregate risk assessment, the indoor surface spray application was the risk driver for the cancer aggregate risk scenario that was above the Agency's level of concern. With implementation of the same risk mitigation measures to address the short-term aggregate risks of concern, the cancer risk estimate on the first day of application for aerosol sprays to treat indoor carpets is 5.7×10^{-8} , and takes 18 exposure events per year to reach the Agency's LOC. Table 36 summarizes the cancer aggregate scenario that was previously of concern and the new risk results based on mitigation measures detailed above.

Table 36: Cancer Aggregate Risk with Mitigation		
Population	Short-Term Scenarios	
	Previous Short-Term Aggregate Cancer Risk [Food, Drinking Water and Residential (Lawn Care and Indoor Surface Spray on Carpet)]	Revised Short-Term Aggregate Cancer Risk [Food, Drinking Water and Residential (Lawn Care and Indoor Aerosol Spray on Carpet)]
U.S. Pop	1.5×10^{-5}	1.1×10^{-8}

d. Occupational Risk Mitigation

It is the Agency's policy to mitigate occupational risk to the greatest extent practical and feasible. Occupational exposure assessments are completed by the Agency considering the use of baseline PPE, and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for permethrin is 100, based on information provided in Section III of this document. For occupational cancer risks, estimates within the negligible risk range of up to 3×10^{-6} do not exceed the Agency's level of concern. When occupational MOEs are estimated to be less than 100 or occupational cancer risk estimates exceed the general range of $\leq 3 \times 10^{-6}$, EPA strives to reduce worker risks through the use of PPE and engineering controls or other mitigation

measures. The Agency generally considers occupational cancer risks in the general range of 1×10^{-6} or less to be negligible, but may accept risks as high as 1×10^{-4} when all mitigation measures that are feasible and practical have been applied, particularly when there are critical pest management needs associated with the use of the pesticide.

Mitigation measures may include reducing application rates, adding PPE to end-product labels, requiring the use of engineering controls, and other measures. Levels of PPE considered, as described in Tables 14 and 15, and applicable to the proposed mitigation are described below:

- Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator. (Baseline)
- Baseline plus chemical-resistant gloves, and no respirator.
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator.
- Baseline plus chemical-resistant gloves and an 80% PF (quarter-face dust/mist) respirator.
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator.
- Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit.

A wide range of factors are considered in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs and cancer risk estimates, incident data, the nature and severity of adverse effects observed in the animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other factors.

Similar to the residential cancer risk assessment, a dermal absorption factor of 15% was used for the dermal part of the cancer equation for the occupational cancer risk assessment. As discussed above, the registrant may voluntarily conduct a guideline dermal absorption study to refine this estimate; however, unlike for some residential exposure scenarios, a reduced dermal absorption factor is not expected to significantly affect the risk mitigation for any of the occupational risks discussed below.

i. Handler Risk Mitigation

As stated in Section III, most of the non-cancer and cancer risk calculations for occupational handlers were below the Agency's LOC when handlers wore baseline PPE and gloves. However, as summarized in Tables 14 and 15, some handler scenarios required additional PPE to be below the Agency's non-cancer and cancer LOCs, respectively. Therefore, specific mitigation measures and additional data needs are necessary to address these risk concerns. Following the implementation of the formulation specific and activity specific risk mitigation measures, handler risks will no longer be of concern to the Agency. The registrants have agreed to the following mitigation:

Mixing, Loading and Applying Emulsifiable Concentrate (EC) and Granular Formulations

All non-cancer risk estimates are below the Agency's LOC for workers handling the granular formulation of permethrin ($\text{MOEs} \geq 1700$) with baseline PPE and gloves. Additionally, all cancer risk estimates were $\leq 1.2 \times 10^{-6}$ with the same level of PPE, which is within the negligible risk range of $\leq 3 \times 10^{-6}$ and not of risk concern.

For all handlers scenarios of the liquid (EC) formulations, except for those which utilize handheld equipment (i.e., handwands, handgun sprayers, backpack sprayer, etc.), all non-cancer risk estimates are below the Agency's LOC ($\text{MOEs} \geq 1500$) with baseline PPE and chemical-resistant gloves, and all cancer risk estimates were $\leq 2.6 \times 10^{-6}$ with the same level of PPE, which is also within the negligible risk range of 1×10^{-6} and not of risk concern. For handlers of the EC formulation with handheld equipment, all non-cancer risk estimates are below the Agency's LOC ($\text{MOEs} \geq 160$) with baseline PPE and chemical-resistant gloves, and all cancer risk estimates were $\leq 2.8 \times 10^{-5}$ with the same level of PPE. Since additional PPE (i.e., double-layer clothing, respirator, etc.) beyond baseline PPE and gloves will only marginally reduce the cancer risk estimates, and instead may cause additional heat related stress to workers, the Agency has determined additional PPE will be an undo burden and is not required. Therefore, products containing the EC or granular formulations of permethrin are eligible for reregistration provided the following PPE is required on the labels: baseline PPE and chemical-resistant gloves.

Mixing, Loading, and Applying Wettable Powder (WP) Formulations

The non-cancer and cancer risk estimates for workers handling WP in the scenarios identified Table 14 and 15, respectively, require additional risk mitigation measures in order for scenarios with the WP formulation to be below the Agency's LOC. The Agency determined that engineering controls (i.e., water soluble packages) significantly reduce the non-cancer and cancer risks associated with mixing and loading activities (all $\text{MOEs} > 100$; MOEs range from 5700 to 420000, and cancer risk estimates are less than 1×10^{-6}). Additionally, the Agency believes that the reduced exposure to mixers/loaders/applicators as a result of the engineering controls does not require additional PPE, and thus, baseline and chemical-resistant gloves are protective. Therefore, in order to be eligible for registration, the following mitigation measures are required: 1) wettable powder formulations must be packaged in water soluble bags (see Table 38 for PPE requirements for engineering control), and 2) all mixers and loaders plus applicators using handheld equipment applicators must wear baseline PPE and chemical-resistant gloves (except RTUs and products applied as fogs or dips, see below). An apron will also be required for handlers exposed to the concentrate and applicators applying liquid via dip application to animals as specified below.

Mixing, Loading and Applying Dry Flowables

Although permethrin is not currently manufactured into a dry flowable formulation, one technical registrant stated the company would prefer to change over all its WP products to dry flowable products, instead of packaging the WP products in water soluble bags as required for reregistration. Because there are no current registrations of permethrin products formulated as dry flowables, an assessment was not conducted to evaluate worker risks associated with the use of these products. However, available information on the units of exposure for both dermal and inhalation routes indicate that they are significantly less for dry flowable formulations than for liquid formulations. As a result, the Agency believes the level of PPE required for mixing,

loading, and applying liquid (EC) formulation products of permethrin will be protective for workers handling dry flowables. Therefore, baseline PPE and chemical-resistant gloves would be required for mixing, loading, and applying dry flowable formulation products, if manufactured.

Mixing, Loading, and Applying Dusts

The non-cancer and cancer risk estimates for workers handling dusts in the scenarios identified Table 14 and 15, respectively, require additional risk mitigation measures in order for scenarios with the dust formulation, for which there is available data, to be below the Agency's LOC. The non-cancer risk estimate for loading the dust formulation into a mechanical duster (poultry use based on the assumption that 100,000 animals are treated each day) requires baseline PPE, chemical-resistant gloves and a PF5 respirator to be below the Agency's non-cancer LOC (MOE=780). The cancer risk for this scenario is 1.6×10^{-5} with this level of PPE; however, additional PPE only marginally decreases the risk estimate. For example, with the maximum PPE feasible for this scenario (i.e., double layers, gloves, and a PF10 respirator), the cancer risk estimate is decreased to only 1.1×10^{-5} . In addition, the assumption that 100,000 animals are treated daily is a high-end estimate and is likely not to be generally performed. Considering the high-end assumption used to estimate the handler risks for this particular scenario, and the fact that additional PPE beyond baseline PPE, gloves, and a PF5 respirator will not measurably reduce exposure, and instead may cause additional heat related stress to the worker, the Agency has determined additional PPE to be an undue burden and is not required for loaders. Additionally, all other loading scenario assessed for the dust formulation resulted in MOEs ≥ 3 million, and cancer risk estimates $\leq 4.1 \times 10^{-9}$ with the same level of PPE. Therefore, the Agency believes baseline PPE, chemical-resistant gloves, and a PF5 respirator is protective of both non-cancer and cancer risks for all scenarios, and is required for loaders handling the dust formulation.

The Agency did not have exposure data to assess the potential exposure to workers applying the dust formulation via shaker can, mechanical duster, or dust bag. Dust applications are made to livestock animals, dogs, and cats. The Agency believes little to no exposure to applicators will occur with the mechanical duster and dust bag application methods because applications are not made manually. Although applications via shaker can are made manually to either a single animal (dog or cat) or to a smaller number of livestock animals, the shaker can is rarely used in an occupational environment. Therefore, the Agency believes the PPE protective of non-cancer and cancer risks for loaders will also be protective for applicators. Thus, dust formulations are eligible for reregistration provided baseline PPE, chemical-resistant gloves, and a PF5 respirator are required for all handler activities, and the Agency will not be requiring additional data.

Applying RTU Products

Although there is no available data to assess potential occupational risks associated with the application of RTU permethrin products, such as RTU wipes, ear tags, animal shampoos and spot-ons, and protective flanges, etc., the Agency believes there will be little to no exposure to handlers and that any potential exposure will be adequately reduced by the use of gloves, since

handler scenarios for agricultural uses, which involve much higher volumes of product, are adequately protected with the same level of PPE. Therefore, in order for RTU permethrin products to be eligible for reregistration, baseline PPE and chemical-resistant gloves are required, and the Agency will not be requiring additional data.

Applying Liquids via Dip

Exposure data is not available to assess the potential risks associated with applying liquid products via dip applications. Currently, the dip application method is registered to treat military battle dress (MBD), as well as to treat livestock animals, dogs, and cats. Permethrin is used by the U.S. Department of Defence to treat MBD while in the field. The dip is provided to the servicemen and women in a RTU package with plastic gloves provided. Based on this use scenario, the Agency believes little to no exposure will occur to the individual treating his/her MBDs with a RTU dip, and that baseline PPE and chemical-resistant gloves, the PPE required for all liquid formulations, will be adequately protective.

Further, the Agency believes little exposure will occur with dip applications to livestock animals. The animals move through the dip relatively unaided, and are primarily handled prior to entering the dip and afterwards. Individuals treating smaller animals, such as dogs or cats, via dip will possibly receive more exposure since they will most likely be lifting the animal in and out of the dip. The Agency believes that based on the non-cancer and cancer risk estimates for occupational handlers using the liquid formulation of permethrin for agricultural crop uses, which involve much higher volume of product, baseline PPE and chemical-resistant gloves will be adequately protective for all dip applications as well. However, to reduce additional exposure that may result from potential splashing of the product onto the individual during the dip application, the Agency is additionally requiring chemical-resistant aprons to be worn for animal use.

Applying Liquids via Handheld Cold Foggers and Fog/Mist Generators

A cold fogger is a handheld ULV application method that is used to treat a number of indoor spaces, such as mushroom houses, animal premises, and warehouses. The Agency does not have permethrin specific data for this application method; however, the exposures for the hand held ULV fogger application were based on surrogate data from a pulse fogger application in a greenhouse (Nigg, 1987). The exposure data used in the risk assessment to estimate the potential risk to occupational handlers using ULV cold fogger application equipment reflect the dermal and respiratory exposure from the use of hand held backpack foggers in a greenhouse. The applicators in this study were wearing chemical resistant protective clothing (Tyvek coveralls) over long sleeve shirt and long pants, gloves, boots, and goggles. Although this study is the best available data to use as surrogate data for the ULV cold fogger application method, the Agency believes there are uncertainties with this data because the study only has three usable replicates.

The workers in this study were wearing chemical resistant protective clothing (Tyvek coveralls); generally the Agency does not require workers to wear Tyvek coveralls because of concerns over potential heat stress related injuries. Therefore, the Agency believes that double

layer PPE (coveralls over long pants and long sleeved shirt with socks and shoes) with gloves will be protective because the dermal exposure an individual will receive from using a cold fogger is likely equivalent to the dermal exposure he/she will receive when applying a liquid-based spray of permethrin via any high pressure handheld application method.

Fog/mist generators are registered for use in similar indoor areas. However, they are not handheld; instead, soon after the product is released the worker leaves the space. Therefore, the Agency believes the potential exposure a worker will receive from application of permethrin via a fog/mist generator is less than a handheld cold fogger. Thus, the level of PPE required for cold fogger applications will be adequately protective for fog/mist generator applications.

The Agency has determined that permethrin products that are applied with cold foggers and fog/mist generators on indoor areas are eligible for reregistration given the following PPE is required: double layer PPE, and gloves. However, confirmatory dosimetry data for cold fogger applications indoors is required. Given that the Agency believes the potential exposure from a cold fogger will be greater than the potential exposure from a fog/mist generator, the outcome of the dosimetry data for cold foggers will be protective of the fog/mist generator use and, therefore, additional exposure data for fog/mist generators is not required.

Applying Liquid Formulations via High Pressure Handwand in Mushroom Houses

The Agency previously assessed the use of high pressure handwands in mushroom houses in the *Updated Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated June 29, 2005. The cancer risk estimates for handlers that mix/load/apply liquids via high pressure handwand in mushroom houses was above the Agency's LOC, 1.3×10^{-4} , assuming the highest level of PPE possible, which is coveralls worn over long-sleeve shirt and long-pants, chemical-resistant gloves, and a 90% respirator. Engineering controls are not feasible with this use scenario.

The American Mushroom Institute (AMI) provided the Agency with information regarding permethrin use in mushroom houses during phase 3, the public comment phase. According to the AMI, they could find no grower that uses high pressure handwands to apply permethrin in mushroom houses. Instead, ULV cold foggers and fog/mist generators are the typical and preferred application methods.

In response to Phase 3 comments, the Agency removed this scenario from the current revised occupational risk assessment. In order to ensure that high pressure handwands are not used in mushroom houses, the registrants have agreed to amend their wettable powder and EC formulation products labeled for use in mushroom houses to specify that high pressure handwands are prohibited. See Section IV, Table 38 for amended label language.

Aerial Applications – Liquid and Granular Formulations

For aerial applications of permethrin liquid or granular formulations, pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].

ii. Post-Application Worker Risk Mitigation

For workers re-entering treated fields to conduct post-application activities, such as irrigation and hand weeding, all non-cancer risk estimates are below the Agency's LOC (MOEs range from 570 to 200,000) at a 12 hour restricted-entry interval (REI). Additionally, most cancer risk estimates are in the 10^{-5} to 10^{-7} range, except for migrant workers engaging in conifer cone seed harvesting and thinning activities in certain tree orchards 30 days per year. The predicted cancer risk for these scenarios is in the 10^{-4} range. Although the Agency typically tries to mitigate all cancer risk estimates to be less than 1×10^{-6} , the Agency does not believe that extending REI is practical for permethrin because, according to Agency use and usage data, most applications of permethrin on agricultural crops coincide with post-application activities, such as trimming, pruning, or harvesting. Moreover, available dislodgeable foliar residue data indicate that permethrin residues on foliage degrade slowly, requiring the REI to be several weeks in order for cancer risk estimates to be below the LOC.

However, according to Agency data, permethrin is primarily used during the post-harvest and dormant season apple and pear production, which indicated little chance for repeated and prolonged exposure to residues. Only about 10-12% of treated acres, on average, are treated during the period between bloom and harvest. Further, only about 5% of pome fruit acreage are treated with permethrin annually. Together, these data suggest that it is unlikely that workers would be annually exposed to permethrin residues for 30 days in commercial orchards (such as migrant workers) or 10 days in small orchards (such as self-employed producers). Production practices in tart cherry imply that exposure concerns are also unlikely. Further, very low and sporadic treatments make it unlikely that frequent exposure would occur in the following crops: hazelnut, walnut, avocado, alfalfa, potato, soybean, and turnip and collard greens.

The Agency also anticipates post-application exposure from conifer cone seed harvesting to be low. According to the U.S. Forest Service, the last application of permethrin each season is usually made at least 30 days prior to cone harvest. Additionally, it is highly improbable that a cone picker would be exposed to permethrin for 30 days in a year because permethrin is not typically used as a final application in very few orchards, and it would be very unusual for migrant pickers to work on two or three permethrin treated orchards sequentially. Considering the use pattern of permethrin on conifer cone seeds, and characterization of the cone seed harvesting, the Agency reassessed the cancer risk estimate with an REI of 30 days. A 30 day REI reduces the cancer risk to the 10^{-5} range. The registrants have agreed to amend their labels to reflect this mitigation.

In addition, the registrants have agreed to reduce maximum application rates and number of applications per year or season to help reduce potential post-application risks to workers. The specific use pattern reductions are listed in Table 37. Based on these measures, and the impracticality to extend the REI, the Agency intends to maintain the current 12 hour REI for all crop uses, except for conifer cone seed harvesting, which will require a 30 day REI.

