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Reregistration Eligibility Decision (RED) Document for Tetramethrin

Revised April 2010

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Revised April 2010

List B

Case No. 2660

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
G	Granular Formulation
GLN	Guideline Number
HP	High pressure
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
LP	Low pressure
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NDETF	Non-Dietary Exposure Task Force
NLAA	Not Likely to Adversely Affect
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor

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Summary of Revisions to the Tetramethrin Reregistration Eligibility Decision

The Reregistration Eligibility Decision (RED) document for Tetramethrin was signed on June 23, 2008, and is available on the Federal Docket Management System (FDMS), available at http://www.regulations.gov (document # EPA-HQ-OPP-2008-0014-0019). Although a public comment period did not follow the RED, the Agency did receive comments from the registrants regarding the need for clarification and corrections in Appendix A, as well as clarification of label statements in Table 12, *Summary of Labeling Changes for Tetramethrin*. Further, in the 2008 RED, the Agency assessed the indoor aerosol space spray scenario at a maximum application rate of 0.25% active ingredient (a.i). To support indoor aerosol space spray products up to 0.35% a.i., the registrants submitted a revised Cumulative and Aggregate Risk Evaluation System (CARES®) assessment for this scenario and a short-term incidental oral benchmark dose (BMD) analysis in order to revise the endpoint for incidental oral exposure. Finally, the registrants requested the Agency review existing acute toxicological studies previously submitted to the Agency in order to address data gaps identified in the 2008 RED document.

As a result of these post-RED discussions with the registrants and the review of existing and new toxicity data, the Agency has revised the Tetramethrin RED, where appropriate, in order to correct any errors, clarify the intent of its risk mitigation captured in Table 12, reflect the revised occupational and residential risk assessments, and revise the acute toxicity data gaps and data-call in requirements.

The major revisions to the human health risk assessment and data needs are as follows:

- The Agency reviewed the Guideline 870.2400 Primary Eye Irritation Testing (MRID# 41609611) submitted by Sumitomo Chemical Inc., and found the study to be acceptable. Therefore, in Section III, *Summary of Tetramethrin Risk Assessments*, the acute toxicity profile (Table 2) was revised to reflect this data requirement as fulfilled and tetramethrin as a category III eye irritant.

- Additionally, the need for Guideline 870.2400 Primary Eye Irritation Testing was removed from Section V, *Additional Generic Data Requirements*.

- The Agency determined the "Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental – Short-term Oral Benchmark Dose Analysis," (MRID# 47921601) submitted by the registrant on November 30, 2009 to be acceptable. As a result, the short-term incidental oral endpoint for use in the human health risk assessment was revised from 25 mg/kg/day to 61.1 mg/kg/day.

- The occupational handler inhalation risk assessment was revised to reflect the increased rate of 0.35% for aerosol space sprays. The revised margin of exposure (MOE) of 9,000 is below the Agency's level of concern (LOC), and therefore, continues to be not of concern to the Agency (MOEs ≥1,000 are not of concern).

- The residential handler risk assessment was also revised to reflect the increased rate of 0.35% for aerosol space sprays. The revised MOE of 54,000 is below the Agency's LOC, and therefore, continues to be not of concern to the Agency. The residential post-application CARES assessment was also revised to reflect the revised short-term incidental oral end-point and the increased use rate for the indoor aerosol space spray. In the 2008 RED, the inhalation MOE for this scenario (using a use rate of 0.25% a.i.) was not of concern (MOEs $\geq$ 1,000) at the 99.88th percentile. In the revised CARES assessment, this use scenario (with an application rate of 0.35% a.i. and revised incidental oral endpoint) is not of concern at the 99.9 percentile (MOE = 1,131), and therefore, is eligible for reregistration. The increased use rate of 0.35% is specified in Appendix A.

Section 5, *What Registrants Need to Do*, has been amended to require two additional generic data requirements, Guideline 830.7050 UV / Visible Absorption and Guideline 870.7800 Immunotoxicity. Both are new studies which are now required for all pesticide active ingredients. The *Additional Product-Specific Data Requirements* section has also been amended to include efficacy data requirements for public health pests and companion animal studies for tetramethrin products used on domestic animals. The determination of which efficacy studies would be required for tetramethrin was still on-going at the time of publication of the June 2008 RED.

A number of revisions have also been made to the *Summary of Labeling Changes for Tetramethrin* (Label Table), Table 12, for clarification and to reflect updates in labeling on tetramethrin end-use products. Among the updates are the following:

- The Agency is requiring the following label statements to reduce the potential ecological exposure of tetramethrin. While some of the label statements are additions to the Label Table, others appeared in Table 12 of the June 28, 2008 Tetramethrin RED document; however, they have been revised slightly to be consistent with other pyrethroid non-agricultural outdoor product labeling.

    - Incorporation of PR Notice 2008-1, "Environmental Hazard General Labeling Statements on Outdoor Residential Use Products" on appropriate outdoor non-agricultural end-use products.

    - **Products labeled for General Outdoor Surface and Space Sprays (except outdoor fogging devices):**

      "All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:
        - Treatment to soil or vegetation around structures;
        - Applications to building foundations up to a maximum height of 3 feet.

      Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to spot treatments or crack-and-crevice applications, only."

- **Products labeled for use around or near floor drains must contain the following statement:**

  "Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application."

- **Products labeled for use in drains or sewers must contain the following statement:**

  "Do not apply directly to sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur, except as directed by this label."

- The Agency is also including the total release fogger (TRF) labeling requirements, intended to improve residential safety, in the Label Table (Table 12). The label requirements were sent to the pyrethrins and pyrethroid registrants in a letter dated March 23, 2010. EPA is requiring the following labeling changes on all TRF by September 30, 2011, except where manufacturers can satisfactorily explain to the Agency that an alternative approach would be adequate to address the causes of bug bomb exposure incidents:

  - Bug bomb labels must be written in plain language with clear headings.
  - The new labels must incorporate pictograms to illustrate the following list of restrictions and directions for use:
    - do not use multiple canisters in a room
    - do not use in small confined areas
    - turn off ignition sources
    - remove or cover exposed food
    - air out the room before entering
  - Instructions to vacate upon use and air out upon return must be very prominent.
  - Door hang-tags must be provided to inform others to stay out of treated areas.

- The following entry restriction label statements that appear in the "End-Use Products Intended for Occupational Use (WPS and Non-WPS)" section of the Label Table (Table 12) have been added to the "End Use Products Primarily Used by Consumers/Homeowners" section since they apply to applications made by both PCOs and consumers.

  - **For products that do not contain directions for use that allow people to be present during application:**

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

- **For products that contain directions for use that allow people to be present during application AND are labeled for use as a directed spray (does not apply to products applied directly to domestic animals):**

  "Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter treated area until sprays have dried."

- **For products that contain directions for use that allow people to be present during application AND are labeled for use as a space spray:**

  "Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated."

- **For total release foggers labeled for indoor use:**

  "Wait at least two (2) hours after application, then open windows, vents and doors for two more hours. If an odor is still detected additional ventilation is required."

A number of revisions have been made to Appendix A, *Non-Food and Non-Feed Use Patterns Subject to the Reregistration of Tetramethrin*, to reflect the maximum use rates assessed for aerosol space sprays. Furthermore, the Agency clarified Appendix A by including Outdoor Jet Sprays (intended for wasp and hornet use) in its own row, with a maximum of 0.20% a.i. and 1 to 2 second bursts per application.

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for tetramethrin and is issuing its risk management decision. Tetramethrin is not registered for use on food and has no U.S. tolerances associated with its use; therefore, it is not subject to Food Quality Protection Act (FQPA). The risk assessments, which are summarized below, are based on the review of the required database supporting the use patterns of currently registered products and additional data provided by the technical registrants, Valent BioSciences Corporation and Sumitomo Chemical Company, Ltd.

Tetramethrin is part of the pyrethroid class of pesticides and was first registered in 1968. It is a broad spectrum, non-systemic, synthetic pyrethroid used to control flying and crawling insects in a number of commercial, horticultural and residential applications. Commercial applications include space, broadcast and crack-and-crevice treatment in a variety of commercial, industrial, residential, and institutional sites. Horticultural applications include foliar and fogger treatment on non-food plants. Residential uses include pest control in homes and outdoor domestic structures, on gardens and direct application to cats, dogs and horses. The registered uses of tetramethrin are not expected to adversely impact groundwater or surface water; therefore, a drinking water assessment was not performed. There are no food uses of tetramethrin or potential for dietary exposures, so no dietary risk assessment was conducted. Therefore, the reregistration action considered only potential residential (inhalation and incidental oral), occupational (inhalation only), and ecological risks. No endpoints were selected for dermal exposure because no effects were observed at the limit dose in available acceptable dermal toxicity studies.

For residential handler inhalation risk, calculated Margins of Exposure (MOEs) for all scenarios assessed were below the Agency's Level of Concern (LOC) (MOEs $\geq$ 1,000) and therefore, are not of concern. For residential post-application inhalation and incidental oral risks, the MOEs are all greater than the target MOE of 1,000 at the 99.9 percentile of the CARES probabilistic risk assessment and are also not of concern.

Occupational handler and post-application inhalation exposures were assessed. All of the MOEs are greater than the Agency's target occupational MOE of 1,000 without respirators, and therefore, the inhalation risks are not of concern. The MOEs for the occupational post-application scenarios assessed exceed the Agency's target MOE of 1,000 and are not of concern.

The Agency evaluated potential ecological risk from both indoor and outdoor uses of tetramethrin. Although the Agency believes exposure to non-target organisms is unlikely, tetramethrin is considered highly toxic to aquatic organisms. Therefore, the Agency is limiting all outdoor uses to localized spot and crack and crevice treatments, with the exception of (1) barrier, perimeter or band applications to soil or vegetation around structures; and (2) band applications to building foundations, up to a maximum of 3 feet up the walls of the building. Since outdoor uses will be limited to spot treatments, no additional mitigation measures for these uses are required. Although these limitations will reduce exposure to tetramethrin, there could be a potential for direct effects for Listed insects or indirect effects to plants if they have an obligate relationship with a Listed insect pollinator.

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 EPA. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for tetramethrin. The document consists of six sections. Section I contains the regulatory framework for reregistration; 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 risk assessments for tetramethrin 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-2008-0014.

II. Chemical Overview

A. Regulatory History

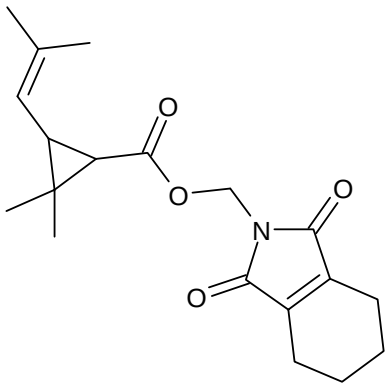
Tetramethrin was first registered in the United States in 1968. Current technical registrants include Valent BioSciences Company and Sumitomo Chemical Corporation. Tetramethrin is on reregistration List B; thus no Registration Standard was completed.