2. Non-Target Organism (Ecological) Risk Management

a. Terrestrial Organisms

Birds and Mammals

EPA's screening-level risk assessment, based on maximum application rates, for both aerial and ground application scenarios for permethrin, suggests no acute risks of concern for birds and mammals. The highest acute RQ is approximately 0.03 for birds feeding on short grass and 0.04 for the smallest mammals feeding on short grass (see Tables 21 and 22). Chronic RQs for mammals were calculated using the results of a developmental toxicity study performed with rats. Dose based RQs based on the Maine Potatoe scenario, which is the most conservative of the crop scenarios assessed, range from 0.02 to 2.57. This study was conducted via oral gavage and represents a more intense dosing regime than that of the 3-generation rat reproduction studies (dietary exposure) which the Agency typically relies on to estimate chronic effects and risk to mammals. Therefore, given the questionable toxicological response and the intense dosing regime, it should be noted that this NOAEC represents a conservative estimate of toxicity and its use may result in the overestimation of chronic risk to mammals. Thus, the results are not tabulated in this document. The Agency is not requiring additional data at this time.

Non-Target Insects

Available toxicity data shows that permethrin is highly toxic to honeybees, as well as beneficial insects on both a contact and oral basis. Further, permethrin was also found to be highly toxic to honeybees exposed to foliage that had been sprayed with a permethrin formulation. Therefore, a precautionary statement is required on permethrin product labels to limit the exposure to honeybees and other beneficial insects during applications of permethrin.

Plants

Although the Agency does not have plant toxicity data to assess risks associated with permethrin exposure to terrestrial plants, permethrin's mode of action for controlling insect pests would not be expected to be a mode of action that would harm plants because it is a neurotoxin. The Agency is not requiring plant toxicity data at this time.

b. Aquatic Organisms

i. Agricultural Uses

Freshwater and Estuarine Fish, Invertebrates, and Sediment Organisms

EPA's screening-level risk assessment for permethrin, based on maximum rates and both aerial and ground application scenarios, suggests it is highly toxic to both freshwater and estuarine aquatic organisms. The acute LOC (0.5) was exceeded for most scenarios modeled for freshwater and estuarine fish, invertebrates, and sediment organisms. The screening-level risk assessment also shows the potential for chronic risks to both freshwater and estuarine invertebrates and sediment organisms. The chronic LOC (1) was exceeded for all scenarios. However, the risk assessment also suggests that chronic risks to freshwater and estuarine fish are less likely to occur. The chronic LOC was only exceeded in the Maine Potatoes scenario, which

assumes a maximum application rate of 0.2 lb ai/A, applied 8 times per year. According to comments received by the National Potatoes Council, permethrin is applied only once or twice per year on potatoes due to treat for Colorado Potato Beetles. Use is limited by the need to rotate products due to the potential for resistance development. Based on this information, the Agency believes chronic risk to fish is below the Agency's LOC.

In order to reduce the exposure of permethrin to aquatic organisms, the registrants have agreed to impose a 150 foot buffer zone for aerial applications, and a 25 foot buffer zone for ground applications. The screening-level risk assessment suggests that the use of a buffer zone will decrease the EEC by approximately 20%, and reduce both the acute and chronic risks to freshwater and estuarine aquatic organisms. Further, the acute and chronic RQs are reduced further when typical application rates and number of applications are considered. Typical application rates and number of applications, which are based on Agency use data, reduce acute RQs by over half for all freshwater and estuarine/marine fish, invertebrate, and sediment organisms, and can result in even greater reduction of chronic RQs.

The registrants have also proposed a number of reductions in single and seasonal maximum application rates, as well as number of applications. In many cases, the registrants reduced the seasonal maximum application rate by half, and in all cases specified a minimum retreatment interval. Although the Agency did not revise its risk estimated based on this mitigation, the Agency believes these reductions will serve to further reduce the risks to aquatic organisms. Table 37 lists the amended use patterns for permethrin on agricultural labels.

Table 37. Amended Agricultural Use Patterns						
Crop	Current Labels			Mitigation Per the RED		
	Max. Rate per application (lb ai/A)	Minimum retreatment interval (days)	Seasonal Maximum Application Rate (lb ai/A)	New Maximum rate per application (lb ai/A)	New Minimum retreatment interval (days)	New Seasonal Maximum Application Rate (lb ai/A)
Alfalfa	0.2	14	0.2 per cutting	0.2	30	0.2 per cutting
Almonds	0.4	3	2	0.25	10	0.75
Hazelnuts	0.4	As needed	1.6	0.25	10	0.75
Pistachios	0.4	As needed	1.6	0.3	10	0.9
Walnuts	0.4	As needed	1.6	0.25	10	0.75
Apples	0.4	As needed	0.6	0.25	10	0.5
Pears	0.4	As needed	0.8	0.25 (0.4 dormant only)	10	0.65
Cherries	0.2	As needed	1.2	0.2	10	0.6
Peaches/Nectarines	0.3	7	1.5	0.25	10	0.75
Artichokes	0.3	As needed	1.5	0.3	10	0.9
Asparagus	0.1	As needed	0.4	0.1	7	0.4
Avocados	0.2	7	1.2	0.2	7	0.8
Broccoli	0.2	As needed	0.8	0.2	5	0.8
Brussels Sprouts	0.2	As needed	0.8	0.1	5	0.4
Cabbage	0.2	5	1	0.2	5	0.4 (0.8 in

Table 37. Amended Agricultural Use Patterns						
Crop	Current Labels			Mitigation Per the RED		
	Max. Rate per application (lb ai/A)	Minimum retreatment interval (days)	Seasonal Maximum Application Rate (lb ai/A)	New Maximum rate per application (lb ai/A)	New Minimum retreatment interval (days)	New Seasonal Maximum Application Rate (lb ai/A)
						HI)
Cauliflower	0.2	As needed	0.8	0.1	5	0.4 (0.6 in HI)
Cantaloupes	0.2	7	1.6	0.2	7	0.8 (1.2 in HI)
Cucumbers	0.2	As needed	1.6	0.2	7	1.2
Pumpkins	0.2	As needed	1.6	0.2	7	1.2
Squash (summer, winter)	0.2	As needed	1.6	0.2	7	1.2
Watermelon	0.2	As needed	1.6	0.2	7	1.2
Eggplant	0.21	3	2	0.15	7	0.6 (1.0 in HI)
Peppers, bell	0.2	As needed	1.6	0.2	5	0.8
Tomatoes	0.2	5	1.2	0.2	7	0.6 (0.8 in HI)
Celery	0.2	As needed	2	0.2	7	1.0 (1.2 in HI)
Lettuce	0.2	3	2	0.2	7	0.8 (1.2 in HI)
Spinach	0.2	As needed	2	0.2	3	0.6
Collards	0.2	As needed	0.8 (0.4 in SC, GA, FL, WA)	0.15	3	0.45
Greens, Turnip	0.2	As needed	0.8 (0.4 in SC, GA, FL, WA)	0.15	3	0.45
Corn, Field	0.2	6	0.6	0.15	7	0.45
Sweet Corn	0.25	3	1.2	0.2	3	0.8
Garlic	0.3	As needed	2	0.2	10	0.8
Onions	0.3	As needed	2	0.3	7	1.0
Horseradish	0.21	As needed	0.6	0.15	10	0.45
Papaya	0.4	7	1.2	0.15	10	0.75
Potatoes	0.2	As needed	1.6	0.2	10	0.8
Soybeans	0.2	As needed	0.4	0.2	10	0.4

ii. Public Health Uses

The Agency has conducted a screening-level ecological risk assessment for the mosquito control use of permethrin based on aerial applications of permethrin to Florida turf. Based on the available data, the Agency has identified potential acute risks of concern to freshwater and estuarine/marine invertebrates, and potential chronic risks of concern for estuarine/marine invertebrates. While there is a slight estimated exceedence of the endangered species LOC (0.5) for freshwater fish at the high-end application rate of 0.007 lb ai/A (RQ=0.07), the Agency expects risks of concern to be limited based on the following: 1) aerial release (boom) heights

typically occur at height much higher than assessed, which will further reduce the risks, and 2) there are no risks of concern associated with this use for freshwater fish at the typical application rate (0.0035 lb ai/A).

Although the acute RQs for freshwater and estuarine invertebrates exceed the restricted use LOC ($RQ > 0.1$), the Agency believes that the use restrictions specified in the guidelines and recommendations of PR-2005-1 will serve to reduce overall risk to aquatic organisms and, therefore, it is not necessary to classify permethrin as a restricted use product for wide area mosquito abatement applications. Additionally, the Agency believes that the typical application practices of mosquito abatement districts, as stated in comments received by the American Mosquito Control Association, such as application rate, number of applications, and release height, etc. employed by public health abatement districts result in a reduced risk to aquatic organisms as compared to the maximum rate and number of applications, and minimum release height assessed in the risk assessment.

Further, in order to reduce the acute and chronic risks to invertebrate organisms, the registrants have agreed to the following mitigation measures for products labeled for wide area mosquito abatement:

- Reduce maximum daily application rate to 0.007 lb ai/A, and a maximum yearly application of 0.18 lb ai/A;
- Require minimum boom height of 100 feet for fixed wing, and 75 feet for helicopter applications;
- For aerial applications made at ≤ 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 60 microns ($Dv\ 0.5 < 60\ \mu m$) and that 90% of the spray is contained in droplets smaller than 100 microns ($Dv\ 0.9 < 100\ \mu m$);
- For aerial applications made at > 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 70 microns ($Dv\ 0.5 < 70\ \mu m$) and that 90% of the spray is contained in droplets smaller than 145 microns ($Dv\ 0.9 < 145\ \mu m$), and
- Specify a droplet size $Dv\ < 30$ microns for ground applications.

Finally, the screening-level ecological risk assessment also determined that the use of a buffer zone during wide area applications of permethrin for mosquito abatement did not serve to reduce the risk to aquatic invertebrates. Therefore, in accordance with PR-2005-1, a 100 foot buffer zone is no longer required for wide area mosquito applications. However, permethrin is also registered as an adult mosquito adulticide for ground barrier treatments. Unlike wide area applications where the permethrin application is intended to stay adrift in the air, and targeted flying mosquitoes, barrier treatments are intended to treat the foliage and target resting mosquitoes. Therefore, the 100 foot buffer zone requirement will still apply to mosquito adulticide barrier applications of permethrin.

Plants

As stated above, although the Agency does not have plant toxicity data to assess risks associated with permethrin exposure to aquatic plants, permethrin's mode of action for controlling insect pests would not be expected to be a mode of action that would harm plants because it is a neurotoxin. The Agency is not requiring plant toxicity data at the time.

iii. Other Non-Agricultural Uses

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 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 homogeneously 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 analyses, 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.

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. All of the pyrethroids were detected in the bed sediment from at least one sampling location. The researchers exposed the aquatic amphipod *Hyaella 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 accordance 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 pyrethroids 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 Tennessee, 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.

Data Needs

The Agency will be issuing a generic data call-in for all registered pyrethroids after the permethrin RED to be used to assess pyrethroids as a group in Registration Review.

Stewardship Language

While the Agency cannot currently assess the potential risks to aquatic organisms from non-agricultural uses of permethrin, the Agency is still seeking to reduce the potential drift and run-off of permethrin 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 reduce the potential run-off and drift that can occur from applications of these products. Label statements

implementing these measures are listed in the "direction for use" section of the label table (Table 38) in Section V of this RED document.

4. Significance of Permethrin to Users

Non-Agricultural Use

According to data provided by the PIRTF, over 70% of permethrin, approximately 1.5 million pounds, is used on non-agricultural settings. Of this amount applied in residential settings: 55% is applied by professionals; 41% is applied by the homeowners; and 4% is used in mosquito abatement districts.

Permethrin is used to control a wide variety of pests in and around residential structures. Although permethrin is heavily relied upon by both pest management professionals (PMPs) and homeowners, and over a million pounds is used on residential areas per year, there are a number of available alternatives registered for similar indoor and outdoor use sites. The recent loss of chlorpyrifos and diazinon for residential pest control has resulted in a greater reliance on permethrin and the pyrethroids among residential users. Based on Agency data, in the absence of permethrin, homeowners and PMPs would most likely substitute other pyrethroid insecticides for use in or around home, such as cyfluthrin, cypermethrin, deltamethrin, esfenvalerate, lambda cyhalothrin, pyrethrins, resmethrin, sumithrin, tetramethrin, and tralomethrin. Permethrin users may also substitute insecticides from other chemical classes, such as malathion, carbaryl, and imidicloprid, as well as a non-chemical methods.

Permethrin is the only pesticide registered to pre-treat fabric. The U.S. Department of Defense uses permethrin as part of its vector control efforts; pre-treated military battle dress (MBD) are made available to servicemen and woman, as well as RTU packages for treatment of MBDs in the field. Comments received by the Armed Forces Pest Management Board strongly support the use of permethrin as a clothing repellent, due to that fact that medical preventive countermeasures (i.e., vaccines) do not exist for many arthropod-borne diseases, such as West Nile Virus, which once acquired can cause permanent disability or death. Therefore, the AFPMB believes permethrin treated fabrics serve as a viable method to control or help prevent the transmission of these diseases.

Given its efficacy at controlling public health pests, permethrin is the most widely used mosquito adulticide in the U.S. and is used to treat 9 to 10 million acres annually (out of 32-39 million acres treated with a mosquito adulticide). Permethrin's widespread use can be attributed to its low cost, high efficacy, low incidence of pest resistance, and broad labeling. Alternatives to permethrin for adult mosquito control include resmethrin, sumithrin, pyrethrins, malathion, and naled. Permethrin alternatives are comparably priced and are likely to be as effective as permethrin in many situations, but are not likely to universally substitute for all permethrin uses because of labeling constraints or resistance concerns. The Agency believes that the loss of permethrin would adversely affect the ability of mosquito abatement professionals to control mosquitoes in some situation, such as agricultural-urban interface and areas with known resistance to alternatives.

Agricultural Uses

Based on Agency data, approximately 600,000 pounds of permethrin is used to treat a variety of crops, such as pome and stone fruit, nut crops, other tree crops (avocado, papaya, conifer), seed cone, ornamentals and cut flowers, field crops, dry bulb crops, greens, and cole crops. According to comments received from various growers, the broad spectrum of pests that permethrin targets makes its use highly beneficial since the agricultural industry has been losing a number of insecticides, and the newer insecticides replacing them have chemistries that target specific insects and are narrow in their spectrum. Further, USDA has established limits on how many insect parts can be present in finished product, and according to growers, many other alternatives have labeled pre-harvest intervals (PHIs) that are too long to accommodate the narrow harvest window required to comply with these standards. Permethrin has a 1 day PHI, which allows for effective pest control near harvest of registered crops.

Further, based on Agency data and analysis, permethrin is considered to be of high benefit to the following crops because it is applied to 30% or more of the growing crop: almonds, artichokes, Brussels sprouts, celery, lettuce, other lettuces, pistachios, and sweet corn. Although permethrin is applied to less than 1% of the soybeans, alfalfa, and corn (field), and maybe considered of low benefit, because approximately 20,000, 40,000, and 100,000 pounds are applied to each crop, respectively, per year, it constitutes a significant amount of use.

In general, the Agency believes that fourth generation pyrethroids (*i.e.*, bifenthrin, lambda-cyhalothrin, cypermethrin, cyfluthrin, deltamethrin, esfenvalerate, fenpropathrin, flucythrinate, fluvalinate, prallethrin, tau-fluvalinate, tefluthrin, tralomethrin, and zeta-cypermethrin) are as effective as permethrin and would be acceptable alternatives as long as they are registered and used on the crops in question. The fourth generation pyrethroids generally control the same pests and have a longer period of residual effectiveness than permethrin. However, these pyrethroids are also assumed to pose a greater ecological risk to aquatic organisms given their persistence in the environment. The Agency has not assessed the comparative ecological toxicity of all registered pyrethroids as part of reregistration, however, it intends to assess pyrethroids as a group in Registration Review, as discussed in section IV.E.2.b.iii above.

5. Risk/Benefit Balancing Analysis

The Agency has determined that permethrin-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. On the human health side, residential risks to homeowners that exceeded the Agency's level of concern have been mitigated completely by discontinuing or restricting certain application methods and reducing some application rates, and occupational risks have been mitigated through personal protective equipment or engineering controls requirements on the labels.

The remaining risks are found on the ecological side. Ecological risks can occur as a result of agricultural use, use of permethrin as a mosquito adulticide, and residential uses, including uses in and around homes. Although data suggest that permethrin is practically non-

toxic to small mammals and avian species on an acute basis, it has a toxic effect on beneficial insects. The Agency is proposing to limit this effect by requiring precautionary labeling on permethrin product labels to limit the exposure to honey bees and other beneficial insects during applications of permethrin. Data also suggest that permethrin is highly toxic to both freshwater and estuarine aquatic organisms. As a result, the Agency is imposing a number of restrictions on agricultural uses (e.g., spray drift buffer zones and reductions in single and seasonal maximum application rates, as well as increased retreatment intervals), which will reduce both the acute and chronic risks to freshwater and estuarine aquatic organisms. The Agency is also imposing a number of requirements on permethrin's use as a mosquito adulticide (e.g., reduction in the maximum application rate, restrictions on number of applications, mandatory boom heights, and specific droplet sizes), which the Agency believes will reduce acute and chronic risks to aquatic invertebrates.

There are a number of reasons why the Agency has concluded that the risk/benefit balance tips in favor of finding permethrin eligible for reregistration despite the ecological risks. With respect to the ecological risks, the Agency has reduced those risks by imposing various conditions that should reduce exposure of aquatic species to permethrin. With respect to the benefits, as described above in the section entitled Significance of Use, permethrin offers substantial benefits to users. In the agricultural area, permethrin provides a high benefit to the agricultural industry because of its broad label and 1 day PHI. According to comments received from various growers, the broad spectrum of pests that permethrin targets makes its use highly beneficial since the agricultural industry has been losing a number of insecticides, and the newer insecticides replacing them have chemistries that target specific insects and are narrow in their spectrum. Further, permethrin has a 1 day pre-harvest interval, which allows for effective pest control near harvest of registered crops. Also alternatives to permethrin, such as the fourth generation pyrethroids, may pose a greater risk to aquatic organisms because of their persistence in the environment.

For the public health use, permethrin is the most widely used mosquito adulticide in the United States because of its low cost, high efficacy, and low incidence of pest resistance. Although permethrin alternatives are comparably priced and are likely to be as effective as permethrin in many situations, they are not likely to universally substitute for all permethrin uses because of labeling constraints or resistance concerns. The Agency believes that the loss of permethrin would adversely affect the ability of mosquito abatement professionals to control mosquitoes in some situation, such as agricultural-urban interface and areas with known resistance to alternatives. With regard to the treatment of fabrics, permethrin is the only pesticide registered to pre-treat fabrics, which the AFPMB strongly supports as a method of preventing many diseases that might afflict military personnel in the field. On other uses, such as residential uses, where there may be a potential for ecological effects due to urban runoff, the Agency intends to identify steps which can be taken to allow a greater understanding of potential ecological risk from urban uses of pyrethroid as a whole during Registration Review.

Given the significance of the use of permethrin and the mitigated nature of the risks of permethrin, the Agency believes, on balance, that the benefits of permethrin outweigh the risks. Therefore, permethrin-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly.

6. Summary of Mitigation Measures

The following mitigation measures are necessary for permethrin to be eligible for reregistration.

Dietary Risk

No label changes are necessary for these risks.

Residential Risk

- Discontinue use of sponge application method for formulations applied as liquids. RTU products, such as wipes and trigger pump sprays will still be available for this use pattern.
- Discontinue use of all directed broadcast and crack and crevice sprays (i.e., low pressure handwand, backpack sprayer, cold fogger) on all residential indoor surfaces, except for aerosol sprays.
 - Limit concentration of RTU consumer sprays to 0.5% ai of permethrin. The Agency will consider products with higher concentrations if the registrants for these products are able to provide justification or data to the Agency which demonstrate that little to no exposure will occur due to the specialized use of the product.
- Limit all total release fogger formulation to 0.25% ai of permethrin.
 - The Agency will consider products with higher concentrations if the registrants are able to provide justification or data that an equivalent indoor surface residue of 2.4 $\mu\text{g}/\text{cm}^2$, or less, will result in a room size of 2000 ft^3 or less.
- Amend all liquid and wettable powder products registered for outdoor residential use to either prohibit use in outdoor residential misting systems, or provide specific use directions.
- Efficacy data for all finished pre-treated permethrin products, and wash-off data to support efficacy claims is required.

Occupational Risk

Handler

- Require wettable powder formulations to be packed in water soluble packaging.
- Require all aerial applications to be in closed cab aircraft.
- Discontinue the use of high pressure handwands in mushroom houses.
- Add PPE requirement to labels as follows:
 - Wettable Powders- baseline PPE and chemical-resistant gloves for mixers, loaders, and applicators.
 - Emulsifiable Concentrations- baseline PPE and chemical-resistant gloves for mixers, loader, and applicators. Additional chemical-resistant apron is required for applicators performing animal dip applications.
 - Dry Flowables- baseline PPE and chemical-resistant gloves.
 - Dust- Double layer, chemical-resistant gloves, and a PF5 respirator for loaders and applicators.

- RTU Formulations- Baseline PPE and chemical-resistant gloves.
- Applicators of liquids via cold foggers and fog mister/generators.
 - Require applicators to wear DL, chemical-resistant gloves, and PF10 respirator.

Post-Application

- Increase REI for conifer cone seed harvesting to 30 days.
- Amend agricultural labels to include new use pattern (rate reductions, seasonal maximum reductions, and minimum retreatment interval) identified for the selected crop uses specified in Table 37 above.

Ecological Risks

- Include standard pyrethroid specific spray drift language, including a 25 foot buffer zone for ground applications, 100-foot for aerial application, and 450 foot for ULV applications.
- Amend agricultural labels to include new use pattern (rate reductions, seasonal maximum reductions, and minimum retreatment interval) identified for the selected crop uses specified in Table 37 above.
- Include the following statement in the environmental hazard section of the end use products, as specified in Table 38 below:
 - This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.
- For all wide area mosquito abatement products:
 - Reduce daily maximum application rate to 0.007 lb ai/A, and a maximum yearly application rate of 0.18 lb ai/A;
 - Remove 100 foot buffer zone restriction;
 - For aerial applications made at ≤ 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 60 microns ($D_v 0.5 < 60 \mu m$) and that 90% of the spray is contained in droplets smaller than 100 microns ($D_v 0.9 < 100 \text{ microns}$); and
 - For aerial applications made at > 200 feet above ground elevation - Spray equipment must be adjusted so that the volume median diameter product is less than 70 microns ($D_v 0.5 < 70 \mu m$) and that 90% of the spray is contained in droplets smaller than 145 microns ($D_v 0.9 < 145 \text{ microns}$), and
 - Specify a droplet size < 30 microns for ground applications.
- Include the following label language in the directions for use section of all products registered for outdoor use.

Products labeled for use on and around buildings and other structures:

“For Band applications to and around buildings foundations, band up to a maximum of 10 feet away from the building and up to a maximum of 3 feet up the walls of the building.”

Products labeled for preconstruction termiticide applications:

“The applicator must insure the treatment site is covered. The applicator can cover the soil him/herself or notify the contractor on the site that: 1) if the concrete slab cannot be poured over the treated soil within 24 hours of application the treated soil should be covered with a waterproof covering (such as polyethylene sheeting), and 2) that the contractor should cover the treated soil if precipitation occurs before the concrete slab is poured.

Do not treat soil that is water-saturated or frozen.

Do not treat when raining.

Do not allow treatment to runoff from the target area.

Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).

Do not make on-grade applications when sustained wind speeds are above 10 mph (at application site) at nozzle end height.”

Requirements for Granular Formulations labeled or intended for outdoor residential uses:

“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Apply this product directly to your lawn or garden, and sweep any product landing on the driveway, sidewalk, gutter, or street, back onto the treated area. Do not water the treated area to the point of run-off or apply when raining or when rain is expected that day.”

Requirements for Liquid, Dust, and Ready to Use Formulations products labeled or intended for outdoor residential uses:

“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Do not water the treated area(s) to the point of run-off or apply when raining or when rain is expected that day. Rinse applicator over treated area only.”

7. Performance Measures

As stated in the EPA’s Strategic Plan, the Agency’s objectives are to protect human health and the environment from pesticide exposures. The mitigation resulting from chemical reviews contributes to the Agency’s ability to meet its strategic targets by reducing pesticide exposure in people’s diet, in and around the home, in occupational settings, to non-target species and to water resources. Because of the tremendous difficulty and costs associated with measuring the direct effects of the work accomplished in OPP, the Agency continues its development of indicators and measures to help evaluate the program’s effect on human health

and the environment.

For permethrin, there were no estimated dietary (food and drinking water) risks of concern. Therefore, no mitigation measures were required to reduce potential permethrin exposure in people's diets. However, risks of concern were identified from various applications of permethrin products in and around homes. Specifically, handler and/or post-application risks of concern were identified for indoor broadcast, and crack and crevice surface spray applications; indoor foggers; and sponge application of EC formulated products on animals. With implementation of the required mitigation measures, the Agency expects that potential exposure to permethrin residues by individuals in the home will be reduced.

For occupational handler risks, the Agency is requiring specific levels of PPE or engineering controls on product labels, depending upon the formulation being used. Most products will include baseline PPE with chemical-resistant gloves, which are likely most commonly being used by workers in the field. In cases where respirators are being additionally required, such as for use of dust formulation or cold foggers, it is likely that most handlers are already using a respirator for these particular uses. Therefore, in these cases, the protective measures being required on the labels will likely not result in measurable reductions in handler exposures or reports of worker incidents. However, for wettable powder formulations, the Agency is requiring that engineering controls (i.e., water soluble packaging) be utilized to reduce exposures to handlers. Some registrants indicated that they may transfer these products to dry flowable formulations, which result in relatively low unit exposures to workers. Thus, these measures may result in possible reductions in worker exposures and incidents.

In addition, the permethrin registrants have agreed to reduce application amounts and/or extend re-treatment intervals for many uses. These changes are stipulated in Table 38. While many of these changes likely reflect actual current use patterns by most users, because of the extensive number of agricultural uses and associated number of products available, the Agency believes that these measures to specify use patterns will limit the number of over-use events, and thus contribute to reducing exposure to workers and the environment.

To address ecological risks, the Agency is requiring spray drift restrictions, such as buffer zones, droplet size, application height, and other requirements. These measures are expected to reduce the amount of exposure to aquatic habitats. In addition, for all wide area mosquito abatement products, a maximum application rate and other similar requirement are being specified. Finally, as stated above, the Agency intends to assess pyrethroids as a class in Registration Review, and in particular, water quality issues resulting from use in urban settings. In order to be able to reduce potential spray drift and run-off of permethrin products used by consumers in a residential outdoor setting, the registrants have agreed to include stewardship language in the directions for use section of all products registered for outdoor use in residential areas.

F. Other Labeling Requirements

To be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing permethrin. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

At this time, the Agency is not requiring label changes specific to the protection of listed species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program. While RQs exceeded the Agency's endangered species LOC for several taxa, these results were based on a screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act. As explained earlier, after a species-specific assessment is conducted, a determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. 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 permethrin at levels of concern.

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, EPA will continue to work with all interested parties on this important issue.

From its assessment of permethrin, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for permethrin, including a requirement for medium to coarse droplet size. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 38) in Section V of this RED document. In the future, permethrin product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that permethrin is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section C below. In the near future, the Agency intends to issue Data Call-In (DCI) Notices requiring label amendments, product-specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for permethrin to be eligible for reregistration.

A. Manufacturing-Use Products

1. Generic Data Requirements

The generic data base supporting the reregistration of permethrin has been reviewed and determined to be substantially complete. However, the Agency has identified data necessary to confirm the reregistration eligibility decision for permethrin. These studies are listed below and will be included in the generic DCI for this RED, which the Agency intends to issue at a future date.

Toxicology:

- 870.6300 Developmental Neurotoxicity Study
- 870.1300 Acute Inhalation Toxicity Study

Residue Chemistry:

- 860.1380 Storage Stability
- 860.1500 Magnitude of the Residue in Crop Plants [collards, cabbage, grass and forage, leaf lettuce, peach, pear, sobean (forage, seed), and tomato]

Occupational Exposure

- 875.1200 Dermal Exposure Indoors (ULV Cold Fogger)
- 875.1400 Inhalation Exposure Indoors (ULV Cold Fogger)

Environmental Toxicology

- EPA/600/R-99/064 (ORD Study Method) Chronic Freshwater Sediment Testing
- EPA/600/R01/020 (ORD Study Method) Chronic Estuarine/Marine Sediment Testing

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MP labeling should bear the labeling contained in Table 38.

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. Registrants 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 product-specific data requirements.

As discussed earlier, the Agency does not have adequate efficacy studies on pre-treated fabrics to support the efficacy claims of finished products. To address this uncertainty, the

Agency is requiring efficacy data for all finished pre-treated permethrin products, and wash-off data to support the efficacy claims. In addition, efficacy data must be submitted, including data for outdoor residential misting systems. Additional information on the efficacy data can be found in the Series 810 Product Performance Test Guidelines on the Agency's website. Finally, permethrin is registered for use on domestic animals. In addition to ensuring a product is efficacious to protect animals from fleas and ticks, the Agency must ensure that pesticide formulations for the treatment of external pests on domestic animals have an adequate margin of safety for the companion animal. Data from companion animal safety studies also serve as a basis for product labeling. This data requirement (870.7200) will also be included in the PDCI.

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 38. 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.

C. Labeling Changes Summary Table

For permethrin to be eligible for reregistration, all permethrin labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 38 describes specific label amendments. This table has been amended from the table included in the Permethrin RED which was signed on April 6, 2006.

Table 38: Summary of Labeling Changes for Permethrin

Table 38: Summary of Labeling Changes for Permethrin		
For all Manufacturing Use Products	<p>“Only for formulation into an <i>insecticide</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”</p> <p>Formulation into Wettable Powder: “Not for formulation into Wettable Powder formulations unless they are packaged in water soluble bags.”</p> <p>Outdoor Residential Misting Systems: If Registrants are not supporting outdoor residential misting systems use for their products, the following statement must appear on the MUP label of all liquid or wettable powder products: “Not for formulation into an end use product for use in outdoor residential misting systems”</p> <p>Formulation into Ready to Use Products labeled or intended for use on residential indoor surfaces:</p> <p>Ready to Use consumer spray products labeled for use on indoor surfaces (broadcast, spot, and crack and crevice) at residential sites must be formulated to contain no more than 0.5% of permethrin active ingredient.</p> <p><i>Note to Registrant:</i> The Agency will consider specialized sprays with higher concentrations, up to 3% ai, which are intended to be injected directly into cracks and crevices and behind walls or spaces if the registrants of the products can provide justification or data to the Agency which demonstrates that the specialized use will result in little to no exposure. In addition, these products must state the following “Not for broadcast use.”</p> <p>Formulation into products intended for use in Total Release Foggers (residential indoor use):</p>	Directions for Use

Table 38: Summary of Labeling Changes for Permethrin

	<p>“Total release foggers labeled for indoor use at residential sites must be formulated to contain no more than 0.25% permethrin active ingredient.”</p> <p><i>Note to Registrant:</i> The Agency will consider products with higher concentrations if the registrants of the products can provide justification or data to the Agency which demonstrates that an equivalent ISR of 2.4 µg/cm², or less, will results in a room size of 2000 ft³ or less.</p> <p>Formulations into products intended for impregnated fabric applications:</p> <p>“Do not exceed an application rate equivalent to 1.25 grams of a.i. per square meter of fabric.”</p>	
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	<p>“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).”</p> <p>“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).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. 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 Pollutant 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.”</p>	Precautionary Statements

Description	Amended Labeling Language	Placement on Label
End Use Products Primarily Intended for WPS and Occupational Use (includes commercial pest control operators)		
Restricted Use Pesticide (For all products used for wide area outdoor broadcast application including agricultural crops, golf courses, nurseries, and sod farms)	“RESTRICTED USE PESTICIDE Due to Toxicity to Fish and Aquatic Organisms. For retail sale to and use only by certified applicators or persons under the direct supervision and only for those uses covered by the certified applicator’s certification.”	Top front panel of label
<p>PPE Requirements Established by the RED¹ For Wettable Powder, Liquid, and Dry Flowable Concentrates (Dry Flowables not registered at this time, but may be registered in the future.)</p> <p>Note: If the use of ULV foggers or fog or mist generators is not permitted or not feasible for the end-use product, the statement requiring special PPE and respirators for those uses may be omitted.</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category@ [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Applicators using ULV cold foggers or fog/mist generators in indoor spaces must wear:</p> <ul style="list-style-type: none"> > Coveralls over long-sleeved shirt and long pants, > Chemical-resistant gloves, > Chemical resistant footwear plus socks, and > Chemical-resistant headgear, if overhead exposure.” <p>“Applicators using ULV cold foggers and/or fog/mist generators in outdoor spaces must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, and > Chemical-resistant gloves.” <p>Note to Registrant: If cold fogger and/or fog/mist generator use is prohibited on the label, the above PPE for these uses may be omitted.</p> <p>“All other mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
	<p>> Shoes plus socks, > Chemical-resistant gloves for all handlers except for applicators using motorized ground equipment, pilots, and flaggers, > Chemical-resistant apron for mixers/loaders, persons cleaning equipment, and persons exposed to the concentrate and for handlers performing animal dip applications.”</p> <p>“See engineering controls for additional requirements.”</p> <p>Instruction to Registrant: Drop the “N” type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.</p>	
PPE Requirements Established by the RED ¹ For Granular Formulations	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All loaders , applicators, and other handlers must wear:</p> <p>> Long-sleeve shirt and long pants, > Shoes plus socks, and > Chemical-resistant gloves for all handlers except for applicators using motorized ground equipment, pilots, and flaggers.”</p> <p>“See engineering controls for more requirements.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the RED¹ For Dust Formulations</p> <p>Note: if application with aerial or motorized ground equipment is not feasible with the labeled uses, the prohibition statement may be eliminated.</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A, B, C, D, E, F, G, or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>“Loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical-resistant gloves, and > A NIOSH-approved respirator with: <ul style="list-style-type: none"> -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter.” <p>“Application with aerial or motorized ground equipment is prohibited.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
User Safety Requirements	<p>“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.</p> <p>Discard clothing and other absorbent materials that have been drenched (except as required by directions for use) or heavily contaminated with this product=s concentrate. Do not reuse them.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately below PPE requirements</p>
<p>Engineering controls for Wettable Powder Formulations</p> <p>Note if aerial application is not permitted or not feasible for the end-use product, the engineering control statements referring to pilots may be omitted.</p>	<p>“Engineering controls</p> <p>Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown chemical resistant footwear and dust/mist respirators. <p>Pilots must use an enclosed cockpit that meets the requirements listed in the</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately below User Safety Requirements</p>