Currently, there are 58 end-use registrants and approximately 300 end-use products containing tetramethrin, of which approximately 30 are manufacturing formulations. Tetramethrin is not registered for direct application to agricultural crops and there are no food tolerances for specific raw agricultural commodities. There are no proposed new uses by any of the registrants for tetramethrin as part of this reregistration.

Prior to the reregistration of this active ingredient, the registrants have requested and the Agency has approved a number of amendments to delete uses or certain registrations for products containing tetramethrin. From 1996 through 2007, the registrants canceled all greenhouse uses of tetramethrin and have also voluntarily canceled certain tetramethrin products. These regulatory actions were published in the *Federal Register* for public comment and were subsequently approved by the Agency.

B. Chemical Identification

TETRAMETHRIN:



Tetramethrin, [(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate] is a mixture of four stereoisomers designated as 1R - trans, 1R – cis, 1S – trans, and 1S – cis in an approximate ratio of 4:1:4:1. The first two isomers are the most insecticidally active, and a mixture of the two has been termed 'd-tetramethrin' and has the trade name Neo-Pynamin Forte (Sumitomo). Neo-Pynamin Forte is not registered in the U.S., but toxicity data on this material have been submitted to fulfill data requirements for tetramethrin.

Common Name: Tetramethrin

Chemical Name: (1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate

Chemical Class: Synthetic pyrethroid

Case Number: 2660

EPA Chemical (PC) Code: 069003

CAS Number: 7696-12-0

Empirical Formula: $C_{19}H_{25}NO_4$

Technical Registrants: Valent BioSciences Corporation
Sumitomo Chemical Company

Table 1. Physicochemical Properties of Technical Grade Tetramethrin.

Parameter	Value
Melting point/range	68 - 70 °C
Molecular Weight	331.4 g/mol
Density	1.1 specific gravity at 20 °C
Water solubility	1.83 mg/L at 25 °C
Solvent solubility	>2 g/100 mL in acetone, ethanol, methanol, hexane and n-octanol
Vapor pressure	0.944 mPa at 30 °C
Dissociation constant, pK_a	Not available
Octanol/water partition coefficient, $Log(K_{OW})$	log P_{ow} = 4.6 at 25 °C
UV/visible absorption spectrum	Not available

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of tetramethrin eligible for reregistration is contained in Appendix A.

Type of Pesticide: Tetramethrin is a broad-spectrum, first-generation synthetic pyrethroid insecticide. Pyrethroids are synthetic esters derived from naturally occurring pyrethrins (insecticides derived from the extract of chrysanthemum flowers). Tetramethrin is a rapid knockdown agent against flying and crawling insects. Tetramethrin may be co-formulated with synergists (e.g., PBO and MGK-264), other active ingredients such as pyrethrins and other pyrethroids (e.g., permethrin, allethrins, phenothrin, resmethrin, and cypermethrin), and growth inhibitors (e.g., fenoxycarb) for greater effectiveness and to control a broader spectrum of insect pests. These other active ingredients are more persistent than tetramethrin and provide residual activity against insects not exposed initially.

Target Organisms: The primary target pests are flying and crawling insects such as wasps, hornets, roaches, ants, fleas, and mosquitoes.

Mode of Action: Tetramethrin is a type 1 pyrethroid (i.e., lacking a cyano group at the α carbon position of the alcohol moiety). Type 1 pyrethroids act on axons in the peripheral and central nervous system by interacting with sodium channels in mammals and/or insects. Tetramethrin is a nerve cell membrane sodium channel modulator, which interferes with entrance of sodium ions into the channel, leading to hyperactivity of the nervous system which can result in paralysis and/or death.

Use Sites: Commercial applications include space sprays, broadcast surface treatments, and crack and crevice treatments in a variety of industrial and institutional sites including: indoor non-food areas; animal premises (not used for human consumption); and outdoors as localized space and contact sprays on ornamental plants and perimeter treatments (sidewalks, entranceways, outside surfaces of buildings, etc.).

Residential uses include: pest control in homes as a space spray, general surface spray, spot and crack and crevice applications, on house plants, clothing and bedding, pet premises, and direct applications to pets. Outdoors it is used as localized space and contact spray on ornamental plants and perimeter treatments (sidewalks, decks, patios, outside surfaces of buildings, etc.).

Horticultural applications include foliar and fogger treatment on non-food plants. There are no registered food use applications for tetramethrin.

Use Classification: Tetramethrin products are designated as general use. However, some end-use products indicate they are for use by pest control operators (PCOs) only.

Formulation Types: Pressurized liquid, ready-to-use (RTU) liquids, emulsifiable concentrates, and liquid concentrates.

Application Methods: Tetramethrin is applied by aerosol can, handheld sprayers, foggers, and mechanical sprayers.

Application Rates: Tetramethrin application rates vary depending on the use pattern, indoor or outdoor use, and consumer and professional or commercial operator use. Typical concentrations of active ingredient (a.i.) in residential use products, including ready to use (RTU) (e.g., ant and roach sprays, wasp and hornet sprays) and indoor and outdoor aerosols or aqueous sprays for crawling and flying insects, range between 0.1 % and 0.35%. Indoor total release foggers are typically around 0.54% a.i. Sprays designed for use on pets are typically 0.063% a.i. Emulsifiable concentrate formulations are approximately 2.5% a.i. The maximum single application rate to an outdoor site is 0.00002 lb a.i./sq ft.

Application Timing: Tetramethrin is typically labeled for use "as needed."

D. Estimated Usage of Pesticide

Based on data provided to the Agency by the tetramethrin registrants, it appears that tetramethrin usage has increased over the past few years. This is likely due to the fact that pyrethroids are alternatives to several organophosphate pesticides, which are no longer registered

for indoor residential areas. The Agency estimates annual usage of tetramethrin to be between 15,000 and 30,000 pounds (lbs) a.i. However, tetramethrin use data is extremely limited and difficult to interpret because tetramethrin products may be stored for periods of time and produced only as inventory is exhausted. In addition, based on its localized use pattern and "use as needed" directions, sales or production data does not accurately reflect usage.

Based on use information provided to the Agency by the tetramethrin registrants, the majority of tetramethrin use is in residential outdoor spaces. It appears residential indoor use sites and institutional and industrial sites make up a small percentage of tetramethrin use. Further, tetramethrin is primarily used by residential consumers as opposed to PCOs. Sources suggest that less than 1,000 lbs a.i. are used annually by professional applicators.

III. Summary of Tetramethrin Risk Assessments

The following is a summary of EPA's revised human health and ecological risk assessments for tetramethrin, as presented fully in the documents, *Tetramethrin Risk Assessment for Reregistration Eligibility Decision,* dated June 18, 2008 and subsequent supplemental assessments discussed below and the *Revised Environmental Fate and Ecological Risk Assessment for the Re-registration Eligibility Decision on Tetramethrin,* dated February 5, 2008, respectively. The purpose of this summary is to assist the reader by identifying key features and findings of these risk assessments, and to help the reader better understand 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 tetramethrin. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2008-0014.

Tetramethrin risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED). EPA has reviewed all the studies in these multi-pesticide generic exposure databases, and on the basis of available evidence has found them to have been neither fundamentally unethical nor significantly deficient relative to standards of ethical research conduct prevailing when they were conducted. There is no regulatory barrier to continued reliance on these studies, and all applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied.

A. Human Health Risk Assessment

The human health risk assessment incorporates all sources of potential exposure, hazard, and risks, including both residential and occupational applications. There are no registered food uses for tetramethrin, and the majority of use is in consumer home products (indoor and outdoor surface and space sprays). There are also commercial and horticultural uses for tetramethrin.

The Human Health *Tetramethrin Risk Assessment for Registration Eligibility Decision* document was completed on June 18, 2008. Since the completion of the Human Health Risk Assessment, the registrants requested the Agency review existing acute primary eye irritation data, and also submitted a benchmark dose (BMD) analysis of the toxicity endpoint for incidental oral exposures. The Agency's review of the BMD analysis, *Tetramethrin: Benchmark Dose Analysis of Toxicity Endpoint for Incidental Oral Exposure*, dated January 6, 2010, found the BMD analysis to be acceptable, and consequently, the short-term incidental oral end point was revised. The Agency also revised the occupational and residential handler risk assessments, as well as the residential post-application CARES portion of the *Tetramethrin: Phase IV Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision,* dated June 13, 2008. Major revisions to the tetramethrin human health risk assessment include the following:

- The acute toxicity profile (Table 2) was revised to reflect the acute eye irritation data requirement as fulfilled and tetramethrin as a category III eye irritant.
- The short-term incidental oral toxicity end point has been revised to 61.1 mg/kg/day based on the BMD analysis.
- Occupational and residential handler exposure and risks were revised from the previous assessment to reflect use of the 0.35% tetramethrin aerosol space spray.
- Revision of the CARES portion of the Residential Exposure Assessment considered the revised incidental oral endpoint and the use of the 0.35% tetramethrin aerosol space spray.

For more information on the human health risk assessment, and the revisions to toxicity and residential portions, see *Tetramethrin Risk Assessment for Registration Eligibility Decision,* dated June 18, 2008; *HED Review of Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Supplemental Assessment for Indoor Space Spray*, dated April 27, 2009; *Tetramethrin: Benchmark Dose Analysis of Toxicity Endpoint for Incidental Oral Exposure,* dated January 6, 2010; and the *HED Review of Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental – Short-Term Oral Benchmark Dose Analysis,* dated February 25, 2010, which are available under docket number EPA-HQ-OPP-2008-0014.

1. Toxicity of Tetramethrin

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 toxicity database for tetramethrin contains acceptable acute toxicity, subchronic, chronic, oncogenecity, and mutagenecity studies. However, the database lacks acceptable developmental studies and acceptable acute neurotoxicity, subchronic neurotoxicity, and developmental neurotoxicity (DNT) studies. Although developmental and neurotoxicity studies are available, these studies are considered inadequate based on the use of carboxymethylcellulose (CMC) as the dosing vehicle. CMC has been found to decrease the absorption rate and thereby lessen the potency and toxicity of pyrethroid compounds. Concerns regarding studies on pyrethroid compounds that used CMC as a vehicle are discussed in published literature and further emphasized in a EPA report released in a July 18, 2007 draft document, "Assessing Approaches for the Development of PBPK Models of Pyrethroid Pesticides" prepared jointly by EPA's Office of Pesticide Programs and Office of Research and Development. Therefore, new developmental toxicity, and acute, subchronic, and developmental neurotoxicity studies utilizing an appropriate dosing vehicle are required to fully evaluate potential risks from exposure to tetramethrin.

Since the tetramethrin database is currently incomplete with respect to data on developmental and neurotoxicity studies, the Agency applied a ten-fold (10x) database uncertainty factor (UF_{DB}) to account for this lack of data.

a. Acute Toxicity Profile

Tetramethrin is slightly toxic (Toxicity Category III or IV) by the oral and dermal routes of exposure, and is a Category III eye irritant. However, in acute oral studies in mice with technical tetramethrin and/or neopynamin forte, clinical signs sometimes included hyper-excitability, muscular fibrillation, tremor, ataxia, limb paralysis, irregular respiration, lacrimation, and salivation. These effects were also seen in acute percutaneous studies in rats. As presented in Table 2, acceptable data on the acute inhalation toxicity, acute dermal irritation, and skin sensitization for technical tetramethrin are unavailable. The Agency is requiring these data.

Table 2. Acute Toxicity Profile – Tetramethrin (Neopynamin)

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral [rat]*	42146405	LD50 > 5,000 mg/kg	IV
870.1200	Acute dermal [rat]	00063574 42146405	LD50 > 5,000 mg/kg	IV
870.1200	Acute dermal [rabbit]	40276101	LD50 > 2,000 mg/kg	III
870.1300	Acute inhalation [rat]	--	--	No data
870.2400	Acute eye irritation [rabbit]	41609611	--	III
870.2500	Acute dermal irritation [rabbit]	--	--	No data
870.2600	Skin sensitization [guinea pig]	--	--	No data

* Clinical signs of neurotoxicity (e.g., hyper-excitability, muscular fibrillation, tremor, ataxia etc.) were present at 2,500 and 5,000 mg/kg/day in acute oral studies in rodents.

b. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for tetramethrin are listed in Table 3 below. There are no registered food uses for tetramethrin and dietary and drinking water exposure to tetramethrin is not expected based on use patterns. Therefore, acute and chronic reference doses are not required and were not selected for this assessment. Non-cancer endpoints were selected for inhalation and incidental oral exposures only.

The short-term incidental oral endpoint was selected from a two-generation rat reproduction study (MRID 00161842) with 1 litter per generation. The no observed adverse effect level (NOAEL) is 50 mg/kg/day and the lowest observed adverse effect level (LOAEL) is 300 mg/kg/day based on decreased body weight and food consumption in both sexes of F0 and F1 parental animals and decreased pup body weight during lactation. A benchmark dose (BMD) analysis was performed to determine the short-term incidental oral endpoint. A BMD is defined as an exposure due to a dose of a substance associated with a specified low incidence of risk, generally in the range of 1% to 10%, of a health effect; or the dose associated with a specified measure or change of a biological effect. The selected toxicological endpoint of 61.1 mg/kg/day was based on decreased offspring body weight on day 21 in the F0 and F1 generations.

There are no dermal absorption studies available with tetramethrin. However, based on available dermal absorption studies in pyrethrins/pyrethroid compounds, dermal absorption of tetramethrin is expected to be very low (i.e., less than 2%). Tetramethrin was tested in a 21-day

dermal toxicity study in rats (MRID 41995004) at doses of 0, 100, 300, or 1,000 mg/kg/day in 5/sex/dose Sprague-Dawley rats. There were no treatment-related systemic toxic effects and a LOAEL was not established. No endpoints were selected for dermal exposure because no effects were observed at the limit dose in available acceptable dermal toxicity studies.

The short and intermediate term inhalation exposure endpoint was selected based on two 90-day inhalation toxicity studies in rats conducted in 1991 (MRIDs 42012101 and 41995003). The systemic toxicity NOAEL of 19.8/20.3 mg/m^3 (3.5 mg/kg/day) was selected based on: increased clinical signs (irregular respiration and bradypnea); decreased body weight gain; changes in hematology, urinalysis, and blood chemistry; gross necropsy findings in liver; hepatocellular hypertrophy; and hyaline droplets in kidney in both sexes at the LOAEL of 134 mg/m^3 (23.5 mg/kg/day).

A combined uncertainty factor or margin of exposure (MOE) of 1,000 for residential and occupational scenarios is based on the standard 10x for interspecies extrapolation and 10x for intraspecies variation, plus an additional database uncertainty factor (UF_{DB}) of 10x for the absence of adequate neurotoxicity studies, since the nervous system is the target site for tetramethrin. Based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the development neurotoxicity study (DNT) is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. EPA has recently determined that, as an alternative to the generation and submission of a new DNT study, pyrethroid registrants may instead choose to cite the six previously submitted DNT studies for pyrethroid pesticides[1]. The Agency is also investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms. Therefore, the Agency is maintaining the 10x database uncertainty factor to account for the outstanding neurotoxicity data gap. The 10x database uncertainty factor is also applicable to workers because occupational exposures may pose neurotoxic and developmental risk concerns. The uncertainty factors (UF) used to account for interspecies extrapolation and intraspecies variability are also described in Table 3.

Table 3. Summary of Toxicological Doses and Endpoints for Tetramethrin for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	Safety Factor and Level of Concern	Study and Toxicological Effects
Acute and Chronic Dietary (general population)	Acute and Chronic RfD's were not selected because there are no registered food uses		
Short-Term Incidental Oral (1 - 30 days)	$BMDL_5$ = 61.1 mg/kg/day UF_A=10 UF_H = 10 UF_{DB} = 10	Residential LOC for MOE = 1,000 Occupational LOC for MOE = N/A	2-Generation Reproduction (rats) The NOAEL is 50 mg/kg/day and the LOAEL is 300 mg/kg/day based on decreased body weight and food consumption in both sexes of F0 and F1 parental animals and decreased pup body weight during lactation.

[1] These conclusions and determinations were communicated to registrants of some pyrethroid active ingredients in a letter from EPA dated September 4, 2009 (available from the public docket EPA-HQ-OPP-2008-0331-0027). Further details are also available from the website http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

Table 3. Summary of Toxicological Doses and Endpoints for Tetramethrin for Use in Human Risk Assessments			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Safety Factor and Level of Concern**	**Study and Toxicological Effects**
Short-, Intermediate- Term Dermal (1 - 30 days, 1-6 months)	No risk is expected from this exposure scenario as no hazard was identified in a 21/28 day dermal toxicity study conducted at the limit dose of 1,000 mg/kg/d.		
Inhalation Short-, Intermediate-Term (1 - 30 days, 1-6 months)	Inhalation NOAEL = 19.8 mg/m3 (3.5 mg/kg/day (oral equivalent) UF_A=10 UF_H = 10 UF_{DB} = 10	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 1,000	90 Day Inhalation Toxicity (rats) LOAEL = 134 mg/ m3 (23.5 mg/kg/day) based on ↑ clinical signs, absolute/relative kidney and liver weights; ↓ body weight, changes in hematology, urinalysis, hypertrophic and gross liver necropsy findings, and hyaline droplets in the kidney
Cancer (oral, dermal, inhalation)	Group C, possible human carcinogen based on evidence of benign testicular tumors in rats and increased hepatocellular carcinomas in male mice at the HDT of 1134 mg/kg/day. Based on a recent review of the cancer data, HED has determined that tetramethrin would likely be reclassified under EPA's 2005 Guidelines for Carcinogen Risk Assessment as "Suggestive Evidence of Carcinogenic Potential."		

UF = uncertainty factor (A= Animal/Interspecies, H= Human/Intraspecies, DB=Data Base)
NOAEL = no observed adverse effect level
LOAEL = lowest observed adverse effect level
MOE = margin of exposure
LOC = level of concern
N/A = Not Applicable

2. Carcinogenicity of Tetramethrin

The Agency concluded that, based on the available information, tetramethrin meets the criteria for Group C, possible human carcinogen. Tetramethrin administered to Sprague-Dawley rats was associated with a statistically significant dose-related increase in the incidence of interstitial cell adenomas in the testes in mid- and high-dose males. These results were reproducible in a second study in Sprague-Dawley rats and another study in Long-Evans rats. This increase was outside the historical control range for Sprague-Dawley rats. No historical control data were available on Long-Evans rats. Tetramethrin administration to $B_6C_3F_1$ mice did not alter the spontaneous tumor profile for this strain of mice. Therefore, the Agency determined that no chronic cancer risk assessment was necessary. The Agency based its decision on the fact that this type of tumor (interstitial cell adenomas of the testes) is a benign tumor that does not progress to a malignant tumor in rats; the tumors occurred at a later stage of the study; the exposure started in utero; and the treatment did not cause reduction in latency.

3. Metabolites and Degradates

The Agency reviewed the metabolism of tetramethrin (MRIDs 42448901 and 42448902), and concluded that for risk assessment, the parent compound, tetramethrin, is the only residue of toxicological concern. For additional details, refer to the *Tetramethrin Risk Assessment for Registration Eligibility Decision*, dated June 18, 2008.

4. Dietary Exposure and Risk (Food and Water)

Tetramethrin currently has no registered food uses and there are no tolerances for specific raw agricultural commodities. Tetramethrin is not registered for direct application to agricultural crops, livestock animals, or livestock premises, where livestock are used for food. Although there are no registered food uses for tetramethrin, there are uses in the home where food may be exposed (e.g., kitchens), but labels for these uses have restrictions to prevent / limit food exposure such as, "In the home, all food-processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Cover exposed food." Therefore, dietary exposure is not of concern.

The Agency did not conduct a quantitative drinking water assessment for tetramethrin, given the limited extent of potential exposure and the chemical's environmental fate properties. Tetramethrin is used by individual homeowners or industrial / commercial property owners, in individual, isolated areas, and in small amounts as opposed to wide scale uses (i.e., for agriculture or mosquito abatement by public authorities). Because tetramethrin products are not expected to adversely impact groundwater or surface water (the sources of drinking water), a quantitative drinking water assessment is not warranted.

5. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure. Tetramethrin has a wide variety of residential uses, including use in/on indoor and outdoor surfaces, and use on pets. Therefore, the Agency has determined that there is a potential for exposure to tetramethrin in residential settings for homeowners who handle (mix, load, and apply) products containing tetramethrin, as well as post-application exposure from entering tetramethrin-treated areas. Non-occupational post-application exposures can result following use of pesticides by homeowners themselves or following applications by professional pest control operators in residential or non-residential settings.

Risk assessments have been completed for both residential handler (inhalation only) and post-application scenarios (inhalation and incidental oral). Though dermal exposure is possible and expected for residential handler and post-application scenarios of tetramethrin, the Agency determined a dermal assessment was not necessary because no systemic effects were observed at the limit dose in dermal toxicity studies in animals.