Description	Amended Labeling Language	Placement on Label
	Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”	
<p>Engineering controls for Liquids, Dry Flowable, and Granular Formulations</p> <p>Note if aerial application is not permitted or not feasible for the end-use product, the engineering control statements referring to pilots may be omitted.</p>	<p>“Pilots must use an enclosed cockpit that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately below PPE requirements</p>
<p>Precautionary statement for all permethrin canine spot on products (i.e. 45/65% permethrin concentrations spot-on products for dogs)</p>	<p>Note to registrant:</p> <p>All cat warning labels will be placed within a shaded box within the Precautionary Statements on the label. The coloring of the box and text will be such to provide a contrasting color to other label text. The shaded box must contain the following.</p> <p>“DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.”</p> <p>Each label must include at least one cat slash icon. This icon may be in the shaded box or in other areas on the label.</p> <p>Each individual tube must be labeled with the “DO NOT USE ON CATS” statement or cat slash icon.</p> <p>Include the following statement prominently on the front panel of product</p>	<p>Precautionary Statements</p>

Description	Amended Labeling Language	Placement on Label
	packaging (in bold), “DO NOT USE ON CATS”	
Environmental Hazards (For Products with any Outdoor Use, except wide area mosquito adulticide application)	<p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.”</p> <p>“Under some conditions, it may also have a potential for transport into surface water in runoff (primarily adsorbed to suspended soil particles), for several months or more after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, and areas overlying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-lying tile drainage systems that drain to surface waters.”</p> <p>“This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.”</p> <p>For commercial, industrial, and institutional use products packaged in containers equal or greater than 5 gallons or 50 pounds, add the following statement:</p> <p>“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 Pollutant 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.”</p>	Precautionary Statements immediately following the User Safety Recommendations

Description	Amended Labeling Language	Placement on Label
<p>Environmental Hazards Statements for products labeled solely for use as a wide area mosquito adulticide:</p> <p>(PR Notice 2005-1 recommends separating labels intended for wide area mosquito adulticide applications.)</p>	<p>“ENVIRONMENTAL HAZARDS”</p> <p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to fish and aquatic invertebrates.”</p> <p>“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.”</p> <p>“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.”</p>	Precautionary Statements under Environmental Hazards
<p>Environmental Hazards Statements for products labeled as a wide area mosquito adulticide and is labeled for other outdoor uses as well:</p> <p>(PR Notice 2005-1 recommends separating labels intended for wide area mosquito adulticiding applications.)</p>	<p>“ENVIRONMENTAL HAZARDS for TERRESTRIAL APPLICATIONS”</p> <p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. This product may contaminate water through drift of spray in wind or via runoff events. Use care when applying in areas adjacent to any body of water. Do not apply when weather conditions favor drift from target area.”</p> <p>“Except as specified in the directions for use, do not apply directly to water, 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 wash-waters or rinsate.”</p> <p>“ENVIRONMENTAL HAZARDS for WIDE AREA MOSQUITO ADULTICIDE APPLICATIONS”</p> <p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to fish and aquatic invertebrates.”</p>	Precautionary Statements under Environmental Hazards

Description	Amended Labeling Language	Placement on Label
	<p>“When applying as a wide area mosquito adulticide, 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.”</p> <p>“When applying as a wide area mosquito adulticide, 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.”</p>	
Environmental Hazards (For Products labeled only for Indoor Use including ready to use impregnated materials (e.g. products used on domestic animals like flea collars and ear tags))	No Environmental Hazard Statement is required.	Precautionary Statements immediately following the User Safety Recommendations
<p>Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)</p> <p>Note: If use on conifer cone seeds is not on the label, the above prohibition statement may be omitted.</p>	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”</p> <p>“PROHIBITION - Harvesting of conifer seed cones is prohibited within 30 days of application.”</p>	Directions for Use, Agricultural Use Requirements Box

Description	Amended Labeling Language	Placement on Label
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	<p>“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:</p> <ul style="list-style-type: none"> * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material” 	<p>Direction for Use</p> <p>Agricultural Use Requirements box</p>
<p>Entry Restrictions for products having non-WPS uses applied as spray</p> <p>Note: This excludes products labeled for use when people are present (e.g. outdoor residential misting systems, fabric treatments and pet applications)</p>	<p>Entry Restriction for products applied as a surface spray (does not apply to products applied directly to domestic animals):</p> <p>“Do not enter or allow others to enter until sprays have dried.”</p> <p>Entry Restriction for products applied as a space spray or fog:</p> <p>“Do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.”</p>	<p>If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.</p>
Entry Restrictions for products having non-WPS uses applied as granular or dusts	<p>“Do not enter or allow others to enter until dusts have settled.”</p> <p>For products with use instructions requiring watering in after application:</p> <p>“Do not enter or allow others to enter the treated area until dusts have settled. If soil incorporation is required after the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry after the watering-in.”</p>	
Entry Restrictions for products labeled solely	No entry restrictions are required. See below under “Use Restrictions” for further	

Description	Amended Labeling Language	Placement on Label
for use when people are present (e.g. fabric treatments, livestock, and pet applications)	requirements.	
Entry Restrictions for products labeled for use when people are present (e.g. fabric treatments, livestock, and pet applications) and for use on other sites as a directed or space spray.	<p>Products labeled for use as a directed spray (does not apply to products applied directly to domestic animals):</p> <p>“Except when (insert application method or site that allows people to be present), do not enter or allow others to enter treated area until sprays have dried.”</p> <p>Products labeled for use as a space spray:</p> <p>“Except when (insert application method or site that allows people to be present), do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.”</p> <p>Note to Registrant: An example is as follows: Except when applying to pets or livestock, do not enter or allow others to enter until sprays have dried.</p>	
<p>General Application Restrictions for products with WPS or non-WPS uses on the label</p> <p>Note: This excludes products that contain any directions for when people are permitted to be present in the treated area (e.g. wide-area mosquito adulticide applications, fabric treatments, and applications to livestock)</p>	<p>“Do not apply this product in a way that will contact workers or other persons, either directly or through drift.”</p> <p>“Only protected handlers may be in the area during application.”</p>	Place in the Direction for Use.

Description	Amended Labeling Language	Placement on Label
and pets)		
General Application Restrictions for products with WPS and non-WPS uses on the label AND are labeled for use when people may be present (e.g. . wide-area mosquito adulticide applications, fabric treatments, and applications to livestock and pets)	<p>“Except when” (insert application method or site that allows people to be present) “do not apply this product in a way that will contact workers or other persons, either directly or through drift.”</p> <p>“Except when” (insert application method or site that allows people to be present) “only protected handlers may be in the area during application.”</p> <p>“Do not breathe dusts, vapors, or spray mist.”</p> <p>For applications to food/feed handling and service areas: “Do not apply when food is present.”</p> <p>“Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served, such as dining rooms, but excluding areas where foods may be prepared or held. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed.”</p>	Place in the Direction for Use.
General Application Restrictions for products solely labeled for use when people may be present (e.g. wide-area mosquito adulticide applications, fabric treatments, and applications to livestock and pets)	No general application restrictions are required. See below under “Use Restrictions” for further requirements.	Place in the Direction for Use.
Other Application	Products labeled for use in mushroom houses:	Directions for Use

Description	Amended Labeling Language	Placement on Label
Restrictions (Risk Mitigation)	<p>“Use of high pressure hand wand prohibited in mushroom houses.”</p> <p>Products formulated as dusts:</p> <p>“Use of handheld power duster equipment is prohibited.”</p> <p>Products labeled for or intended to be applied by sponge application:</p> <p>Application instruction for sponge application must be removed from the label, and the following statement must be added: “This product may not be applied by sponge application.”</p> <p>Products labeled for or intended for use as directed surface sprays for use on residential indoor surfaces (excludes Ready to Use products and Total Release Foggers):</p> <p>Application instruction for directed surface sprays (such as low pressure hand wand, backpack sprayer, and ULV cold fogger) to indoor surfaces at residential sites must be removed from the label, and the following statement must be added: “Do not apply as a broadcast, crack and crevice, or spot treatment to indoor surfaces at residential sites, including nurseries, day care centers, schools, hospitals, and nursing homes.”</p> <p>Total release foggers labeled for indoor use must contain the following entry restriction:</p> <p>“Wait two (2) hours after application, then open windows, vents and doors for two hour. If an odor is still detected additional ventilation is required.”</p> <p><i>Note to registrant-</i> If you have any information that justifies a change in the duration after application (2 hours), submit the information to the Agency.</p>	

Description	Amended Labeling Language	Placement on Label
	<p>Products labeled for use around or near floor drains. Products labeled for use in drains or sewers are excluded from this label requirement:</p> <p>“Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.”</p>	
Additional Application Restrictions For Outdoor Use	<p>Products labeled for use on and around buildings and other structures:</p> <p>“For Band applications to and around buildings foundations, band up to a maximum of 10 feet away from the building and up to a maximum of 3 feet up the walls of the building.”</p> <p>Products labeled for preconstruction termiticide applications:</p> <p>“The applicator must insure the treatment site is covered. The applicator can cover the soil him/herself or notify the contractor on the site that: 1) if the concrete slab cannot be poured over the treated soil within 24 hours of application the treated soil should be covered with a waterproof covering (such as polyethylene sheeting), and 2) that the contractor should cover the treated soil if precipitation occurs before the concrete slab is poured.”</p> <p>“Do not treat soil that is water-saturated or frozen.”</p> <p>“Do not treat when raining.”</p> <p>“Do not allow treatment to runoff from the target area.”</p> <p>“Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).”</p> <p>“Do not make on-grade applications when sustained wind speeds are above 10 mph (at application site) at nozzle end height.”</p>	

Description	Amended Labeling Language	Placement on Label																																
	<p>Requirements for Granular Formulations labeled or intended for outdoor residential uses:</p> <p>“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Apply this product directly to your lawn or garden, and sweep any product landing on the driveway, sidewalk, gutter, or street, back onto the treated area. Do not water the treated area to the point of run-off or apply when raining or when rain is expected that day.”</p> <p>Requirements for Liquid, Dust, and Ready to Use Formulations products labeled or intended for outdoor residential uses:</p> <p>“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Do not water the treated area(s) to the point of run-off or apply when raining or when rain is expected that day. Rinse application equipment over treated area only.”</p>																																	
Use-Specific Application Rate and Related Restrictions (Note: The maximum application rate and maximum seasonal rates specified in this table must be listed as pounds or gallons of formulated product per acre/square ft/ppm/cubic feet etc., not just as pounds active ingredient)	<p>Amend all agricultural use product labels with the following crops to reflect the following maximum application rate, retreatment intervals, and seasonal maximum application rates:</p> <table><tr><th>Crop</th><th>Maximum rate per application (lb ai/A)</th><th>Retreatment interval (Days)</th><th>Seasonal Maximum Application Rate (lb ai/A)</th></tr><tr><td>Alfalfa</td><td>0.2</td><td>30</td><td>0.2 per cutting</td></tr><tr><td>Almonds</td><td>0.25</td><td>10</td><td>0.75</td></tr><tr><td>Hazelnuts</td><td>0.25</td><td>10</td><td>0.75</td></tr><tr><td>Pistachios</td><td>0.3</td><td>10</td><td>0.9</td></tr><tr><td>Walnuts</td><td>0.25</td><td>10</td><td>0.75</td></tr><tr><td>Apples</td><td>0.25</td><td>10</td><td>0.5</td></tr><tr><td>Pears</td><td>0.25 (0.4 dormant only)</td><td>10</td><td>0.65</td></tr></table>	Crop	Maximum rate per application (lb ai/A)	Retreatment interval (Days)	Seasonal Maximum Application Rate (lb ai/A)	Alfalfa	0.2	30	0.2 per cutting	Almonds	0.25	10	0.75	Hazelnuts	0.25	10	0.75	Pistachios	0.3	10	0.9	Walnuts	0.25	10	0.75	Apples	0.25	10	0.5	Pears	0.25 (0.4 dormant only)	10	0.65	Directions for Use under Application Instructions
Crop	Maximum rate per application (lb ai/A)	Retreatment interval (Days)	Seasonal Maximum Application Rate (lb ai/A)																															
Alfalfa	0.2	30	0.2 per cutting																															
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Pistachios	0.3	10	0.9																															
Walnuts	0.25	10	0.75																															
Apples	0.25	10	0.5																															
Pears	0.25 (0.4 dormant only)	10	0.65																															

Description	Amended Labeling Language				Placement on Label
	Cherries	0.2	10	0.6	
	Peaches/ Nectarines	0.25	10	0.75	
	Artichokes	0.3	10	0.9	
	Asparagus	0.1	7	0.4	
	Avocados	0.2	7	0.8	
	Broccoli	0.2	5	0.8	
	Brussels Sprouts	0.1	5	0.4	
	Cabbage	0.2	5	0.4 (0.8 in HI)	
	Cauliflower	0.1	5	0.4 (0.6 in HI)	
	Cantaloupes	0.2	7	0.8 (1.2 in HI)	
	Cucumbers	0.2	7	1.2	
	Pumpkins	0.2	7	1.2	
	Squash (summer, winter)	0.2	7	1.2	
	Watermelon	0.2	7	1.2	
	Eggplant	0.15	7	0.6 (1.0 in HI)	
	Peppers, bell	0.2	5	0.8	
	Tomatoes	0.2	7	0.6 (0.8 in HI)	
	Celery	0.2	7	1.0 (1.2 in HI)	
	Lettuce	0.2	7	0.8 (1.2 in HI)	
	Spinach	0.2	3	0.6	
	Collards	0.15	3	0.45	
	Greens, Turnip	0.15	3	0.45	
	Corn, Field	0.15	7	0.45	
	Sweet Corn	0.2	3	0.8	
	Garlic	0.2	10	0.8	
	Onions	0.3	7	1.0	
	Horseradish	0.15	10	0.45	
	Papaya	0.15	10	0.75	
	Potatoes	0.2	10	0.8	
	Soybeans	0.2	10	0.4	
Use-Specific Application Restrictions for all liquid and wettable powder	Products not labeled or intended for use in outdoor residential misting systems must contain the following statement:				Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	Amended Labeling Language	Placement on Label
<p>labels</p> <p>(Outdoor residential misting system requirement)</p> <p>Note to registrant: also express this application rate as pounds or gallons of end-use product formulation.</p>	<p>“Not for use in outdoor residential misting systems.”</p> <p>Products labeled or intended for use in outdoor residential misting systems must contain the following statements:</p> <p>“Directions for use in outdoor residential misting systems:</p> <p>When using this product installers and service technicians must comply with the license, certification, or registration requirements of the state(s), tribe(s), or local authority(ies) where they are installed.”</p> <p>“Do not apply this pesticide when people, pets, and/or food are present.”</p> <p>“Do not use in an evaporative cooling system.”</p> <p>“Direct nozzles to spray towards the target area and away from swimming pools, water bodies, or eating and cooking areas.”</p> <p>“Do not set nozzles to direct mist near outside air condition systems or other home air intakes.”</p> <p>“If used in a system with a reservoir tank for the end use dilution, the system reservoir tank must be locked. Securely attach the end use pesticide label and a dilution statement to the system reservoir tank in a weather protected area or plastic sleeve. The dilution statement must be phrased as follows: this container holds __ parts [<i>product name</i>] to __ parts water”</p> <p>“If used in a direct injection system, the pesticide container must be locked. Securely attach the end use label to the pesticide container in a weather protected area or plastic sleeve.” (These instructions not applicable to wettable powder products).</p> <p>“If the system works on an automatic timer, set the timing for application when people, pets, and/or food are unlikely to be present.”</p>	