To estimate residential (inhalation and incidental oral) risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the toxicity endpoint (NOAEL or BMDL) selected for risk assessment to the exposure value. The MOE is then compared to a level of concern (LOC), 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). However, since the tetramethrin database is currently incomplete, the Agency applied a ten fold (10x) database uncertainty factor (UF_{DB}) to account for this lack of certain data; thus, for residential exposures to tetramethrin, MOEs greater than the target LOC of 1,000 are not of concern to the Agency. For detailed information on the residential risk assessment, see the *Tetramethrin Risk Assessment for Registration Eligibility Decision*, dated

June 18, 2008*; HED Review of Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Supplemental Assessment for Indoor Space Spray*, dated April 27, 2009; and the *HED Review of the Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental Short-Term Oral Benchmark Dose Analysis,* dated February 25, 2010.

a. Residential Handler Risks

The Agency determined that exposure to homeowners handling a tetramethrin product is likely to occur via the inhalation route during the residential use of tetramethrin in a variety of indoor and outdoor settings. The risk assessment considered three major residential exposure scenarios, based on the types of equipment and techniques that can potentially be used to make tetramethrin applications. While some tetramethrin products are packaged as RTU trigger sprayer bottles, the handler risks calculated from aerosol can application are protective of risks from trigger sprayer applications because the unit exposure values are lower for trigger sprayer application. The Agency only considered short-term (1-30 days) inhalation exposure due to infrequency of use associated with homeowner products and the non-persistence of tetramethrin. Additionally, as discussed above, dermal exposures were not assessed, because no effects were observed at the limit dose in available acceptable dermal toxicity studies. The following scenarios were assessed:

- Mix / Load / Apply liquids with a backpack sprayer or low pressure hand wand.
- Aerosol can application
- Load / Apply liquids with a trigger-pump sprayer.

Pesticide handler exposure database (PHED) unit exposure values were used to assess exposures, because chemical-specific monitoring data were not available. The following assumptions were also used in estimating risks from residential handler exposure to tetramethrin:

- The body weight of an adult handler is 70 kg.
- The amount handled per day is based on formulation type:
    - Aerosol can: One 16 ounce can is used per day.
    - Trigger- pump Sprayer: 1 gallon of diluted solution per day.
    - Low-pressure handwand sprayer: 5 gallons of diluted solution per day.

Table 4 summarizes the inhalation risk estimates for residential handlers of tetramethrin products. All MOEs are well below the Agency's LOC (MOEs ≥ 1,000 are not of concern), with values ranging from 54,000 to 100,000.

Table 4. Residential Handler Risk Estimates from General Spray Applications

Exposure Scenario	Application Rate	Amount Sprayed per Day	Pound a.i. handled per day	Inhalation MOE
M/L/A Liquids with LP Hand-wand or Backpack Sprayer	0.02 lb a.i./gallon solution	5 gallons	0.1	82,000
Aerosol Can	0.35% a.i.	1 can (16 oz ea)	0.0025	54,000

Table 4. Residential Handler Risk Estimates from General Spray Applications				
Application				
L/A RTU with a Trigger-pump Sprayer	0.02 lb a.i./gallon solution	1 gallon	0.02	100,000

M/L/A = Mix / load / apply
LP = Low pressure
L/A = Load / apply
RTU = Ready-to-use

b. Residential Post-Application Risks

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an area that has been previously treated with a pesticide. Unlike residential handler exposure, where the Agency assumed only adults will be handling and applying tetramethrin products, individuals of varying ages can potentially be exposed when reentering or performing activities in areas that have been previously treated. Tetramethrin can also be used on pets, which can lead to exposure by contact with the treated animals.

Tetramethrin post-application incidental oral exposures may occur after applications are made to residential areas resulting in residues on surfaces, such as carpets and vinyl flooring. Post-application inhalation exposures are possible from residue concentrations in air following applications such as space sprays and fogging applications. Post-application incidental oral exposures were assessed for children only, and inhalation exposures were assessed for both adults and children. Again, dermal exposures were not assessed, because no effects were observed at the limit dose in available acceptable dermal toxicity studies. The following scenarios were assessed:

- Inhalation exposure (adults and children) indoors:
  - Space spray and total release fogger;
- Inhalation exposure (adults and children) outdoors:
  - Handheld foggers and aerosols;
- Incidental oral ingestion (children only) of residues indoors:
  - Total release aerosol fogger treatment,
  - Aerosol and spray surface treatments,
  - Aerosol and spray treatments to pets; and,
- Incidental oral ingestion (children only) of residues outdoors:
  - Handheld fogger applications, and
  - Aerosol surface treatments.

The Agency assessed the post-application exposure to tetramethrin using two approaches: a deterministic approach and a probabilistic approach. A deterministic approach uses a point estimate from a data set, e.g., a single maximum value or an average value, as an input variable in the exposure model. This approach does not consider the range of potential exposures incurred by members of a population and does not describe the potential or probability of exposure to individuals within a population. Rather, the deterministic approach produces an output value that represents the potential exposure or risk of a group; depending on how the

estimate was generated, the output value may reflect a "central tendency," a "high-end," or an "upper-bound." In contrast, a probabilistic approach uses the full range of available data and produces a distribution of values as output, and is recognized as a refinement over the deterministic assessment. More detail is provided below regarding the probabilistic risk assessment.

i. Deterministic Risk Approach and Assessment

The February 5, 2008, *Tetramethrin: Phase 1 Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision* presented results of the Agency's deterministic post-application risk assessment. Risks of concern were identified for hand-to-mouth exposures following indoor aerosol can space spray treatments (MOEs of 290 and 430 for children on carpet and vinyl, respectively), inhalation exposure following indoor aerosol can treatments (MOE of 850 for children), and hand-to-mouth exposure following indoor ready-to-use liquid spray treatments (MOEs of 570 and 840 for children on carpet and vinyl, respectively). Because these risks of concern were identified using the screening-level deterministic approach, a more refined probabilistic assessment was conducted for the residential post-application exposure scenarios.

ii. Probabilistic Risk Approach and Assessment

In the *Tetramethrin Risk Assessment for Registration Eligibility Decision,* dated June 18, 2008, the Agency presents the results of the probabilistic exposure assessment, using the Cumulative and Aggregate Risk Evaluation System (CARES® Version 3.0; http://cares.ilsi.org/), a publicly available software program. Probabilistic exposure assessment is recognized as a refinement over deterministic assessment because it allows users to identify percentiles of risk by using inputs in the form of distributions rather than point estimates. In the *HED Review of the Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental Short-Term Oral Benchmark Dose Analysis,* dated February 25, 2010, the CARES assessment was revised to reflect the revised short-term oral endpoint and the use rate of 0.35% a.i. for indoor aerosol applications.

a. Tetramethrin CARES Post-Application Risk Assessment

The Agency completed a CARES probabilistic residential exposure and risk assessment, which verified the CARES assessment that was submitted by tetramethrin registrants Valent BioSciences Corporation; Sumitomo Chemical Company, LTD; S. C. Johnson & Son, Inc.; and McLaughlin Gormley King Company. CARES utilizes a reference population of 100,000 individuals selected from the 1990 U.S. Census. It is considered appropriate for use in exposure analysis due to its similarity with the U.S. Census Public Use Micro Data Sample (PUMS), a statistically representative dataset that contains data for statistical weights from sampled individuals of the general U.S. population, provided by the U.S. Department of Commerce, Bureau of the Census, Economics and Statistics Administration. Key sub-populations relevant to exposure analysis within CARES include different races (e.g., white, black, Hispanic, etc.) and different age groups (e.g., children 1-3 years old, male 20-54 years old, etc.) (Driver et al, 2008).

CARES simulates daily (24-hour) exposures over the course of one calendar year for each person in the specified sub-population based on user-specified routes of exposure (e.g., dietary, dermal, non-dietary ingestion), empirical data, and exposure algorithms. It can provide cumulative exposures for more than one chemical, aggregate across exposure routes, and provide results for different exposure patterns (e.g., acute or chronic exposures). Additionally, each input (e.g., chemical residue, exposure duration, and mouthing behavior) is described and used as a distribution in a Monte Carlo simulation to identify percentiles of risk and enable users to conduct analyses to identify major exposure contributors.

The calculations and algorithms used to estimate exposure for the various scenarios and routes are consistent with standard Agency practice for residential pesticide exposure assessment. Risks of concern were not identified for residential handler scenarios in the deterministic assessment; therefore, the CARES assessment considered only post-application exposure routes. The tetramethrin exposure scenarios were assessed using standard EPA algorithms for exposure estimation. Distributional inputs were included in the probabilistic assessment where possible. The probabilistic assessment assumes post-application exposure occurs on the "day of application," which is the most conservative assumption.

The tetramethrin CARES assessment calculated risk for adults (defined as males and females 20 - 49 years old) and children (defined as males and females 1 - 2 years old). Though older or younger children may be exposed to tetramethrin, the selection of 1 - 2 year olds is appropriate since this age group exhibits the highest degree of mouthing behavior – a major route of exposure for this assessment (Tulve et al., 2002). Combined male/female populations are also appropriate since the toxicological endpoints used in the risk assessment are not gender specific. The risk percentages generated by the CARES model correspond only to those individuals who use tetramethrin as a pesticide (i.e., the population is "users only") and those that reside within the home. The assessment does not characterize risk relative to the percentage of the population that does not use tetramethrin.

Exposure factors used in the CARES assessment were determined based on consultation between EPA and the tetramethrin registrants. Many of the non-tetramethrin-specific distributional inputs are based on EPA's n-methyl Carbamate Revised Cumulative Risk Assessment (NMCCRA), the most recent EPA publication using probabilistic methods and distributional inputs for residential exposure assessment. For more information on the inputs and distributions considered for the children's non-dietary ingestion exposure following use of 0.35% tetramethrin aerosol space sprays, refer to the *HED Review of "Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental – Short-term Oral Benchmark Dose Analysis,"* dated February 25, 2010. For all other post-application scenarios, refer to the *Tetramethrin: Phase IV Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision,* dated June 13, 2008, for more information on the inputs and distributions considered for the CARES assessment.

Table 5. CARES Residential Post-Application Assessment – Tetramethrin MOEs for Adults (20 - 49 years)			
Percentile	Exposure Scenario and Route		
	Outdoor Treatment	Indoor Treatment (Spray)	
	Inhalation	Inhalation (Applicator)	Inhalation (Post-application)
100	1,690	37,336	5,834
99.9	2,051	47,342	6,726
99.8	2,117	48,848	7,162
99.7	2,150	48,848	7,432
99.6	2,188	48,848	7,510
99.5	2,215	48,848	7,673

Table 6. CARES Residential Post-Application Assessment – Tetramethrin MOEs for Children (1 - 2 years)						
Percentile	Exposure Scenario and Route					
	Outdoor Treatment		Indoor Treatment			Pet Care
			Fogger	Spray		
	Ingestion	Inhalation	Ingestion	Ingestion	Inhalation	Ingestion
100	1,808	1,034	3,351	754	3,007	3,725
99.9	2,123	1,040	5,347	1,131	3,113	5,135
99.88	2,188	1,042	5,487	1,247	3,130	5,207
99.8	2,387	1,045	6,085	1,455	3,160	5,770
99.7	2,603	1,045	6,952	n/a	3,221	6,131
99.6	2,771	1,046	7,951	n/a	3,246	6,482
99.5	2,870	1,048	8,475	n/a	3,285	6,719

n/a- The *"Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental – Short-term Oral Benchmark Dose Analysis"* submitted by the registrant in November 2009 only provided MOEs down to the 99.8 percentile, which were all below the Agency's LOC (MOE >1000).

As demonstrated in Tables 5 and 6, for the tetramethrin CARES probabilistic residential exposure assessment, all MOEs were above 1,000 at the 99.9 percentile for all scenarios assessed for both adults and children.

6. Aggregate Exposure and Risk

For tetramethrin, short term aggregate risk potentially involves adding exposure estimates for incidental oral exposure and inhalation exposure pathways for young children. However, exposures from incidental oral and inhalation pathways may not be aggregated for tetramethrin because the toxicity endpoints for these exposure routes are not based on common toxic effects (i.e., body weight changes are considered to be non-specific, and there are no common specific target organ effects observed in the oral and inhalation toxicity studies.)

7. Occupational Exposure and Risk

The occupational risk assessment addresses risks to workers who may be exposed to tetramethrin when mixing, loading, or applying a pesticide (i.e., handlers), and when entering treated sites for routine tasks (post-application). Exposure for workers generally occurs via the dermal or inhalation route. However, for tetramethrin, only inhalation exposures were calculated since there were no treatment related systemic toxic effects at the highest dose tested in the 21 day dermal toxicity study. The target MOE is 1,000 for occupational exposures.

Occupational exposure to tetramethrin was assessed using data from the Pesticide Handler Exposure Database (PHED), and worker exposure and risk estimates are based on the best data currently available to the Agency. In addition, standard default assumptions pertaining to average body weight, work day, and area treated daily were used to calculate risk estimates. Application rates used in this assessment are derived directly from current tetramethrin labels. The occupational risk assessment is summarized here. For further detail, see the *Tetramethrin Risk Assessment for Registration Eligibility Decision,* dated June 18, 2008, and *HED Review of Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Supplemental Assessment for Indoor Space Spray*, dated April 27, 2009.

a. Occupational Handler Exposure and Risks

The term "handler" applies to individuals who mix, load, and apply the pesticide product. Because most tetramethrin products are packaged in aerosol cans, most of the uses will involve application only (i.e., there is no mixing or loading activities for aerosol cans). However, some products are packaged as ready-to-use liquids or liquid concentrates, which are applied with mechanical sprayers, compressed air sprayers or foggers (i.e., equipment and formulation that do require mixing and loading activities). Based upon the currently registered product labels, the Agency assessed the following occupational handler scenarios:

Pesticide Control Operator Scenarios

1. Mix/Load/Apply (M/L/A) liquids with a backpack sprayer or low pressure handwand
2. M/L/A liquids with handheld fogging equipment
3. Applying with an aerosol can
4. Load/Apply (L/A) liquids with a trigger-pump sprayer

Occupational handler exposure assessments are conducted by the Agency using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then adds protective measures in a tiered approach to determine the level of protection necessary to obtain appropriate MOEs. Dermal exposures were not assessed because no systemic effects were observed at the limit dose in available acceptable dermal toxicity studies. Inhalation exposures were assessed at the minimum level of protection, which is no respirator. Risk estimates (i.e., MOEs) for the general surface and space sprays and handheld fogger handler scenarios are summarized in Tables 7 and 8. All MOEs are above the target MOE of 1,000 (ranging from 9,000 to 50,000), and therefore, are not of concern.

Table 7. Short / Intermediate-term Inhalation MOEs for Occupational Handlers Applying General Surface and Space Sprays

Exposure Scenario	Unit Exposure[A] (µg/lb a.i.)	Application Rate[B]	Amount Sprayed per Day	lb a.i. handled per day	Inhalation Dose[E] (mg/kg/day)	Inhalation MOE[F]
M/L/A liquids with LP hand-wand or backpack sprayer	30	0.02 lb a.i./gallon solution	40 gallons[C]	0.8	0.00034	10,000
L/A liquids with Trigger-pump Sprayer	123		2 gallons[D]	0.04	0.00007	50,000

Table 7. Short / Intermediate-term Inhalation MOEs for Occupational Handlers Applying General Surface and Space Sprays						
Exposure Scenario	**Unit Exposure[A] (µg/lb a.i.)**	**Application Rate[B]**	**Amount Sprayed per Day**	**lb a.i. handled per day**	**Inhalation Dose[E] (mg/kg/day)**	**Inhalation MOE[F]**
Aerosol can application	1300	0.35% a.i.	6 cans[D]	0.015	0.00039	9,000

A. Unit Exposure values are from PHED.
B. Application rates are from labels 769-939 (0.02 lb a.i./gallon solution) and 4822-513 (0.35%)
C. Based upon ExpoSAC Policy 9.
D. Screening level estimate based upon professional judgment.
E. Inhalation dose (mg/kg/day) = [unit exposure (ug/lb a.i.) * 0.001 mg/ g * lb a.i. handled per day)] / Body weight (70 kg).
F. MOE = NOAEL (3.5 mg/kg/day) / Dose

Table 8. Inhalation MOEs for Occupational Handlers Applying Sprays using Handheld Fogging Equipment				
Application Rate		**Inhalation Exposure[C] (mg/day)**	**Inhalation Dose[D] (mg/kg/day)**	**Inhalation MOE[E]**
(lb a.i./ft^3)[A]	**(mg/m^3)[B]**			
0.00000001	0.218	0.0174	0.00025	14,000

A. Based on EPA Reg. No. 73049-432: 1 fluid ounce of 0.10% RTU solution per 600 square feet at an approximate spray height of 8 feet. [1 fl.oz./600 ft^2] * [1 gallon/128 fl.oz.] * [8.35 lb soln/gallon] * [0.1% a.i.] / 8 ft = 0.00000001 lb a.i./ft^3
B. Application rate (mg/m^3) = 0.00000001 lb a.i./ft^3 * [454000 mg/lb] * [35 ft^3/m^3] = 0.218 mg/m^3
C. Inhalation Exposure (mg/day) = [Application Rate (mg/m^3) * Breathing Rate (1 m^3/hr) * Exposure Time (8 hours/day)] / Outdoor Dilution Factor (100)
D. Inhalation Dose (mg/kg/day) = Inhalation Exposure (mg/day) / Body Weight (70 kg)
E. MOE = NOAEL/Dose where the NOAEL is 3.5 mg/kg/day.

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 re-entry exposure). The Agency did not conduct a post-application risk assessment for tetramethrin for occupational exposures. Although dermal exposure is possible and expected, no occupational post-application assessment was conducted because no systemic effects were observed at the limit dose in available acceptable dermal toxicity studies in animals. Additionally, inhalation post-application exposures were not assessed because tetramethrin is applied in areas where prolonged occupational presence in areas with low ventilation following application (e.g., following greenhouse applications) is not expected.

8. Cumulative Exposure and Risk

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Tetramethrin is a member of the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, fluvalinate, bifenthrin, fenpropathrin, and lambda-cyhalothrin, among others. EPA developed a draft science policy document on the proposed

common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009; http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a62df). This document was supported by the FIFRA Scientific Advisory Panel (SAP) and EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the Stochastic Human Exposure and Dose Simulation (SHEDS) probabilistic exposure model which are important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts will be reviewed by the FIFRA SAP in July, 2010. For information regarding EPA's efforts to evaluate the risk to pyrethroids, see http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

9. Tetramethrin Human Incident Reports

The OPP Incident Data System (IDS) and Poison Control Centers (PCC) databases were consulted for poisoning incident data on the active ingredient tetramethrin. Reports submitted to the IDS and PCC typically represent anecdotal reports or allegations only; therefore, no conclusions can be drawn implicating tetramethrin as a cause of any of the reported health effects unless supported by results from other data sources or unless the individual incidents are well documented.

There were approximately 98 reported incidents in the IDS database over the five year period from 2002 to 2007 (for which the incident report was conducted) for products containing tetramethrin. Since there are no pesticide products for which tetramethrin is the sole active ingredient, reported incidents cannot be solely attributed to exposure to tetramethrin. The incidents are classified as mild to moderate human incidents (less than 1% involved major effects). The majority (approximately 85%) of incidents with documented health effects reported either no effects or mild effects resulting from tetramethrin-related exposures. The majority of the symptoms included respiratory irritation, shortness of breath, blisters, welts, hives, dizziness, rashes, coughing, and eye irritation, which are similar to that of other pyrethroid compounds. The PCC incidents involved a wide range of effects including cardiovascular, gastrointestinal, respiratory, dermal, and ocular effects.

The Agency believes the number of reported incidents is small in relation to the estimated usage of tetramethrin, which is approximately 15,000 to 30,000 pounds per year. Tetramethrin applications are primarily residential localized or spot treatments via aerosol or RTU sprays on an "as needed" basis (residential exposures accounted for 98% of the reported cases involving tetramethrin); therefore, given this broad spectrum residential use pattern, the Agency estimates the number of applications per year could range in the hundreds of thousands or greater.

In conclusion, the incident report does not garner greater concern for the active ingredient tetramethrin solely. Furthermore, in a recent review of the pyrethroid class of chemicals and aggravated dermal and asthmatic reactions, titled *"A Review of the Relationship between Pyrethrins, Pyrethroid Exposure and Asthma and Allergies,"* dated September 18, 2009, the

Agency concluded, based on the weight of the evidence, there is not a clear relationship between pyrethrins/pyrethroid exposure and asthma and allergies. Therefore, the Agency is not requiring additional warnings or label statements specific to asthmatics on pyrethroids and pyrethrins end-use product labels at this time. For more information on this review, please refer to http://www.epa.gov/oppsrrd1/reevaluation/pyrethrins-pyrethroids-asthma-allergy-9-18-09.pdf.

B. Environmental Risk Assessment

Tetramethrin is used in residential and industrial/commercial areas in relatively small quantities through aerosols, foggers, and space sprays. On a nationwide basis, tetramethrin use is relatively limited. It is not used on a wide scale, such as agriculture or in mosquito abatement by public authorities. The use pattern is, therefore, in individual, isolated areas, and again, in small amounts. Tetramethrin also decomposes rapidly by photolysis and hydrolysis. The localized use pattern of tetramethrin, combined with the low total pounds used on a national basis, and rapid degradation due to photolysis and hydrolysis, make it highly unlikely that non-target organisms will be exposed at harmful levels. Non-target organism exposure is most likely to result from outdoor uses, such as spraying wasp or hornet nests under the eaves of houses, and backyard foggers for flying insects. Further, because of the very rapid photolytic decomposition of tetramethrin, only those organisms present at the time of spraying are likely to be exposed and are at risk of acute effects.