Description	Amended Labeling Language	Placement on Label
	<p>“If the system works when a person operates a remote activation device, then application of this pesticide when people, pets, and/or food are present is prohibited.”</p> <p>“Contact the system manufacture for guidance or assistance to ensure compliance with the following requirement:</p> <p>This product may only be used in systems that have been calibrated to apply no more than the maximum application rate of 0.25 grams per 1000 cubic feet per day.”</p>	
<p>Products with use instructions for use as a wide area mosquito adulticide</p> <p>(PR Notice 2005-1 recommends that separate registrations be issued for products with these use patterns.)</p>	<p>Amend label instruction to reflect the following:</p> <ul style="list-style-type: none"> • Recommendations and requirements specified in Pesticide Registration Notice 2005-1; • Remove 100 foot buffer zone use restriction from the product label; and • Maximum application rate 0.007 lb ai/A. <p>In addition, labels must be amended to include the following statements:</p> <p>“Do not retreat site more than once in 3 days. Do not exceed 25 applications at 0.007 pounds of permethrin per acre or 0.18 pounds of permethrin per acre in any given season. 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 diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.”</p> <p>“Apply when wind speed is greater than 1 mph.”</p> <p>“Do not apply by fixed wing aircraft at a height less than 100 feet, or by helicopter at a height less than 75 feet unless specifically approved by the state or tribe based on public health needs.”</p>	<p>Directions for Use under General Precautions and Restrictions and/or Application Instructions</p>

Description	Amended Labeling Language	Placement on Label
	<p>“Aerial Application made at ≤ 200 above ground elevation: Spray equipment must be adjusted so that the volume median diameter product is less than 60 microns ($D_v 0.5 < 60 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 100 microns ($D_v 0.9 < 100 \text{ microns}$). 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. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.”</p> <p>“Aerial Application made at > 200 above ground elevation: Spray equipment must be adjusted so that the volume median diameter product is less than 70 microns ($D_v 0.5 < 70 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 145 microns ($D_v 0.9 < 145 \text{ microns}$). 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. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.”</p> <p>“Ground-based application: Spray equipment must be adjusted so that the volume median diameter is less than 30 microns ($D_v 0.5 < 30 \text{ um}$) and that 90% of the spray is contained in droplets smaller than 50 microns ($D_v 0.9 < 50 \text{ um}$). Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a laser-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.”</p>	
Buffer Zone Requirements	BUFFER ZONES	Directions for Use under General Precautions and Restrictions and/or

Description	Amended Labeling Language	Placement on Label
	<p>Vegetative Buffer Strip “Construct and maintain a minimum 10-foot-wide vegetative filter strip of grass or other permanent vegetation between the field edge and down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).”</p> <p>“Only apply products containing permethrin onto fields where a maintained vegetative buffer strip of at least 10 feet exists between the field and down gradient aquatic habitat.”</p> <p>For guidance, refer to the following publication for information on constructing and maintaining effective buffers: <i>Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. USDA, NRCS. 2000. Fort Worth, Texas. 21 pp.</i> http://www.in.csusda/v/technical/agronom/newconbuf.pdf</p> <p>Buffer Zone for Ground Application (groundboom, overhead chemigation, or airblast) “Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).”</p> <p>Buffer Zone for ULV Aerial Application “Do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).”</p> <p>Buffer Zone for Non-ULV Aerial Application “Do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).”</p>	Application Instructions
	<p>Spray Drift Requirements</p> <p>Wind Direction and Speed</p>	Directions for Use under Spray Drift Requirements.

Description	Amended Labeling Language	Placement on Label
	<p>“Only apply this product if the wind direction favors on-target deposition.” “Do not apply when the wind velocity exceeds 15 mph.”</p> <p>Temperature Inversion</p> <p>“Do not make aerial or ground applications into temperature inversions.”</p> <p>“Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.”</p> <p>Droplet Size</p> <p>“Use only Medium or coarser spray nozzles (for ground and non-ULV aerial application) according to ASAE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.”</p> <p>Additional Requirements for Ground Applications</p> <p>“Wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.”</p> <p>“For ground boom applications, apply using a nozzle height of no more than 4 feet above the ground or crop canopy.”</p> <p>“For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy.”</p> <p>Additional Requirements for Aerial Applications</p> <p>“The spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used</p>	

Description	Amended Labeling Language	Placement on Label
	<p>and must not exceed 75% of the wing span or 80% rotor diameter.”</p> <p>“Flight speed and nozzle orientation must be considered in determining droplet size.”</p> <p>“Spray must be released at the lowest height consistent with pest control and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.”</p> <p>“When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.”</p>	
End Use Products Primarily Intended for Residential Use		
Environmental Hazard Statements	<p>For products that have outdoor uses:</p> <p>“This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. 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.”</p>	Precautionary Statements
Precautionary statement for all permethrin canine spot on products (i.e. 45/65% permethrin concentrations spot-on products for dogs)	<p>Note to registrant:</p> <p>All cat warning labels will be placed within a shaded box within the Precautionary Statements on the label. The coloring of the box and text will be such to provide a contrasting color to other label text. The shaded box must contain the following.</p> <p>“DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.”</p>	Precautionary Statement

Description	Amended Labeling Language	Placement on Label
	<p>Each label must include at least one cat slash icon. This icon may be in the shaded box or in other areas on the label.</p> <p>Each individual tube must be labeled with the “DO NOT USE ON CATS” statement or cat slash icon.</p> <p>Include the following statement prominently on the front panel of product packaging (in bold), “DO NOT USE ON CATS”</p>	
Entry Restrictions for products labeled solely for use when people are present (e.g. fabric treatments, livestock, and pet applications)	No entry restrictions are required. See below under “Use Restrictions” for further requirements.	Directions for use under General Precautions and Restrictions
Entry Restrictions for products labeled for use when people are present (e.g. fabric treatments, livestock, and pet applications) and for use on other sites as a directed or space spray.	<p>Products labeled for use as a directed spray (does not apply to products applied directly to domestic animals):</p> <p>“Except when (insert application method or site that allows people to be present), do not enter or allow others to enter treated area until sprays have dried.”</p> <p>Products labeled for use as a space spray:</p> <p>“Except when (insert application method or site that allows people to be present), do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.”</p> <p>Note to Registrant: An example is as follows: Except when applying to pets or livestock, do not enter or allow others to enter until sprays have dried.</p>	
General Application Restrictions for products	No general application restrictions are required. See below under “Use Restrictions” for further requirements.	Place in the Direction for Use.

Description	Amended Labeling Language	Placement on Label
solely labeled for use when people may be present (e.g. misting systems, fabric treatments and pet applications)		
Additional Application Restrictions For Outdoor Residential Use	<p>Products labeled for use around or near floor drains. Products labeled for use in drains or sewers are excluded from this label requirement:</p> <p>“Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.”</p> <p>Requirements for Granular Formulations labeled or intended for outdoor residential uses:</p> <p>“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Apply this product directly to your lawn or garden, and sweep any product landing on the driveway, sidewalk, gutter, or street, back onto the treated area. Do not water the treated area to the point of run-off or apply when raining or when rain is expected that day.”</p> <p>Requirements for Liquid, Dust, and Ready to Use Formulations products labeled or intended for outdoor residential uses:</p> <p>“Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. Do not water the treated area(s) to the point of run-off or apply when raining or when rain is expected that day. Rinse application equipment over treated area only.”</p> <p>Products labeled for or intended to be applied by sponge application:</p> <p>Application instruction for sponge application must be removed from the label, and the following statement must be added: “This product may not be applied by sponge application.”</p>	Directions for Use under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Additional Application Restrictions For Indoor Residential Use	<p>Products labeled for or intended for use as directed surface sprays for use on residential indoor surfaces (excludes Ready to Use products and Total Release Foggers:</p> <p>Application instruction for directed surface sprays (such as low pressure hand wand, backpack sprayer, and ULV cold fogger) to indoor surfaces at residential sites must be removed from the label, and the following statement must be added: “Do not apply as a broadcast, crack and crevice, or spot treatment to indoor surfaces at residential sites, including nurseries, day care centers, schools, hospitals, and nursing homes.”</p> <p>Total release foggers labeled for indoor use must contain the following entry restriction:</p> <p>“Wait two (2) hours after application, then open windows, vents and doors for two hour. If an odor is still detected additional ventilation is required.”</p> <p><i>Note to registrant-</i> If you have any information that justifies a change in the duration after application (2 hours), submit the information to the Agency.</p> <p>Products labeled for use around or near floor drains. Products labeled for use in drains or sewers are excluded from this label requirement:</p> <p>“Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.”</p>	Directions for Use under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Additional Application Restrictions For Either Indoor and Outdoor Residential Use	<p>Products labeled for use around or near floor drains. Products labeled for use in drains or sewers are excluded from this label requirement:</p> <p>“Do not apply directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.”</p>	
<p>Use-Specific Application Restrictions for all liquid and wettable powder labels</p> <p>(Outdoor residential misting system requirement)</p> <p>Note to registrant: also express this application rate as pounds or gallons of end-use product formulation.</p>	<p>Products not labeled or intended for use in outdoor residential misting systems must contain the following statement:</p> <p>“Not for use in outdoor residential misting systems.”</p> <p>Products labeled or intended for use in outdoor residential misting systems must contain the following statements:</p> <p>“Directions for use in outdoor residential misting systems:”</p> <p>“When using this product installers and service technicians must comply with the license, certification, or registration requirements of the state(s), tribe(s), or local authority(ies) where they are installed.”</p> <p>“Do not apply this pesticide when people, pets, and/or food are present.”</p> <p>“Do not use in an evaporative cooling system.”</p> <p>“Direct nozzles to spray towards the target area and away from swimming pools, water bodies, or eating and cooking areas.”</p> <p>“Do not set nozzles to direct mist near outside air condition systems or other</p>	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	Amended Labeling Language	Placement on Label
	<p>home air intakes.”</p> <p>“If used in a system with a reservoir tank for the end use dilution, the system reservoir tank must be locked. Securely attach the end use pesticide label and a dilution statement to the system reservoir tank in a weather protected area or plastic sleeve. The dilution statement must be phrased as follows: this container holds ___ parts [<i>product name</i>] to ___ parts water”</p> <p>“If used in a direct injection system, the pesticide container must be locked. Securely attach the end use label to the pesticide container in a weather protected area or plastic sleeve.” (These instructions not applicable to wettable powder products).</p> <p>“If the system works on an automatic timer, set the timing for application when people, pets, and/or food are unlikely to be present.”</p> <p>“If the system works when a person operates a remote activation device, then application of this pesticide when people, pets, and/or food are present is prohibited.”</p> <p>“Contact the system manufacture for guidance or assistance to ensure compliance with the following requirement:</p> <p>This product may only be used in systems that have been calibrated to apply no more than the maximum application rate of 0.25 grams per 1000 cubic feet per day.”</p>	

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-1**Food and Feed Use Patterns Subject for Reregistration of Permethrin**

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Food/Feed Crop Uses					
Alfalfa (including alfalfa grown for seed)					
Postemergence broadcast Ground and aerial equipment	EC WP	0.2 lb/A	1 per cutting	Not Specified (NS)	A 0-day PHI is specified following applications at #0.1 lb/A, and a 14-day PHI is specified following applications at >0.1 lb/A. Do not exceed 0.2 lb ai/A/cutting. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Alfalfa (grown for seed)					
Postemergence broadcast Ground and aerial equipment	EC	0.2 lb/A	NS	NS	SLN No. AZ850006: Apply in a minimum of 5 and 10 gal/A using aerial or ground equipment, respectively. SLN No. CA820081: Apply in a minimum of 10 gal/A using aerial equipment. Do not feed treated hay or straw. Do not use seed for feed or food.
Almonds					
Foliar and soil broadcast applications Ground and aerial equipment	EC G	0.4 lb/A	5	NS	A 7-day PHI is specified. Apply no more than 2 lb ai/A/season with no more than 0.8 lb ai/A applied during hull split. Apply in a minimum of 15 gal/A using aerial or ground equipment. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Foliar and soil broadcast applications Ground equipment	EC				A 7-day PHI is specified. Apply no more than 2 lb ai/A/season. Apply in a minimum of 25 gal/A using ground equipment only. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Apples					
Broadcast foliar application Ground equipment	EC WP	0.25 lb ai/A	2	10	Do not apply more than 0.5 lb ai/A/season. Do not apply after petal fall. Apply in a minimum of 25 gal/A using ground equipment. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Artichoke					
Broadcast foliar application Ground and aerial equipment	EC WP	0.3 lb/A	3	10	A 0-day PHI is specified. Do not apply more than 0.9 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Broadcast foliar application Ground equipment	EC WP				A 0-day PHI is specified. Do not apply more than 1.5 lb ai/A/season. Apply in a minimum of 10 gal/A using ground equipment only.
Foliar application Aerial equipment	EC		NS	NS	No PHI is specified. Apply in a minimum of 10 gal/A
Asparagus					
Broadcast postemergence application Ground equipment	EC WP	0.1 lb/A	4	7	A 1-day PHI is specified. Do not apply more than 0.4 lb ai/A/season. A minimum application volume of 10 gal/A is specified.
Avocados					
Broadcast foliar application Ground equipment	EC WP	0.2 lb/A	4	7	A 7-day PHI is specified. Do not apply more than 0.8 lb ai/A/season or make more than 6 applications/season. Apply in a minimum of 25 gal/A. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Broccoli, Chinese broccoli					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	5	4	A 1-day PHI is specified. Do not apply more than 0.8 lb ai/A/season. Labels specify minimum application volumes of 2 or 10 gal/A using aerial or ground equipment, respectively.
Brussel sprouts					
Broadcast foliar application Ground and aerial equipment	EC WP	0.1 lb/A	4	5	A 1-day PHI is specified. Do not apply more than 0.4 lb ai/A/season. Labels specify minimum application volumes of 2 or 10 gal/A using aerial or ground equipment, respectively.
Cabbage and Chinese cabbage (tight-heading varieties only)					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	2 (4 in HI)	5	A 1-day PHI is specified. Do not apply more than 0.4 (0.8 in HI) lb ai/A/season. Labels specify minimum application volumes of 2 and 10 gal/A using aerial or ground equipment, respectively.
Cantaloupe					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	4 (6 in HI)	7	A 0-day PHI is specified. Do not apply more than 0.8 (1.2 in HI) lb ai/A/season. Apply in a minimum of 4 or 5 gal/A using aerial equipment and 20 gal/A using ground equipment.
Cauliflower					
Broadcast foliar application Ground and aerial equipment	EC WP	0.1 lb/A	4 (6 in HI)	5	A 1-day PHI is specified. Do not apply more than 0.4 (0.6 in HI) lb ai/A/season. Labels specify minimum application volumes of 2 and 10 gal/A using aerial or ground equipment, respectively.
Celery					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	5 (6 in HI)	7	A 1-day PHI is specified. Do not apply more than 1.0 (1.2 in HI) lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Cherry					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Broadcast foliar application Ground equipment	EC WP	0.2 lb/A	3	10	A 3-day PHI is specified. Do not apply more than 0.6 lb ai/A/season. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock. Apply in a minimum of 25 gal/A.
Collards (only in AR, AZ, GA, IL, NC, OK, SC, and TX)					
Broadcast foliar application Ground equipment	EC WP	0.15 lb/A	3	3	A 1-day PHI is specified. The maximum seasonal use rate is specified as 0.45 lb ai/A. Apply in a minimum of 10 gal/A.
Broadcast foliar application Ground and aerial equipment	EC				For use only in AR, IN, and TN. A 1-day PHI is specified. Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 1 or 10 gal/A using aerial and ground equipment, respectively.
Corn, field and pop					
Broadcast or banded preemergence application and broadcast foliar applications Ground and aerial equipment	EC WP G	0.15 lb/A	3	7	Apply preemergence from 5 days prior to planting up to emergence. A 0-day PHI is specified for forage, and a 30-day PHI is specified for grain and fodder (stover). Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial and ground equipment, respectively.
Corn, sweet					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Broadcast preemergence and foliar applications Ground and aerial equipment	EC WP G	0.2 lb/A	4	3	A 1-day PHI is specified. Do not apply more than 0.8 lb ai/A/season Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Cucurbit vegetables (except cantaloupes)					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	6	7	A 0-day PHI is specified. Do not apply more than 1.2 lb ai/A/season. Apply in a minimum of 4 or 5 gal/A using aerial equipment and 20 gal/A using ground equipment.
Eggplant					
Broadcast foliar application Ground or aerial equipment	EC WP	0.15 lb/A	4 (except HI see use limitation)	7	A 3-day PHI is specified. Do not apply more than 0.6 (1.0 in HI) lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Filberts					
Broadcast foliar application Ground and aerial equipment	EC WP	0.4 lb/A	4	NS	A 14-day PHI is specified. Do not apply more than 1.6 lb ai/A/season. Labels specify minimum application volumes of 10 gal/A using ground equipment and 25 or 50 gal/A using aerial equipment. Do not graze livestock in treated areas or feed cover crops from treated orchards to livestock.
Garlic					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Broadcast foliar application Ground or aerial equipment	EC WP	0.2 lb/A	4	10	A 1-day PHI is specified. Do not apply more than 0.8 lb ai/A/season. Apply in a minimum of 5 or 6 gal/A using aerial equipment, and 20 gal/A using ground equipment.
Grass, rangeland (NM only)					
Broadcast application Ground and aerial equipment	EC WP	0.01 lb/A	1	NA	Do not apply more than once per year. Cattle may be present during application. Do not harvest or feed hay to livestock. The Label 100-985 has no regional restriction. Apply in a minimum of 2 or 10 gal/A using aerial and ground equipment, respectively. SLN No. NM840005 specifies a minimum volume of 1 qt/A for aerial application. SLN No. NM840006 specifies a minimum volume for aerial application of 1 qt/A of vegetable oil or 1 gal/A of water.
Horseradish					
Preplant dip	EC	0.83 lb/100 gal (0.1% ai solution)	1	NA	Soak sets for 30 minutes and air-dry prior to planting.
Broadcast foliar application Ground equipment	EC WP	0.15 lb/A	3	10	A 30-day PHI is specified. Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 20 gal/A using ground equipment.
Leafy Vegetables (except Brassica, Celery, Lettuce, and Spinach)					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	10	3	A 1-day PHI is specified. Do not apply more than 2 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Lettuce					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	4 (6 in HI)	7	A 1-day PHI is specified. Do not apply more than 0.8 (1.2 in HI) lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.

Mushrooms (mushroom houses and adjacent premise areas)					
Fogging or aerosol application prior to filling house, during cool-down, during spawning, up to pinning, and between breaks.	EC D	2.5 oz. per 30 oz water	30 per crop of 5 breaks	1	A 3-day PHI is specified. Do not use when mushrooms are present. Do not make more than 20 applications prior to pinning of first break; more than 2 applications between each break; and no more than a total of 30 applications per crop of 5 breaks.
Surface application until runoff to walls and ceilings prior to filling house, during cool-down, during spawning, up to pinning, and between breaks.	WP	0.14 oz/gal (0.34 oz/1,000 ft²)			
Onions (dry bulb only)					
Broadcast foliar application Ground or aerial equipment	EC WP	0.3 lb/A	1.0 lb ai seasonal max.	7	A 1-day PHI is specified. Do not apply more than 1.0 lb ai/A/season. Apply in a minimum of 5 or 6 gal/A using aerial equipment, and 20 gal/A using ground equipment.
Papayas (FL only)					
Broadcast foliar application Ground Equipment	EC WP	0.15 lb/A	5	10	A 7-day PHI is specified. Do not make more than 5 applications per season, or apply more than 0.15 lb ai/A/season. Apply in a minimum of 25 gal/A. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Peaches/Nectarines					
Broadcast foliar application Ground and aerial equipment	EC WP	0.25 lb/A	3	10	A 14-day PHI is specified. Do not apply more than 0.75 lb ai/A/season. Apply in a minimum of 10 and 25 gal/A using aerial or ground equipment, respectively. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Pears					

Dormant through delayed dormant (prebloom) applications Ground and aerial equipment	EC WP	0.25 lb/A (0.4 lb/A for dormant only)	0.65 lb/A seasonal max.	10	Do not apply more than 0.65 lb ai/A/season. Dormant applications of EC formulations may include 2-8 gal of spray oil/acre. Apply in a minimum of 10 and 25 gal/A using aerial or ground equipment, respectively. Do not graze livestock in treated area or feed livestock cover crops from treated areas.
Peppers, bell					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	4	5	A 3-day PHI is specified. Do not apply more than 0.8 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Pistachios					
Broadcast foliar application prior to 10% hull split Ground and aerial equipment	EC WP G	0.4 lb/A	2 or 4	NS	A 0-day PHI is specified. The maximum seasonal rate is 1.6 lb ai/A on FMC labels and 0.8 lb ai/A on all other labels. Do not apply after 10% hull split. Apply in a minimum of 10 and 25 gal/A using aerial or ground equipment, respectively. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock. The label for the 1.5% G allows aerial applications, but prohibits use on pistachios grown in CA.
Potatoes					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	4	10	A 14-day PHI is specified. Do not apply more than 0.8 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial and ground equipment, respectively.
Potatoes (for greenhouse grown seed potatoes or transplants)					
Foliar application Handsprayers	EC	0.03 oz/gal	9	NS	Only for use in CA. A maximum of 9 applications per crop is specified. The use of treated potatoes for human or livestock consumption is prohibited.
Soybeans					

Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	2	10	A 60-day PHI is specified. Do not apply more than 0.4 lb ai/A/season. Do not graze or feed soybean forage or hay. Apply in a minimum of 2 and 10 gal/A using aerial and ground equipment, respectively. Applications may be made in vegetable oil at a minimum of 1 qt oil/A.
	EC	0.1 lb/A	2	10	For use only in AR, FL, LA, MS, OK, and TX. A 40-day PHI is specified. Do not apply more 2 time per season. Do not graze or feed soybean forage. Apply in a minimum of 1 and 5 gal/A using aerial and ground equipment, respectively. Applications can include vegetable oil at 1 qt/A.
				10	For use only in AL, GA, MS, SC, and TX. A 60-day PHI is specified. Do not apply more than 2 times per season. Do not graze or feed soybean forage. GA830007 specifies minimum application volumes of 1 and 5 gal/A using aerial and ground equipment, respectively; the other SLNs do not specify application volumes. Applications can include vegetable oil at 1 qt/A.
Spinach					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	3	3	A 1-day PHI is specified. Do not apply more than 0.6 lb ai/A/season. Apply in a minimum of 2 and 10 gal/A using aerial or ground equipment, respectively.
Tomatoes					
Broadcast foliar application Ground and aerial equipment	EC WP	0.2 lb/A	6	NS	FMC labels include use on tomatillos A 0-day PHI is specified. Do not apply more than 1.2 lb ai/A/season. Do not apply as a banded application. Do not apply to tomato varieties which produce mature fruit <1 inch in diameter. Apply in a minimum of 2 and 10 gal/A using ground or aerial equipment, respectively.
Turnips (only in FL, GA, IL, IN, OK, SC, TX, and WA)					

Broadcast foliar application Ground equipment	EC WP	0.15 lb/A	3	3	A 1-day PHI is specified. Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 10 gal/A.
Broadcast foliar application Ground and aerial equipment	EC	0.1 lb/A	8	NS	For use only in AR, IN, and TN. A 1-day PHI is specified. Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 1 or 10 gal/A using ground and aerial equipment, respectively. Do not graze treated areas or feed crop refuse to livestock.
Walnut					
Broadcast foliar application Ground and aerial equipment	EC WP	0.25 lb/A	3	10	A 1-day PHI is specified. Do not apply more than 0.45 lb ai/A/season. Apply in a minimum of 10 or 20 gal/A using aerial equipment and 25 gal/A using ground equipment. Do not graze livestock in treated areas or feed cover crops from treated areas to livestock.
Seed Treatments					
Seed Treatments (commercial seed treaters only)					
Seed Treatment by commercial seed treaters	EC WP	0.5 oz/100 lb seed	1	NA	For application to seeds of the following crops: broccoli, Brussel sprouts, cabbage, cauliflower, celery, corn (all types), cucurbits, eggplant, leafy vegetables (except Brassica), peppers (Bell), soybean, and tomato. Not for use on agricultural establishments in seed treatment equipment at or immediately before planting. Do not use treated seed for food, feed, or processing.
Livestock Uses					
Livestock Housing and Premises (dairies, barns, feedlots, stables, poultry houses, swine and livestock houses)					
Surface application to building walls and ceilings	EC WP	0.17 oz/1000 ft ²	NS	1-2 weeks	Do not treat manure or litter. Do not apply directly to livestock or poultry.
Dairy and Beef Cattle, Goats, and Sheep					
Dilute whole body spray	EC	0.05% a.i. solution at 1-2 qt/animal (.907 mg ai/animal)	NS	10	No PSI is specified
Concentrated Mid-line and ear spray		0.5% a.i. solution at -6 fl oz/animal (.212 mg/animal)	NS	NS	
Self oiler		0.125% ai in oil	NA	NA	

Poultry					
Whole body spray	EC	0.33% a.i. solution at 1 gal/100 birds (.120 mg ai/bird)	NS	NS	
Swine					
Whole body spray or dip	EC	0.05% a.i. solution at 1-2 qt/animal (.907 mg ai/animal)	NS	14	A 5 day PSI is specified
Horses					
Spot application to back, face, legs, tail, and ears	EC	0.63% ai solution at 2 fl. oz/animal (.354 mg ai/animal)	NS	NS	
Whole body wash/dip		0.063% ai solution	NS	NS	

Appendix A-2**Non-Food and Non-Feed Use Patterns Subject for Reregistration of Permethrin**

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
AGRICULTURAL UNCULTIVATED AREAS	EC	0.2125	lb/A	Remove or carefully protect food products and food packaging. Do not treat animals under 12 weeks of age.
		0.0523	lb/1K sq.ft	
		0.0801	lb/mound	
AGRICULTURAL/FARM PREMISES	WP	0.1212	bag/1K sq.ft	14 day MRI. 12 hour REI
ALFALFA	WP	0.2	lb/A	12 hour REI.
ANIMAL KENNELS/SLEEPING QUARTERS (COMMERCIAL)	EC	0.1067	lb/A	Remove animals prior to treatment. Remove feed and water prior to treatment. Do not apply to plant foliage.
		0.0801	lb/mound	
		0.04	lb/1 gal	
		6.18E-04	lb/1K cu.ft	For use only in New Mexico (SLN Registration) Remove animals prior to treatment. Remove feed and water prior to treatment. Do not apply to plant foliage. 14 day MRI.
		0.4604	lb/1K sq.ft	For use only in New Mexico (SLN Registration) Remove animals prior to treatment. Remove feed and water prior to treatment. Do not apply to plant foliage. Do not treat animals under 12 weeks of age.
	EC*RTU	0.008	lb/1K sq.ft	
	PRL	NS		Remove or carefully protect food products and food packaging. Cover feed and water prior to treatment. Do not allow children or pets on treated areas until surfaces are dry. 14 day MRI.
	SC/L	0.0974	lb/A	Cover feed and water prior to treatment.
		2.72E-04	lb/1K cu.ft	
		0.0457	lb/1K sq.ft	
		0.0366	lb/1 gal	
	SC/L* RTU	0.0974	lb/A	
	SC/L* RTU	0.0098	lb/1K sq.ft	
AUTOMOBILES - TAXIS - LIMOUSINES - RECREATIONAL VEHICLES - & TIRES	PRL	NS		Do not allow children or pets on treated areas until surfaces are dry.

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
BATHROOM PREMISES/HARD SURFACES	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry.
BATHROOM PREMISES/HARD SURFACES	PRL	NS		Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry. 14 day MRI.
CADAVERS AND CASKETS	PRL	NS		Do not allow children or pets on treated areas until surfaces are dry.
CATS (ADULTS/KITTENS)	D	1.56E-04	lb/Animal	Do not treat animals under 12 weeks of age. 14 day MRI.
	EC	0.0039	lb/1 gal	
	PRL	NS		Do not treat animals under 30 weeks of age. 90 day MRI.
	RTU	1	sec lb body wt (L)	Do not treat animal under three months of age. 14 day MRI.
CATTLE FEEDLOTS	SC/L	0.0175	lb/1 gal	Retreat as needed.
CHRISTMAS TREE PLANTATIONS	EC	1.047	lb/A	Do not allow children or pets on treated areas until surfaces are dry. Disallowed in CA. 5 day MRI. 12 hour REI.
		0.02	lb/tree	Do not allow children or pets on treated areas until surfaces are dry. 5 day MRI. 12 hour REI.
CHRISTMAS TREE PLANTATIONS	WP	0.2	lb/A	Disallowed in CA. 5 day MRI. 12 hour REI.
COMMERCIAL STORAGES/WAREHOUSES PREMISES	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry.
	SC/L	0.0366	lb/1 gal	
		2.72E-04	lb/1K cu.ft	
		0.0457	lb/1K sq.ft	

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
	PRL	NS		Remove animals prior to treatment. 14 day MRI.
COMMERCIAL TRANSPORTATION FACILITIES- NONFEED/NONFOOD	EC	0.4604	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry.
		0.08	lb/1 gal	
	SC/L	2.72E-04	lb/1K cu.ft	
		0.0457	lb/1K sq.ft	
		0.0366	lb/1 gal	
	PRL	NS		Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry. 14 day MRI.
COMMERCIAL/INDUSTRIAL LAWNS	EC	2.47E-04	lb/1K sq.ft	Do not allow children or pets on treated areas until surfaces are dry. 12 hours REI.
COMMERCIAL/INSTITUTIONAL /INDUSTRIAL PREMISES/EQUIP. (INDOOR)	EC	0.4604	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry.
		0.08	lb/1 gal	
	SC/L* RTU	0.0974	lb/A	
	SC/L	0.0974	lb/A	
		2.72E-04	lb/1K cu.ft	
		0.0457	lb/1K sq.ft	
		0.0366	lb/1 gal	
	PRL	NS		Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry. 14 day MRI.
COMMERCIAL/INSTITUTIONAL /INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR)	FM	1.75	fl.oz (L)	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry. 12 hour REI.
	SC/L	0.0175	lb/1 gal	
	EC	0.85	lb/A	
		0.7805	lb/1K sq.ft	
		0.1561	lb/mound	
		0.04	lb/1 gal	

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
CONIFERS (SEED ORCHARD)	EC	0.016	lb 1K trees	For use in Florida and Texas (SLN Registrations) 1 application per crop cycle or year.
DOGS/CANINES (ADULTS/PUPPIES)	D	7.81E-06	lb/Animal	Do not treat animals under 12 weeks of age. 14 day MRI.
	EC	0.0067	lb/Animal	
		0.1727	lb/1 gal	
		0.1068	lb/20 gal	
	PRL	8	sec lb body wt (L)	Do not treat animals under 26 weeks of age. 90 day MRI.
				Do not treat animals under 3 months of age. 14 day MRI.
	RTU	8	sec lb body wt (L)	Remove or carefully protect food products and food packaging. Do not treat animals under 12 weeks of age. 14 day MRI.
	SC/L	0.0438	lb/12.5 gal	Do not treat animals less than 4 weeks of age.
DRAINAGE SYSTEMS	EC	0.4604	lb/1K sq.ft	Remove or carefully protect food products and food packaging.
EATING ESTABLISHMENTS	EC	0.1992	lb/minute	Remove or carefully protect food products and food packaging.
	SC/L	0.0974	lb/A	
	SC/L* RTU	0.0974	lb/A	
EATING ESTABLISHMENTS NON-FOOD AREAS (NONFOOD CONTACT)	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
	SC/L	2.72E-04	lb/1K cu.ft	
	SC/L	0.0457	lb/1K sq.ft	
	SC/L	0.0366	lb/1 gal	
	PRL	NS		Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried. 14 day MRI.
FOREST TREES (SOFTWOODS - CONIFERS)	WP	0.2	lb/A	5 day MRI. 12 hour REI. 30 day REI for Conifer Cone Seed Harvesting only.
	EC	1.047	lb/A	
		0.02	lb/tree	

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
		0.016	lb/1K trees	For use only in Alabama, Arkansas, Georgia, Louisiana, North Carolina, South Carolina, Tennessee, Texas, and Virginia (SLN Registrations). 1 day MRI. 12 hour REI. 30 day REI for Conifer Cone Seed Harvesting only.
GOLF COURSE TURF	EC	0.1992	lb/minute	
	SC/L	0.0974	lb/A	
		0.0175	lb/1 gal	
	SC/L* RTU	0.0974	lb/A	
GREENHOUSE-EMPTY	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Do not allow children or pets on treated areas until surfaces have dried.
HORSES (SHOW/RACE/SPECIAL/PONIES)	D	2	oz/animal	Do not treat more than once every three days.
	RTU	6.52E-04	lb/Animal	1 day MRI.
	SC/L	0.0366	lb/1 gal	
	SC/L* RTU	0.0098	lb/1K sq.ft	
	WP	0.1212	bag 1K sq.ft	14 day MRI. 12 hour REI
		0.0455	lb/1K sq.ft	
	EC	7.69E-04	lb/1K cu.ft	For use only in New Mexico (SLN Registration). 14 day MRI.
		0.1068	lb/1K sq.ft	
		0.0021	lb/Animal	
		0.0268	lb/unit	
		0.1727	lb/1 gal	5 days preslaughter interval. Do not treat animals under 12 weeks of age.
HOSPITALS/MEDICAL INSTITUTIONS PREMISES (HUMAN/VETERINARY)	EC	6.18E-04	lb/1K cu.ft	For use only in New Mexico (SLN Registration). Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Remove feed and water prior to treatment.
		0.4604	lb/1K sq.ft	
		0.08	lb/1 gal	
	EC*RTU	0.0488	lb/1K sq.ft	Remove food and animals from premises prior to treatment.
	SC/L	2.72E-04	lb/1K cu.ft	Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
		0.0457	lb/1K sq.ft	
		0.0366	lb/1 gal	