The standard models (GENEEC, PRZM-EXAMS, T-REX, Terrplant) used to calculate and quantify risks to terrestrial and aquatic organisms do not fit with the localized use patterns of tetramethrin. As a result, tetramethrin's ecological risk assessment did not follow the standard methodology and the acute risks will be characterized qualitatively rather than quantitatively. 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 February 5, 2008 *Revised Environmental Fate and Ecological Risk Assessment Chapter in Support of Phase I of the Re-registration Eligibility Decision on Tetramethrin,* which is available under docket number EPA-HQ-OPP-2008-0014.

1. Environmental Fate and Transport

Tetramethrin is not a persistent pyrethroid in the environment. It may be co-formulated with synergists, other active ingredients such as pyrethrins and pyrethroids, and growth inhibitors. These other ingredients are more persistent than tetramethrin and provide residual activity against insects not initially exposed. Tetramethrin decomposes rapidly by photolysis and hydrolysis in shallow, non-turbid water. Photolysis in air is expected to be rapid (half-life 30 minutes) based on reaction with ozone. Tetramethrin is more susceptible to hydrolysis at pH 7 and 9 than pH 5. The half-lives were 15.9 – 19.7 days (pH 5), 0.89 – 1.06 days (pH 7), and 0.009 – 0.014 days (pH 9). Tetramethrin is slightly mobile in soil (Koc value range from 1,249-2,939), has a vapor pressure of 7.1x10-6 mm Hg, water solubility of 1.83 mg/L, and an estimated Henry's law constant of 1.7x10-6 atm-m3/mol-1.

At least nine degradates were detected in a column leaching study, and in an aerobic soil metabolism study, seven degradates were identified including one (acid-NPY) that retains the

entire ester structure and possibly the mode of action of the parent tetramethrin. However, it too is subject to rapid hydrolysis, and therefore, exposure to acid-NPY is unlikely. In two acceptable field dissipation studies, tetramethrin dissipated from the upper 15 cm of soil with a DT50 (time to 50% degradation) of 3 hours in a California study, and less than one hour in a Florida study. No toxicity data are available for tetramethrin degradates.

Indoor uses of tetramethrin are not expected to result in significant exposure pathways to terrestrial and aquatic ecosystem as they are confined indoors, and tetramethrin rapidly degrades in hours. While there are numerous outdoor uses, these applications are limited to spot treatments in localized areas and, again, the degradation of tetramethrin to non-toxic degradates is rapid. There is potential for tetramethrin residues to be transported to aquatic systems from use in drainage systems, but only in acidic water where hydrolysis is slower. However, the Agency believes exposure is unlikely because product labels prohibit direct application to water.

2. Ecological Exposure and Risk

The possible exposure mechanisms considered following tetramethrin applications were runoff, spray drift, and direct spray. Only direct spray is considered to be a completed exposure pathway, since tetramethrin is too non-persistent to be transported via runoff, and it is not used in sufficient quantities for spray drift to be of concern. As stated above, neither indoor nor outdoor uses of tetramethrin are expected to result in significant exposure pathways to terrestrial and aquatic ecosystems since they are limited and tetramethrin degrades rapidly. Given that degradation of tetramethrin to non-toxic degradates is rapid, the primary risk will be acute exposure to tetramethrin at the time of application and a brief period thereafter.

Acute toxicity data from studies submitted by pesticide registrants along with the available open literature were used to evaluate the potential direct effects of tetramethrin aquatic and terrestrial organisms. This includes toxicity data on the technical grade active ingredient, degradates, and formulated products when available. The open literature studies are indentified through EPA's ECOTOX database (https://cfpub.epa.gov/ecotox/), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of both sources of data can also provide insight into the direct and indirect effects of tetramethrin on biotic communities from loss of species that are sensitive to the chemical and from changes in structure and functional characteristics of affected communities.

a. Terrestrial Organisms

No terrestrial modeling was conducted for tetramethrin because exposure of non-target organisms to harmful levels is unlikely based on the localized use patterns, low total pounds used on a national basis, and rapid degradation due to photolysis and hydrolysis. Instead, the Agency conducted a qualitative assessment using submitted studies and review of the literature.

The Agency developed an effects characterization, which describes the potential effects a pesticide can produce in a terrestrial organism, and is based on registrant-submitted studies that describe acute effects toxicity information for various terrestrial animals. Table 9 summarizes

the specific measurement endpoint value selected to evaluate risks for tetramethrin to mammals and birds.

Table 9. Summary of Specific Measurement Endpoint Values Selected to Evaluate Risk for the Associated Terrestrial Animal Assessment Endpoints

Assessment Ends	Acute Measurement Endpoint (most sensitive)	Selected Measurement Endpoint Values and Source				
		Species	Study Duration	Toxicity Value	Most Sensitive Endpoint (MRID)	Acute Toxicity Classification
Survival and Reproduction of Birds, Reptiles and Amphibians	Acute oral toxicity	Bobwhite quail	Single oral dose	LD_{50} >2250 mg/kg-bw	Mortality* (416096-04/ Acceptable)	Practically non-toxic
	Acute dietary toxicity	Bobwhite quail and Mallard duck	8 days	LC_{50} >5620 mg/kg/-diet	Mortality* (416096-05, 416096-06/ Acceptable)	
Survival and Reproduction of Terrestrial Mammals	Acute oral toxicity, LD_{50}	Rat	Single oral dose	LD_{50} >5000 mg/kg-bw	Mortality* (00063574/ Acceptable)	Practically non-toxic
	Dermal toxicity, LD_{50}	Rat	Not available	LD_{50} >5000 mg/kg-bw	Mortality* (00063574/ Acceptable)	
	Inhalation toxicity, LC_{50}	Rat	Not available	LC_{50} >1.18 mg/L	Mortality* (421464-01/ Acceptable)	
	Reproduction NOAEL	Rat	Two – generation	25 mg/kg/day	Mortality* (161842/ Acceptable)	
Survival of Terrestrial Invertebrates and Beneficial Insects	Contact LD_{50} (µg/bee)	Honey bee (*Apis mellifera*)	48 hours	LD_{50} 0.155 µg/bee	Mortality (416096-13/ Acceptable)	Highly Toxic
	Foliar residue toxicity (honey bee)	Honey bee (*Apis mellifera*)	24 hours post treatment	< 3 hours post treatment	Mortality (419408-01/ Acceptable)	

*None observed at the highest dose

Birds and Mammals

Non-target terrestrial animals are not likely to be subject to mortality from the use of tetramethrin because it is practically non-toxic to birds and mammals on an acute exposure basis.

The limitation of outdoor applications to spot treatments and the non-persistent nature of tetramethrin make it unlikely that exposure sufficient to cause the chronic effects seen in laboratory studies would occur in the field. The Agency's conceptual model for assessing risk to terrestrial animals assumes that the animals derive the entirety of their diet from treated feed items. The use of tetramethrin as a spot treatment in residential and/or commercial settings is unlikely to result in extensive treatment of potential feed items. In addition, although chronic toxicity studies are not designed to determine how long an exposure is necessary to cause adverse chronic effects, the quick degradation of tetramethrin would reduce the amount of time that toxic residues are available for potential dietary exposure.

Given that tetramethrin is an insecticide, it is considered highly toxic to invertebrates, including beneficial insects, such as honey bees, on an acute contact exposure basis. Non-target invertebrates present at the time of spraying and shortly thereafter are considered to be at risk of acute effects.

Terrestrial Plants

Toxicity data are not available for terrestrial plants. Therefore, the potential for risk to terrestrial plants from exposure to tetramethrin cannot be assessed, and remains an uncertainty. The Agency believes there is a low likelihood of exposure to non-target terrestrial plants because outdoor applications are limited to spot treatments, and therefore, is not requiring additional toxicity data at this time. The Agency, however, may reevaluate the need for this data during registration review, which is scheduled to being in 2012.

b. Aquatic Organisms

No aquatic exposure modeling was conducted for tetramethrin because exposure of non-target organisms to harmful levels is unlikely based on the localized use patterns, low total pounds used on a national basis, and rapid degradation due to photolysis and hydrolysis. Also, the aquatic exposure models assume that the chemical is applied to a ten-acre watershed draining to a one-acre pond, which is unlikely for current use scenarios for tetramethrin. Instead, the Agency conducted a qualitative assessment using submitted studies and review of the literature.

The Agency developed an effects characterization, which describes the potential effects a pesticide can produce in an aquatic organism, and is based on registrant-submitted studies that describe acute effects for various aquatic animals. Table 10 summarizes the toxic effects and reference values used to assess risks for tetramethrin to aquatic organisms.

Table 10. Summary of Specific Measurement Endpoint Values Selected to Evaluate Risk for the Associated Terrestrial Animal Assessment Endpoints

Assessment Ends	Acute Measurement Endpoint (most sensitive)	Selected Measurement Endpoint Values and Source				
		Species	Study Duration	Toxicity Value	Most Sensitive Endpoint (MRID)	Acute Toxicity Classification
Survival and Reproduction of Freshwater Vertebrates (fishes, etc.)	Freshwater fish or amphibian LC_{50}	Rainbow trout (*Oncorhynchus mykiss)*	96 hr LC_{50}	3.7 ppb	Mortality (416096-08/ Acceptable)	Very Highly Toxic
Survival and Reproduction of Freshwater Invertebrates	Freshwater invertebrates	Water flea (*Daphnia magna)*	48 hr EC_{50} flow-through	45 ppb	Immobilization and mortality (416096-09/ Supplemental)	Very Highly Toxic

Freshwater and Estuarine/Marine Fish and Invertebrates

The acute toxicity of tetramethrin was tested in two species of freshwater fish (rainbow trout and bluegill sunfish) and one freshwater invertebrate. Based on submitted studies,

tetramethrin is classified as very highly toxic to fish and invertebrates on an acute exposure basis. No chronic toxicity data were available for freshwater fish or invertebrates. However, the limitation of outdoor applications to spot treatments and the non-persistent nature of tetramethrin make it unlikely that exposure sufficient to cause the chronic effects would occur. The use of tetramethrin as a spot treatment in residential and/or commercial settings is unlikely to result in spray drift or run-off activities that would lead to exposure to non-target aquatic organisms. In addition, although chronic toxicity studies are not designed to determine how long an exposure is necessary to cause adverse chronic effects, the quick degradation of tetramethrin would reduce the amount of time that toxic residues are available for potential dietary exposure.