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
	SC/L* RTU	0.0098	lb/1K sq.ft	
	PRL	NS		Remove food and animals from premises prior to treatment. Do not allow children or pets on treated areas until surfaces have dried. 14 day MRI.
HOUSEHOLD/DOMESTIC DWELLINGS CONTENTS	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
	RTU	NS		
	PRL	NS		Do not allow children or pets on treated areas until surfaces have dried. Do not enter treated areas without protective clothing until spray has dried. 14 day MRI.
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
	RTU	NS		
	SC/L	2.72E-04	lb/1K cu.ft	
		0.0457	lb/1K sq.ft	
		0.0366	lb/1 gal	
	PRL	NS		Do not allow children or pets on treated areas until surfaces have dried. Do not enter treated areas without protective clothing until spray has dried. 14 day MRI.
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
		0.0076	lb linear ft	Remove food and animals from premises prior to treatment. Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
		0.042	lb min	
		0.1561	lb/mound	Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
		0.04	lb/1 gal	
		1	part (L)	
	0.2422	lb/A	Disallowed in FL.	
	RTU	NS		
	RTU	0.1	lb/A	Remove food and animals from premises prior

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
	G	1.56E-04	gal mound	to treatment. Remove feed or carefully protect food products and food packaging. Do not allow children or pets on treated areas until surfaces have dried.
		0.005	lb/1K sq.ft	
		0.0038	Tsp ant hill	
	RTU	0.0554	lb/1K sq.ft	
		5.57E-05	lb ft	
	SC/L	0.0974	lb/A	
		0.0175	lb/1 gal	
SC/L* RTU	0.0974	lb/A		
HUMAN BEDDING/MATTRESSES	EC	0.4604	lb/1K sq.ft	Remove or carefully protect food products and food packaging. Remove animals prior to treatment. Do not allow children or pets on treated areas until surfaces are dry.
	RTU	NS		
HUMAN CAMPING EQUIPMENT	PRL	NS		Do not enter treated areas without protective clothing until sprays have dried. 14 day MRI.
HUMAN CLOTHING (INSECT AND MOLD/MILDEW CONTROL)	PRL	NS		Do not enter treated areas without protective clothing until sprays have dried. 14 day MRI.
		60	sec (L)	14 day MRI.
	RTU	NS		
MEAT PROCESSING PLANT PREMISES (NONFOOD CONTACT)	EC	0.0035	lb/1K sq.ft	For use only in New Mexico (SLN Registration). Remove animals prior to treatment. Cover feed and water prior to treatment. 14 day MRI.
MEAT PROCESSING PLANT PREMISES (NONFOOD CONTACT)	EC*RTU	0.0488	lb/1K sq.ft	Remove animals prior to treatment.
	SC/L	2.72E-04	lb/1K cu.ft	
	SC/L	0.0457	lb/1K sq.ft	
	SC/L	0.0366	lb/1 gal	
	SC/L* RTU	0.0098	lb/1K sq.ft	
MORGUES/MORTUARIES/AUTOPSY/EMBALMING ROOM PREMISES	PRL	NS		Do not allow children or pets on treated areas until surfaces are dry. 120 MRI.
MUSHROOM HOUSES-EMPTY PREMISES/EQUIPMENT	D	0.0017	lb/1K cu.ft	3 day PHI. 1 day MRI. 24 hour REI. Maximum of 30 applications per crop cycle.
	FM/S	2.18E-04	gal 1K cu.ft	

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
	EC	0.0019	lb/1K cu.ft	12 hour REI. Maximum of 30 application per crop cycle.
	WP	0.375	lb/A	3 day PHI. 12 hour REI. Maximum of 30 application per crop cycle.
		0.0057	gal 1K sq.ft	
		0.0455	lb/1K sq.ft	
NONAGRICULTURAL AREAS (PUBLIC HEALTH USE)	SC/L	0.0974	lb/A	
	SC/L* RTU	0.0974	lb/A	
NONAGRICULTURAL OUTDOOR BUILDINGS/STRUCTURES	EC	0.85	lb/A	Do not allow children or pets in treated area until sprays have dried. 12 hour REI.
		0.04	lb/1 gal	
		0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and packaging. Do not allow children or pets in treated area until surfaces are dry.
		0.1561	lb/mound	
	SC/L	0.0974	lb/A	
	SC/L* RTU	0.0974	lb/A	
NONAGRICULTURAL RIGHTS- OF- WAY/FENCEROWS/HEDGEROW S	EC	0.85	lb/A	Do not allow children or pets in treated area until surfaces are dry. 12 hours REI.
NONAGRICULTURAL RIGHTS- OF- WAY/FENCEROWS/HEDGEROW S		0.04	lb/1 gal	
NONAGRICULTURAL RIGHTS- OF- WAY/FENCEROWS/HEDGEROW S		0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
NONAGRICULTURAL RIGHTS- OF- WAY/FENCEROWS/HEDGEROW S		0.1561	lb/mound	
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS	EC	0.85	lb/A	Do not allow children or pets in treated area until surfaces are dry. 12 hours REI.
		0.3951	lb/1K sq.ft	
		0.0801	lb/mound	
		0.04	lb/1 gal	
	RTU	0.0316	lb min	
		0.0053	lb/A	Disallowed in Florida.
ORNAMENTAL AND/OR SHADE TREES	D	NS		
	WP	0.0195	lb/10 gal	Do not apply through any type of irrigation system.
		0.2	lb/100 gal	12 hour REI.
		0.2	lb/A	Disallowed in California.
	EC	0.2	lb/A	12 hour REI.
	EC	0.7805	lb/1K sq.ft	See below.

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
	EC	0.0319	lb lin. ft/ft depth	Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
		0.1992	lb minute	
		0.1561	lb/mound	
		4.28	lb/tree	
		0.08	lb/1 gal	
		0.02	lb/10 gal	
		4.28	lb/100 gal	
	PRL	NS		
	RTU	NS		
ORNAMENTAL HERBACEOUS PLANTS	WP	0.0195	lb/10 gal	Do not apply through any type of irrigation system.
		0.5	lb/100 gal	Disallowed in California. 12 hour REI. 7 day MRI.
		0.2	lb/A	For use in California and Florida. 12 hour REI.
	EC	0.2	lb/A	For use only in Florida. Disallowed in California. Do not allow children or pets in treated area until surfaces are dry. 12 hour REI.
		0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
		0.1992	lb minute	
		0.1561	lb/mound	
		0.0355	lb/1 gal	
		0.02	lb/10 gal	
		0.5	lb/100 gal	
	PRL	NS		
	RTU			
	ORNAMENTAL LAWNS AND TURF	EC	0.7805	lb/1K sq.ft
0.0319			lb lin. ft/ft depth	
0.1561			lb/mound	
0.08			lb/1 gal	
G		1.56E-04	gal mound	
		0.0075	lb/1K sq.ft	
		0.0038	Tsp ant hill	
ORNAMENTAL NONFLOWERING PLANTS	EC	0.2	lb/A	For use in Florida. Disallowed in California. Do not allow chilren or pets in treated area until surfaces are dry. 12 hour REI.

Site	Form Code	Max.App Rate/App	Unit (ai)	Use Pattern/Limitations
		0.2	lb/100 gal	12 hour REI.
		0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
		0.1992	lb/minute	
		0.1561	lb/mound	
		0.0355	lb/1 gal	
		0.02	lb/10 gal	
	RTU	NS		
	WP	0.1	lb/A	12 hour REI.
		0.2	lb/100 gal	
		0.0195	lb/10 gal	Do not apply through any type of irrigation system.
PRL	NS			
ORNAMENTAL WOODY SHRUBS AND VINES	PRL	NS		Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
	RTU			
	EC	0.7805	lb/1K sq.ft	
		0.0319	lb lin. ft/ft depth	
		0.1992	lb minute	
		0.1561	lb/mound	
		0.08	lb/1 gal	
		0.02	lb/10 gal	
		0.25	lb/A	Disallowed in California. Do not allow children or pets in treated area until surfaces are dry.
	WP	0.2	lb/100 gal	Disallowed in California. 12 hour REI.
		0.5	lb/A	
		0.2	lb/100 gal	
		0.0195	lb/10 gal	Do not apply through any type of irrigation system.
PATHS/PATIOS	EC	0.0523	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
		2.72E-05	lb linear ft	
		1	part (L)	
	RTU	5.57E-05	lb ft	
PET LIVING/SLEEPING QUARTERS	D	NS		Remove food and animals from premises prior to treatment. Remove animals prior to treatment. Do not allow children or pets in treated area until surfaces are dry.
	EC	0.7805	lb/1K sq.ft	
	PRL	NS		
	RTU	NS		

PINE (FOREST/SHELTERBELT)	EC	1.047	lb/A	Do not allow children or pets in treated area until surfaces are dry. 12 hours REI.
		0.02	lb/tree	
PINE (SEED ORCHARD)	EC	1.05	lb/A	Do not allow children or pets in treated area until surfaces are dry. 12 hours REI. Maximum of 6 applications per crop cycle.
		0.02	lb/tree	
	WP	1.6	lb/A	28 day MRI. 12 hour REI. Maximum of 6 applications per crop cycle.
		1.6	lb/tree	
POME FRUITS	WP	0.2	lb/100 gal	12 hour REI.
POULTRY PROCESSING PLANT PREMISES (NONFOOD CONTACT)	EC	3.27E-04	lb/1K cu.ft	For use only in New Mexico (SLN Registration). 14 day MRI.
		0.0139	lb/1K sq.ft	
	EC*RTU	0.0488	lb/1K sq.ft	Do not allow children or pets in treated area until surfaces are dry.
RECREATION AREA LAWNS	EC	2.47E-04	lb/1K sq.ft	12 hour REI.
RECREATIONAL AREAS	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Do not allow children or pets in treated area until surfaces are dry.
		0.1953	lb min	
		0.1561	lb/mound	
		1	part (L)	
		2.422	lb/A	
	RTU	0.1341	lb minute	Disallowed in Florida.
		0.1	lb/A	
		NS		
		0.0077	lb/A	
		0.0422	lb min	
		0.0464	lb minute	
	SC/L	0.0974	lb/A	Do not allow children or pets in treated area until surfaces are dry. For use only in Utah (SLN Registration).
		0.0175	lb/1 gal	
		0.0011	part A	
	SC/L* RTU	0.0974	lb/A	
0.1406		lb minute		
REFUSE/SOLID WASTE CONTAINERS (GARBAGE CANS)	PRL	NS		
REFUSE/SOLID WASTE SITES (INDOOR)	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Remove or carefully protect food products and food packaging. Do not allow children or pets in treated area until surfaces are dry. 12 hour REI.
REFUSE/SOLID WASTE SITES (OUTDOOR)	EC	0.85	lb/A	
REFUSE/SOLID WASTE SITES (OUTDOOR)	EC	0.3951	lb/1K sq.ft	
REFUSE/SOLID WASTE SITES (OUTDOOR)	EC	0.04	lb/1 gal	

RESIDENTIAL LAWNS	EC	2.47E-04	lb/1K sq.ft	Do not allow children or pets in treated area until surfaces are dry.
SHEEP	EC	6.18E-04	lb/1K cu.ft	
	EC	0.0021	lb/Animal	
	EC	1.65E-04	lb ear	
	EC	0.1068	lb/10 gal	
	SC/L* RTU	0.0098	lb/1K sq.ft	
	SC/L* RTU	0.0017	lb/Animal	14 day MRI.
	SC/L	0.0089	lb/1 gal	
SPECIALIZED ANIMALS	EC	0.1992	lb minute	Do not treat animals under 12 weeks of age. 1 day MRI.
	PRL	NS		14 day MRI.
	SC/L	0.0974	lb/A	
		0.0175	lb/1 gal	
	SC/L* RTU	0.0974	lb/A	
URBAN AREAS	EC	2.422	lb/A	
		0.1953	lb min	
		0.1992	lb minute	
		NS		
	EC*RTU	0.1341	lb minute	Disallowed in Florida.
		0.1	lb/A	
	RTU	0.0077	lb/A	
		0.0422	lb min	
		0.0464	lb minute	
	SC/L	0.0974	lb/A	
		0.0175	lb/1 gal	
		0.0011	part A	
	SC/L* RTU	0.0974	lb/A	UT-a FL-d
		0.1406	lb minute	
WIDE AREA/GENERAL OUTDOOR TREATMENT (PUBLIC HEALTH USE)	EC	2.422	lb/A	
		0.1953	lb min	
		1	part (L)	
	EC*RTU	0.1	lb/A	Disallowed in Florida.
		0.1341	lb minute	
	RTU	0.0077	lb/A	Disallowed in Florida.
		0.0422	lb min	
		0.0464	lb minute	
	SC/L	0.0011	part A	
	SC/L* RTU	0.0234	lb/A	For use only in Utah (SLN Registration).
0.1406		lb minute		

WOOD PRESSURE TREATMENT TO FOREST PRODUCTS	EC	3.2	lb/40 gal	12 hour REI.
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS INDOOR	EC	0.7805	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Do not allow children or pets on treated areas until surface has dried.
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS OUTDOOR	EC	0.1	lb/1K sq.ft	Remove food and animals from premises prior to treatment. Do not allow children or pets on treated areas until surface has dried.
		0.0319	lb lin. ft/ft depth	
		0.08	lb/1 gal	
		0.0324	lb linear ft	For use only in Mississippi (SLN Registration). Do not allow children or pets on treated areas until surface has dried.
		0.0081	lb sq.ft	
		3.2	fl.oz (L)	
WOOD PROTECTION TREATMENT TO FOREST PRODUCTS (SEASONED)	EC	0.0379	lb/1 gal	Do not allow children or pets on treated areas until surface has dried.
WOOD PROTECTION TREATMENT TO FOREST PRODUCTS (UNSEASONED)	EC	3.2	lb/A	Remove food or animals from premises prior to treatment. Do not allow children or pets on treated areas until surface has dried.
		0.7805	lb/1K sq.ft	
		0.1561	lb/mound	
		3.2	lb/40 gal	
NS- The use rate is not specified because product is labeled as a spot treatment.				

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.

Data Supporting FIFRA Guideline Requirements for the Reregistration of Permethrin

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
PRODUCT CHEMISTRY			
830.1550	61-1	Chemical Identity & Composition	44994001, 44707101, 44841201, 40955301
830.1600 830.1620	61-2A	Starting Material & Manufacturing Process	44994001, 40943601, 44707101, 44841201, 40955301
830.1670	61-2B	Formation of Impurities	44994001, 40943601, 44707101, 44841201, 40955301
830.1700	62-1	Preliminary Analysis	44812001, 41136401, 44707101, 44841201, 41150901
830.1750	62_2	Certification of limits	44994001, 41136401, 44707101, 44841201, 41150901, 40955301
830.1800	62_3	Enforcement Analytical Method	44812001, 41136401, 44707101, 44841201, 41150901
830.6302	63-2	Color	44994002, 42377601, 44707201, 44841202, 42109801
830.6303	63-3	Physical State	44994002, 42377601, 44707201, 44841202, 42109801
830.6304	63-4	Odor	44994002, 42377601, 44707201, 44841202, 42109801
830.7050		UV/Visible Absorption	44994002, 44707201, 44841202
830.7200	63-5	Melting Point	44994002, 42377601, 44707201, 42109801, 42802701
830.7220	63-6	Boiling Point	42377601, 44707201, 44841202, 42109801, 42802701
830.7300	63-7	Density	44994002, 42377601, 44707201, 44841202, 42109801
830.7840 830.7860	63-8	Solubility	44994002, 45095801, 42109801, 44707201, 44841202
830.7950	63-9	Vapor Pressure	45095801, 42109801, 44707201, 44841202
830.7370	63-10	Dissociation Constant	45095801, 44841202
830.7550	63-11	Octanol/Water Partition Coefficient	44994002, 42109801, 43651601, 44707201, 44841202, 42109801

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
830.7000	63-12	pH	44994002, 43164801, 44707201, 44841202, 42109801
830.6313	63-13	Stability	44994002, 42377601, 43651601, 44707201, 44841202, 42109801, 42802701
	<u>ECOLOGICAL EFFECTS</u>		
850.1735	73-1	Whole sediment: acute freshwater invertebrates	Data Gap
850.1735	73-1	Whole sediment: acute marine invertebrates	Data Gap
850.1740	74-1	Whole sediment: chronic freshwater invertebrates	Data Gap
850.1740	74-1	Whole sediment: chronic marine invertebrates	Data Gap
850.2100	71-1	Avian Acute Oral Toxicity - Quail	41888402
850.2200	71-2A	Avian Dietary Toxicity – Quail	41888403
850.2200	71-2B	Avian Dietary Toxicity – Duck	41888401
850.2300	71 4A	Avian Reproduction - Quail	42322902
850.2300	71 4B	Avian Reproduction – Duck	42322902
850.1075	72-1A	Fish Toxicity Bluegill	40098001
850.1075	72-1B	Fish Toxicity Sheepshead Minnow	42277001
850.1075	72-1D	Fish Toxicity Rainbow Trout- TEP	43740601
850.1010	72-2A	Acute Aquatic Invertebrate Toxicity	40098001, 00110690
850.1010	72-2B	Invertebrate Toxicity- TEP	42277004, 43740602, 42584002
	72-3A	Acute Estuarine/Marine Tox Fish (Active)	40228401
	72-3B	Acute Estuarine/Marine Mollusk (Active)	00042140