Additionally, no acute or chronic toxicity data were available for estuarine/marine fish or invertebrates. The Agency is not requesting this toxicity data for estuarine/marine fish or invertebrates because the outdoor uses of tetramethrin should not pose an acute risk to aquatic animals (fish, aquatic-phase amphibians, and invertebrates) since exposure levels are not expected to reach thresholds where adverse effects would be likely for such uses. Additionally, based on the rapid photolytic and hydrolytic degradation of tetramethrin, and its demonstrated rapid dissipation in field studies, the exposure duration is not expected to be sufficient to cause reproductive effects. There are potential acute risks to non-target aquatic organisms from direct application to drainage systems, but only in acidic waters where hydrolysis is slower. This remains an uncertainly in the risk assessment; however, the Agency believes exposure is unlikely because product labels prohibit direct application to water.

Aquatic Plants

Toxicity data are lacking for vascular and nonvascular aquatic plants. However, tetramethrin is not expected to reach water bodies in sufficient concentrations to induce phytotoxic effects in aquatic plants. Runoff exposure is not expected due to very short photolysis, hydrolysis, and field dissipation half-lives. Spray drift exposure is expected to be minimal based on use patterns and label restrictions. Therefore, the Agency is not requiring additional toxicity data at this time. The Agency, however, may reevaluate the need for this data during registration review, which is scheduled to being in 2012.

c. Data Gaps

As stated above, the Agency does not have chronic toxicity data for either terrestrial or aquatic organisms, acute or chronic toxicity data for terrestrial or aquatic plants, nor acute toxicity data for are estuarine/marine animals. Although these data are guideline requirements, the available effects data, non-persistent nature of tetramethrin, and low potential for environmental exposure indicate this data would not affect the outcome of the risk assessment. No additional environmental fate studies are needed to complete this assessment.

3. Adverse Ecological Incidents

A search of the EIIS (Environmental Incident Information System) database for ecological incidents (run on Dec. 2, 2005) identified no ecological incidents involving

tetramethrin. The number of documented incidents in EIIS is believed to be a very small fraction of total mortality caused by pesticides for a variety of reasons. An absence of reports does not necessarily equate to an absence of incidents given the nature of the incident reporting.

4. Endangered Species Considerations

Table 11 provides a matrix that depicts the potential for direct and indirect effects to listed species resulting from the use of tetramethrin. No direct or indirect effects to endangered species are expected, except the potential for direct effects for Listed insects or indirect effects to plants if they have an obligate relationship with a Listed insect pollinator.

Table 11. Listed Species Associated With Direct or Indirect Effects Due to Applications of Tetramethrin for all Outdoor Uses

Listed Taxon	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots	None (1)	Possible (2)
Terrestrial and semi-aquatic plants - dicots	None (1)	Possible (2)
Insects	Yes (acute)	None
Birds	None (3)	None (4)
Terrestrial phase amphibians	None (3)	None (4)
Reptiles	None (3)	None (4)
Mammals	None (5)	None (4)
Aquatic vascular plants	None (1)	None
Freshwater fish	None (6)	None (4)
Aquatic phase amphibians	None (6)	None (4)
Freshwater crustaceans	None (6)	None (4)
Mollusks	None (6)	None (4)
Marine/estuarine fish	None (6)	None (4)
Marine/estuarine crustaceans	None (6)	None (4)

(1) Direct effects to plants are not anticipated based on lack of incident reports, registration on ornamental plants, and no identified mechanism of toxicity.
(2) Indirect Effects on plants are possible if they have an obligate relationship with a Listed insect pollinator.
(3) Direct Effects are considered unlikely due to low toxicity to birds and low exposure.
(4) Indirect effects via loss of prey base (insects and invertebrates) not likely due to low magnitude of effect.
(5) Direct effects are considered unlikely due to low toxicity to mammals and low exposure.
(6) Direct Effects are not anticipated due to low exposure, despite high toxicity to freshwater fish and invertebrates.

Specific levels of concern could not be evaluated for the supported use of tetramethrin because risk quotients (RQs) were not calculated in this assessment. However, acute risks from tetramethrin's outdoor uses to listed aquatic species are not expected due to low application rates, the localized and spatially fragmented use patterns, and rapid dissipation of the chemical stressor due to photolysis and hydrolysis.

In terrestrial environments, vertebrates such as mammals, birds, reptiles and amphibians are not expected to be at risk because tetramethrin is practically non-toxic to birds and mammals, and because of the localized and fragmented use patterns. Insects, if directly exposed, are at risk of mortality.

The potential for chronic risk to any listed animal cannot be dismissed at this time because of a lack of available data. However, tetramethrin is not expected to persist long enough to lead to chronic exposure.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

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 the active ingredient tetramethrin. 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 tetramethrin.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing the tetramethrin. The Agency has determined that tetramethrin-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of the tetramethrin 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 tetramethrin, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of tetramethrin, the Agency has determined that products containing tetramethrin, 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 label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of tetramethrin. If all changes outlined in this document are incorporated into the product labels, then all current risks for tetramethrin will be adequately mitigated for the purposes of this determination under FIFRA.

B. Public Participation

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for tetramethrin. EPA released the tetramethrin preliminary risk assessments for public comment on February 27, 2008, 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 April 28, 2008, the Agency received comments from: the registrant McLaughlin, Gormley, King Company; the California Regional Water Quality Control Board, S.F. Bay Region; the California Stormwater Quality Association (CASQA); California Tri-TAC; as well as from 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-2008-0014) at http:www.regulations.gov.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that products containing tetramethrin are eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of tetramethrin. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V. Maximum application rates eligible for reregistration are set forth in Appendix A.

a. Human Health Risk Management

There are no human health risks of concern for tetramethrin, and therefore, no risk mitigation is necessary. The personal protective equipment (PPE) for all occupational handlers is baseline (long-sleeve shirt, long pants, and shoes plus socks), and the re-entry interval (REI) is 12 hours.

b. Ecological Risk Management

The Agency evaluated potential ecological risk from both indoor and outdoor uses of tetramethrin. However, although the Agency believes exposure to non-target organisms is unlikely, tetramethrin is considered highly toxic to aquatic organisms. Therefore, the Agency is requiring the following label statements to reduce the potential exposure of tetramethrin to aquatic organisms as stipulated in the Label Table, Table 12. Because outdoor uses will be limited to localized spot treatments, no additional mitigation measures, beyond those specified below, are required.

- Incorporation of PR Notice 2008-1, "Environmental Hazard General Labeling Statements on Outdoor Residential Use Products" on appropriate outdoor non-agricultural end-use products.

- Products labeled for General Outdoor Surface and Space Sprays (except outdoor fogging devices):

  "All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:
  - Treatment to soil or vegetation around structures;
  - Applications to building foundations up to a maximum height of 3 feet.

  Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to spot treatments or crack-and-crevice applications, only."

- Products labeled for use around or near floor drains must contain the following statement:

  "Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application."

- Products labeled for use in drains or sewers must contain the following statement:

"Do not apply directly to sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur, except as directed by this label."

2. Endocrine Disruptor Screening Program

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Tetramethrin is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all registration review cases, including those for which EPA has already opened a registration review docket for a pesticide active ingredient. The tetramethrin registration review docket is currently scheduled to open in 2012.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

3. 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 tetramethrin "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

No direct or indirect effects to endangered species are expected due to tetramethrin applications, except the potential for direct effects for Listed insects or indirect effects to plants if they have an obligate relationship with a Listed insect pollinator. 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 tetramethrin 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.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing tetramethrin. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that products containing tetramethrin are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific 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. Additionally, below are the label amendments that the Agency intends to require for tetramethrin to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of tetramethrin for currently registered uses has been reviewed and determined to be substantially complete. However, a few data gaps remain, and these are listed below.

Product Chemistry
All product chemistry data requirements will be required for the technical grade active ingredient (see Appendix B).

Toxicology

830.7050	UV / Visible Absorption
870.1300	Acute Inhalation
870.2500	Acute Dermal Irritation
870.2600	Skin Sensitization
870.3700a	Developmental Toxicity (rodent)
870.6200a	Acute Neurotoxicity
870.6200b	Subchronic Neurotoxicity study
870.6300	Developmental Neurotoxicity study[2]
870.7800	Immunotoxicity

2. Labeling for Manufacturing-Use Products

[2] Based on the Agency's review of existing pyrethroid data, EPA has come to the conclusion that the DNT is not a particularly sensitive study for comparing the sensitivity of young and adult animals to pyrethroids. EPA has recently determined that, as an alternative to the generation and submission of a new DNT study, pyrethroid registrants may instead choose to cite the six previously submitted DNT studies for pyrethroid pesticides. The Agency is also investigating the need for additional experimentation, specific to the mode of action and pharmacokinetic characteristics of pyrethroids, to evaluate the potential for increased susceptibility of young organisms. These conclusions and determinations were communicated to registrants of some pyrethroid active ingredients in a letter from EPA dated September 4, 2009 (available from the public docket EPA-HQ-OPP-2008-0331-0027). Further details are also available from the website http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the label statements contained in Table 12.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria, and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrant's Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Karen Jones at (703) 308-8047.

In addition to the standard product-specific data requirements, efficacy data for all applications that target public health pests must be submitted. Additional information on the efficacy data can be found in the Series 810 Product Performance Test Guidelines on the Agency's website (http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/ 810_Product_Performance_Test_Guidelines/index. html).

Efficacy Data

810.3000	General considerations for efficacy of invertebrate control agents
810.3100	Soil treatments for imported fire ants
810.3200	Livestock, poultry, fur- and woo-bearing animal treatment
810.3300	Treatments to control pests of humans and pets
810.3400	Mosquito, black fly, and biting midge (sand fly) treatments
810.3500	Premises treatments
SS	Special study for arthropods

The Agency is also requiring a companion animal study (870.7200) for tetramethrin 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.

870.7200	Companion animal study

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 12. 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

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 12 describes how language on the labels should be amended.