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
	<u>72-3C</u>	<u>Acute Estuarine/Marine Shrimp (Active)</u>	40228401
<u>None</u>	<u>72-3D</u>	<u>Estuarine/Marine Toxicity Fish – TEP</u>	43394601
<u>None</u>	<u>72-3E</u>	<u>Estuarine/Marine Toxicity Mollusk – TEP</u>	42723301
<u>None</u>	<u>72-3F</u>	<u>Estuarine/Marine Toxicity Shrimp – TEP</u>	00110661
<u>850.1400</u>	<u>72-4A</u>	<u>Fish Early Life Stage</u>	Hansen et al., 1983
	<u>72-4B</u>	<u>Life Cycle Aquatic Invertebrate</u>	43745701, 41315701
<u>850.1500</u>	<u>72-5</u>	<u>Fish Lifecycle Toxicity</u>	00110666
<u>850.3020</u>	<u>141-1</u>	<u>Honey Bee, acute contact</u>	42674501
	<u>141-2</u>	<u>Honey Bee Residue on Foliage</u>	42009301
<u>TOXICOLOGY</u>			
<u>870.1100</u>	<u>81-1</u>	<u>Acute Oral Toxicity-Rat</u>	242899
<u>870.1200</u>	<u>81-2</u>	<u>Acute Dermal Toxicity-Rabbit/Rat</u>	242899
<u>870.1300</u>	<u>81-3</u>	<u>Acute inhalation toxicity</u>	Data Gap
<u>870.2400</u>	<u>81-4</u>	<u>Primary Eye Irritation-Rabbit</u>	242899
<u>870.2500</u>	<u>81-5</u>	<u>Primary Skin Irritation</u>	242899
<u>870.2600</u>	<u>81-6</u>	<u>Dermal Sensitization</u>	EPA Memorandum, June 13, 1995, “Permethrin: Review of a series 81-6 dermal sensitization study (guinea pig maximization test) and a series 85-2 dermal penetration study.”
<u>870.6200</u>	<u>81-8-SS</u>	<u>Acute Neurotoxicity Study – Rat</u>	43046301, 45657401
<u>870.3100</u>	<u>82-1A</u>	<u>90-Day Feeding – Rodent</u>	92142123
<u>870.3150</u>	<u>82-1B</u>	<u>90-Day Feeding - Non-rodent (Dog)</u>	92142123
<u>870.3200</u>	<u>82-2</u>	<u>21-Day Dermal - Rabbit/Rat</u>	41143801, 42653301

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
870.4100	83-1A	Chronic Feeding Toxicity – Rodent	92142123
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	00129600
870.4200	83-2A	Oncogenicity – Rat	See 870.4100 (a)
870.4200	83-2B	Oncogenicity – Mouse	00102110, 92142032, 00062806, 92142033
870.3700	83-3A	Developmental Toxicity – Rat	40943603
870.3700	83-3B	Developmental Toxicity – Rabbit	92142091, 40943602, 92142036
870.3800	83-4	2-Generation Reproduction – Rat	00102108, 00120271, 92142092, 92142037
870.5100	84-2	Gene Mutation	41031107
870.5395	84-2	In Vivo Mammalian Cytogenetics Tests: Erythrocyte Micronucleus Assay	42723302
870.5550	84-2	Other Genotoxic Effects	40943604
870.7485	85-1	General Metabolism – Rat	00089006, 00054719, 92142041, 92142042, 00102185, 00065903
870.7485	85-1	General Metabolism – Dog	0054721, 00042160
870.6200	82-7	Subchronic Neurotoxicity Screening Battery	40766807
870.6300	83-6	Developmental Neurotoxicity Study	Data Gap
870.7600	85-3	Dermal Absorption in Rats	43169001
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>			

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
875.1100	231	Dermal Exposure – Outdoor	ORETF Data PHED v. 1.1 Data See Appendix D for Chemical Specific Studies
875.1200	232	Inhalation Exposure – Outdoor	
875.1200	233	Dermal Exposure- Indoor	
875.1400	234	Inhalation Exposure- Indoor	
875.2100	132-1A	Foliar Residue Dissipation	
875.2200	132-1B	Soil Residue Dissipation	
875.2400	133-3	Dermal Passive Dosimetry Exposure	
875.2500	133-4	Inhalation Passive Dosimetry Exposure	
875.2500	133-4	Inhalation Passive Dosimetry Exposure	
None	231	Estimation of Dermal Exposure at Outdoor Sites	
None	232	Estimation of Inhalation Exposure at Outdoor Sites	
<u>ENVIRONMENTAL FATE</u>			
835.2120	161-1	Hydrolysis	102043, 112936
835.2240	161-2	Photodegradation - Water	40242801
835.2410	161-3	Photodegradation - Soil	40190101
835.4100	162-1	Aerobic Soil Metabolism	41970602, 42410002
835.4200	162-2	Anaerobic Soil Metabolism	41970601
835.4400	162-3	Anaerobic Aquatic Metabolism	43982001
835.4300	162-4	Aerobic Aquatic Metabolism	43938201
835.1240	163-1	Leaching/Adsorption/Desorption	41868001, 45170102, 43424901, 42196701

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
<u>835.6100</u>	<u>164-1</u>	<u>Terrestrial Field Dissipation</u>	42359101
<u>835.1200</u>	<u>164.2</u>	<u>Aquatic Field Dissipation</u>	44030501, 44157101
<u>None</u>	<u>165-4</u>	<u>Bioaccumulation in Fish</u>	41300401, 41300402, 41300403
<u>RESIDUE CHEMISTRY</u>			
<u>860.1200</u>	<u>171-3</u>	<u>Directions for Use</u>	
<u>860.1300</u>	<u>171-4A</u>	<u>Nature of Residue - Plants</u>	00025919, 00025920, 00094393, 00094394, 43307801, 92142094, 9214209
<u>860.1300</u>	<u>171-4B</u>	<u>Nature of Residue - Livestock</u>	42196702, 42196703, 42410001, 42503201, 43458801, 43458802, 43505201, 43713301, 43713302, 43713303, 43713304, 43962801, 44196101, 44196102, 44417803
<u>860.1340</u>	<u>171-4C</u>	<u>Residue Analytical Method - Plants</u>	00043877, 00054724, 00072582, 00160394, 40404002, 40446403, 40446404, 40556804, 41641001, 42137202, 43364705, 44428204
<u>860.1340</u>	<u>171-4D</u>	<u>Residue Analytical Method - Animals</u>	00064675, 00064678, 00070916, 43962801, 44196103, 44417801, 44417802
<u>860.1380</u>	<u>171-4E</u>	<u>Storage Stability Data</u>	00102107, 00110622, 00137902, 00165525, 41560202, 42919201, 43494701, 43505201, 44135001
<u>860.1480</u>	<u>171-4J</u>	<u>Magnitude of Residues - Meat/Milk/Poultry/Egg</u>	00054723, 00064674, 00064676, 00064679, 00064680, 00064682, 00064683, 00064684, 00064685, 00064686, 00070914, 00070915, 00070917, 00079385, 00079386, 00079387, 00110624, 41560201
<u>860.1850</u>		<u>Confined Accumulation in Rotational Crops</u>	43174401
<u>860.1900</u>		<u>Field Accumulation in Rotational Crops</u>	44428201, 44428202, 44428203
<u>Crop Field Trials – Root and Tuber Vegetable Group</u>			

Guideline Requirement			
Guideline Number		Study Title	
New	Old		
860.1500	171-4K	Crop field trial- horseradish	00035517, 41565404
860.1500	171-4K	Crop field trial- potatoes	00025985, 00025986, 00081578, 00081579, 43343102, 44162601
860.1500	171-4K	Crop field trial- turnip roots	00155947, 41575901
<u>Crop Field Trials – Leafy Vegetables (Except <i>Brassica</i>) Group</u>			
860.1500	171-4K	Crop field trial- cabbage	00034779, 00080054, 00080055, 00080057, 00080058 00110693, 00156265, 41065802
860.1500	171-4K	Crop field trial- celery	00025921, 00081628, 00102082, 00139530, 43350501
860.1500	171-4K	Crop field trial- lettuce, leaf	00034780, 00034781, 00110622, 00139530, 00140140, 00156265, 42322904
860.1500	171-4K	Crop field trial- spinach	00150293, 41065808, 42431401, 42979901, 43350502
860.1500	171-4K	Crop field trial- turnip greens	00155947, 41575901
<u>Crop Field Trials – Bulb Vegetables</u>			
860.1500	171-4K	Crop field trial- onions	40404001
<u>Crop Field Trials – Brassica (Cole) Leafy Vegetables</u>			
860.1500	171-4K	Crop field trial- broccoli	00034774, 00034778, 00080054, 41065802, 43903501
860.1500	171-4K	Crop field trial- Brussels Sprouts	00034775, 00080054
860.1500	171-4K	Crop field trial- cauliflower	00034776, 00080054, 41065802
860.1500	171-4K	Crop field trial- collards	0015029, 00155947, 41575901
<u>Crop Field Trials –Legume Vegetables (Succulent or Dry)</u>			
860.1500	171-4K	Crop field trial- soybeans	00026542 00026548 00057091 00110622 00135413 00137902 00144855 00155947 00165525 43364704
<u>Crop Field Trials –Fruiting Vegetables</u>			
860.1500	171-4K	Crop field trial- eggplant	00129296, 41565403

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
860.1500	171-4K	Crop field trial- pepper	00129296, 41565403, 43494701
860.1500	171-4K	Crop field trial- tomato	00026543, 00026546, 00034785, 00110622, 00140140, 41404301, 42322903
<u>Crop Field Trials – Cucurbit Vegetables</u>			
860.1500	171-4K	Crop field trial- vegetable, cucurbit group	00126691, 00151251, 00155167, 40556801, 40556802, 40556803, 41565402, 41565405, 44182701, 44182702
<u>Crop Field Trials – Pome Fruits</u>			
860.1500	171-4K	Crop field trial- apple	4283810
860.1500	171-4K	Crop field trial- pear	00042620, 00042621, 00083972, 42322905
<u>Crop Field Trials – Stone Fruit</u>			
860.1500	171-4K	Crop field trial- cherry	41065803, 44135001
860.1500	171-4K	Crop field trial- peach	00118504, 43348101
<u>Crop Field Trials – Trees Nuts</u>			
860.1500	171-4K	Crop field trial- almond	00100520, 00110564, 42322903, 43938801
860.1500	171-4K	Crop field trial- almond, hull	00100520, 00110564, 42322903, 43938801
860.1500	171-4K	Crop field trial- filbert	00142263
860.1500	171-4K	Crop field trial- walnut	00072833, 42322906
<u>Crop Field Trials – Cereal Grains</u>			
860.1500	171-4K	Crop field trial- Corn (field and pop)	00069651, 00069652, 00088973, 41065804, 43149501, 43364701, 43364702
860.1500	171-4K	Corn, sweet (kernel, plus cob with husks removed)	00034777, 00034778, 41052402, 43350503
<u>Crop Field Trials - Forage, Fodder, and Straw of Cereal Grains</u>			
860.1500	171-4K	Corn (Forage and Fodder)	00069651, 00069652, 00080047, 43149501, 43350503, 43364701, 43364702

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
<u>Crop Field Trials – Grass, Forage, Fodder, and Hay</u>			
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- grass range</u>	00128728, 41565406
<u>Crop Field Trials – Non-Grass Animal Feed Group</u>			
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- alfalfa, fresh</u>	00025992, 00026551, 00026552, 00047632, 00047634, 00047635, 00151832, 40072401, 42909001, 43343101
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- alfalfa, hay</u>	00047634, 00047635, 00151832, 40072401, 42909001, 43343101
<u>Crop Field Trials – Misc. Commodities</u>			
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- artichoke</u>	00145266, 42137201
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- asparagus</u>	40446401, 40446402
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- avocado</u>	00144307, 41565401, 44229501
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- cottonseed</u>	00043877, 00043879, 00043883, 00054888, 00057091, 00064451, 00093708, 00102107, 00109336, 00110610, 00110622, 00110634, 00137902, 00151832, 00155947
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- mushroom</u>	00165524
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- papaya</u>	00144307, 41565401, 44453101
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- pistachios</u>	00133293, 41065805, 41641002
<u>860.1500</u>	<u>171-4K</u>	<u>Crop field trial- watercress</u>	00145971
<u>Processed Food/Feed Studies</u>			
<u>860.1520</u>	<u>171-4I</u>	<u>Processed foods/feed – apple</u>	42824702
<u>860.1520</u>	<u>171-4I</u>	<u>Processed foods/feed – corn</u>	42860601, 42910101, 43374601
<u>860.1520</u>	<u>171-4I</u>	<u>Processed foods/feed – cottonseed</u>	00044517
<u>860.1520</u>	<u>171-4I</u>	<u>Processed foods/feed – Potato</u>	42824701

Guideline Requirement			MRID Citation
Guideline Number		Study Title	
New	Old		
860.1520	<u>171-4I</u>	<u>Processed foods/feed – soybean</u>	00070912, 43364703
860.1520	<u>171-4I</u>	<u>Processed foods/feed- tomato</u>	41404301

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. *Permethrin. Fifth Revision of the HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated April 4, 2006;
2. *Permethrin. Second Revised Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document*, dated February 1, 2006;
3. *Permethrin. Revised Residue Chemistry Chapter of the Reregistration Eligibility Decision*, dated March 17, 2005;
4. *Permethrin. Third Revision of the Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated April 4, 2006;
5. *Permethrin: Toxicology Discipline Chapter for the Reregistration Eligibility Decision Document (RED)*, dated December 16, 2003;
6. *Permethrin. Product Chemistry Chapter for the Reregistration Eligibility Decision (RED) Document*, dated June 4, 2004.

Environmental Fate and Effects Documents;

1. *The Agency Revised Risk Assessment for the Reregistration Eligibility Decision on Permethrin After Public Comments, Phase III*, dated April 5, 2006;
2. *Addendum to the EFED Red Chapter for Permethrin*, dated April 5, 2006;
3. *Second Revision Tier II Estimated Drinking Water Concentrations of Permethrin*, dated January 17, 2006.

And the following documents on use and usage, and biological and economic analysis;

1. *BEAD Review of American Mosquito Control Association Comments and Alternative Analysis Regarding the User of Permethrin for Adult Mosquito*

2. *Control and Indoor; Outdoor Residential Uses*, dated March 14, 2006;
Qualitative Information about the Role of Permethrin in Select Uses to Inform Risk-Benefit Decision, dated March 01, 2006.

Appendix D

Bibilography

<u>MRID</u>	<u>Citation Reference</u>
00025919	Capps, T.M.; Munger, D.M.; Reynolds, J.L.; et al. (1979) Metabolism of Permethrin in Cabbage: M-4130. (Unpublished study received Mar 7, 1980 under 10182-18; prepared by FM1978 under 275-18; Mar 7, 1980 under 10182-18; prepared by FMC, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:099273-F)
00025920	Capps, T.M.; Munger, D.M.; Reynolds, J.L.; et al. (1979) Isolation and Structure Elucidation of FMC 33297 Metabolites in Cabbage: M 4331. (Unpublished study received Mar 7, 1980 under 10182 18; prepared by FMC, submitted by ICI Americas, Inc., Wilmington,Del.; CDL:099273 G)
00025921	Ussary, J.P. (1979) Permethrin Metabolite Residues on Celery: Report Series TMU0439/B. Including method dated Nov 1978. (Unpublished study received Mar 7, 1980 under 10182 18; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:099273 H)
00025922	Hillhouse, T.L.; Daniel, J.; Sexson, G.D.; et al. (1979) Permethrin Metabolite Residues on Soybeans: Report Series TMU0449/B. (Unpublished study received Mar 7, 1980 under 10182 18; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:099273 I)
00025985	Ussary, J.P.; Whiteman, C.R.; Sexson, G.D.; et al. (1979) Permethrin Residues on Potatoes: Report Series TMU0451/B. (Unpublished study received Feb 18, 1979 under 10182 18; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:099148 H)
00025986	Ussary, J.P.; Ekeh, M.K.; Whiteman, C.R. (1979) Permethrin Metabolite Residues on Potatoes: Report Series TMU0458/B. (Unpublished study received Dec 18, 1979 under 10182 18; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:099148 I)
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