Table 12. Summary of Labeling Changes for Tetramethrin

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
Maximum application rates eligible for reregistration are set forth in Appendix A.		
For Manufacturing Use Products that will be formulated into total release fogger end-use products that contain directions for use indoors	**If information is available that justifies a duration longer than 2 hours for the waiting period before beginning ventilation following an application or a duration longer than 2 hours as the length of the ventilation period, submit that information to the Agency.**	Directions for use
For all Manufacturing Use Products	"Only for formulation into an ***insecticide*** for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "This pesticide is highly toxic to aquatic organisms, including fish and aquatic 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 Eliminations 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	Precautionary Statements: Environmental Hazards

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	Water Board or Regional Office of the Environmental Protection Agency."	
End-Use Products Intended for Occupational Use (WPS and Non-WPS)		
Maximum application rates eligible for reregistration are set forth in Appendix A.		
PPE Requirements for Ready To Use (RTU) Formulations (RTU Liquids and Pressurized Liquids)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]." For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart. "Applicators and other handlers must wear: > Long-sleeve shirt and long pants, and > Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Liquid Concentrates including Emulsifiable Concentrates	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]." For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart. "Mixers, Loaders, Applicators and other handlers must wear: > Long-sleeve shirt and long pants, and > Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE immediately if pesticide gets inside,	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	
Environmental Hazards Statements for Outdoor Aerosols and Foggers AND Outdoor Products Registered **Only** for Commercial Use Sites (eg. golf-courses).	"ENVIRONMENTAL HAZARDS" "This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate." "This product 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 area."	Precautionary Statements: Hazards to Humans and Domestic Animals
Environmental Hazard Statements on Liquid Concentrate **consumer** outdoor products (e.g., liquids mixed with water by the user for a tank sprayer or hose-end attachment)	"This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems. 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."	Environmental Hazard Statement
Environmental Hazard Statements on Liquid Ready-to-Use (except aerosols and foggers) **consumer** outdoor products	"This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this	Environmental Hazard Statement

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. 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."	
Environmental Hazards Statements for Products Labeled for Indoor Uses Only	"ENVIRONMENTAL HAZARDS" "This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor commercial, industrial or institutional products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
Environmental Hazards Statements for Products Labeled for Both Indoor and Outdoor Uses Only	"ENVIRONMENTAL HAZARDS for TERRESTRIAL APPLICATIONS" Refer to appropriate consumer outdoor environmental hazard statements above. "ENVIRONMENTAL HAZARDS for INDOOR USE" "This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor commercial, industrial or institutional products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements: Hazards to Humans and Domestic Animals
Restricted-Entry Interval for Products with Directions for use within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) *For Products Subject to WPS as required by Supplement 3 of PR Notice 93-7*	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, in the Agricultural Use Requirements Box

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
Early Entry Personal Protective Equipment *For Products Subject to WPS as required by Supplement 3 of PR Notice 93-7*	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is coveralls, shoes and socks, and waterproof gloves."	Directions for Use, in Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Do not apply when food is present." "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."	Place in the Directions for Use directly above the Agricultural Use Box
Entry Restrictions for NonWPS Uses	**For products that do not contain directions for use that allow people to be present during application:** "Do not enter or allow others to enter treated area until sprays have dried." **For products that contain directions for use that allow people to be present during application AND are labeled for use as a directed spray (does not apply to products applied directly to domestic animals):** "Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter treated area until sprays have dried." **For products that contain directions for use that allow people to be present during application AND are labeled for use as a space spray:**	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.

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	"Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated." **For total release foggers (TRF) labeled for indoor use (see additional requirements in TRF section below):** "Wait at least two (2) hours after application, then open windows, vents and doors for two more hours. If an odor is still detected additional ventilation is required."	
General Application Restrictions for all products that do not contain directions for use in drains or sewers	**Products labeled for use around or near floor drains must contain the following statement.** "Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application."	Directions for Use
General Application Restrictions for all products that contain directions for use in drains or sewers	"Do not apply directly to sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur, except as directed by this label."	Directions for Use
General Application Restrictions for Total Release Foggers (TRF) labeled for indoor use	Note to registrants: The following labeling was sent to pyrethrins and pyrethroid registrants on March 23, 2010. The following label statements are required to appear on TRF EUPs, except where manufacturers can satisfactorily explain to the Agency that an alternative approach would be adequate to address the causes of bug bomb exposure incidents. Use simple terms to express the volume of space treated in terms of linear dimensions, with an assumed ceiling height, rather than in terms of cubic feet. Update the current statements to follow this model in the Directions for Use: Example: "One canister of fogger will treat a room up to x feet by y feet with an 8 foot ceiling."	Directions for Use

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	All current restrictions and requirements regarding the size of the treated area remain unchanged. At a minimum include pictograms, where applicable, to illustrate the following list of restrictions and directions for use: • do not use multiple canisters in a room • do not use in small confined areas • turn off ignition sources • remove or cover exposed food • air out the room before entering Include the following directions that prohibit use in closed, confined spaces: • "Do not use in small, enclosed spaces such as closets, cabinets or under counters or tables. Use of a fogger in an enclosed space may cause the product to explode, resulting in injury to people or damage to property." Include prominent headings using different font size or style (e.g., bold) in the directions, such as: • To Use This Product Correctly [before the standard language about small spaces and ignition sources] • Before you fog [cover food, remove pets, etc] • To Start Fogging [how to set up and activate] • Airing Out [how long] Include the following phrase in a prominent place in the directions and in boldface type: • "Vacate the treated house, individual apartment unit, or other structure immediately" In addition to the standard Precautionary Statements, add the following language to the Precautionary Statements section of the label: • "Breathing spray mist may be harmful."	

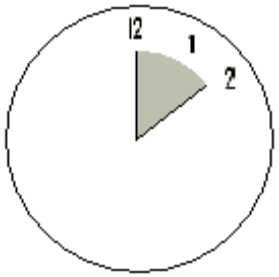
Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	Include the following statement in bold font in the Directions for Use: • "Does not control bed bugs" Include the phrase "Do Not Re-enter for X Hours" in a prominent place in the directions and in boldface type. Include a clock face pictogram shading the entry restriction immediately above or below this direction. Example:  Provide door knob hang tags at the point-of-sale with a space for customers to write-in when the entry restricted time has expired. • For example, the text on the hang tag could state: "Do not enter until [space for time] on [space for date]." Add the following statement to tell others of the treatment: • "Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for X hours." Include label statements in both English and Spanish on all indoor total release fogger product labels. Verify that the Spanish language text is a true and accurate translation of the English text and submit verification	

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	statement to EPA. Include both language versions of the labeling on the product container. Note: EPA is working to develop more general guidance for non-English pesticide labeling. If companies are interested in substituting a different language on product labels, in place of Spanish, please submit a rationale for such substitution along with the alternate label language.	
Additional Application Restrictions For Outdoor Residential Use	**Products labeled for General Outdoor Surface and Space Sprays (except outdoor fogging devices):** "All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: (1) Treatment to soil or vegetation around structures; (2) Applications to building foundations, up to a maximum height of 3 feet. Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to spot and crack-and-crevice applications, only." Note to registrant: If the end use product does not contain directions for use consistent with the exceptions above the exceptions may be eliminated from the label. **Requirements for Granular Formulations labeled or intended for outdoor residential uses:** "Apply this product directly to the lawn or garden area. Water treated area as directed on this label. Do not water to the point of run-off." "Do not make applications during rain." **Requirements for Liquid, Dust, and Ready to Use Formulations products labeled or intended for outdoor residential uses:**	Directions for Use under General Precautions and Restrictions

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	"Do not water the treated area to the point of run-off." "Do not make applications during rain."	
End Use Products Primarily Used by Consumers/Homeowners		
Maximum application rates eligible for reregistration are set forth in Appendix A.		
Environmental Hazards Statements for Outdoor Aerosols (including TRF) AND Outdoor Products Registered **Only** for Commercial Use Sites (eg. golf-courses).	"ENVIRONMENTAL HAZARDS" "This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate." "This product 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 area."	Precautionary Statements: Hazards to Humans and Domestic Animals
Environmental Hazard Statements on Liquid Concentrate **consumer** outdoor products (e.g., liquids mixed with water by the user for a tank sprayer or hose-end attachment)	"This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems. 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."	Environmental Hazard Statement
Environmental Hazard Statements on Liquid Ready-to-Use (except aerosols, including TRF) **consumer** outdoor products	"This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the	Environmental Hazard Statement

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. 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."	
Environmental Hazards Statements for Products Labeled for Indoor Uses Only	"ENVIRONMENTAL HAZARDS" "This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor commercial, industrial or institutional products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements: Hazards to Humans and Domestic Animals
Environmental Hazards Statements for Products Labeled for Both Indoor and Outdoor Uses Only	"ENVIRONMENTAL HAZARDS for TERRESTRIAL APPLICATIONS" Refer to appropriate consumer outdoor environmental hazard statements above. "ENVIRONMENTAL HAZARDS for INDOOR USE" "This pesticide is extremely toxic to aquatic organisms, including fish and	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	aquatic invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor commercial, industrial or institutional products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	
Entry Restrictions for Non-WPS Uses	**For products that do not contain directions for use that allow people to be present during application:** "Do not enter or allow others to enter treated area until sprays have dried." **For products that contain directions for use that allow people to be present during application AND are labeled for use as a directed spray (does not apply to products applied directly to domestic animals):** "Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter treated area until sprays have dried." **For products that contain directions for use that allow people to be present during application AND are labeled for use as a space spray:** "Except when (insert application method or site that allows people to be present during application), do not enter or allow others to enter until	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.

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated." **For total release foggers labeled for indoor use (see additional requirements in TRF section below):** "Wait at least two (2) hours after application, then open windows, vents and doors for two more hours. If an odor is still detected additional ventilation is required."	
General Application Restrictions	"Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift."	Place at the beginning of the Direction for Use
General Application Restrictions for all products that do not contain directions for use in drains or sewers	**Products labeled for use around or near floor drains must contain the following statement.** "Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application."	Directions for Use
General Application Restrictions for all products that contain directions for use in drains or sewers	"Do not apply directly to sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur, except as directed by this label."	Directions for Use
Additional Application Restrictions For Outdoor Residential Use	**Products labeled for General Outdoor Surface and Space Sprays (except outdoor fogging devices:** "All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: (1) Treatment to soil or vegetation around structures; and, (2) Applications to building foundations, up to a maximum height of 3 feet. Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves) are limited to spot and crack-and-crevice applications, only." Note to registrant: If the end use product does not contain directions for use consistent with the exceptions above the exceptions may be eliminated	Directions for Use under General Precautions and Restrictions

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	from the label. **Requirements for Granular Formulations labeled or intended for outdoor residential uses:** "Apply this product directly to the lawn or garden area. Water treated area as directed on this label. Do not water to the point of run-off." "Do not make applications during rain." **Requirements for Liquid, Dust, and Ready to Use Formulations products labeled or intended for outdoor residential uses:** "Do not water the treated area to the point of run-off." "Do not make applications during rain."	
Application Restrictions for End Use Products containing directions for indoor use	"Do not apply when food is present. Exposed food should be covered or removed. All food preparation surfaces and utensils should be covered during treatment or thoroughly washed before use."	Directions for use, within the application restrictions area
General Application Restrictions for Total Release Foggers (TRF) labeled for indoor use	Note to registrants: The following labeling was sent to pyrethrins and pyrethroid registrants on March 23, 2010. The following label statements are required to appear on TRF EUPs, except where manufacturers can satisfactorily explain to the Agency that an alternative approach would be adequate to address the causes of bug bomb exposure incidents. Use simple terms to express the volume of space treated in terms of linear dimensions, with an assumed ceiling height, rather than in terms of cubic feet. Update the current statements to follow this model in the Directions for Use: Example: "One canister of fogger will treat a room up to x feet by y feet with an 8 foot ceiling." All current restrictions and requirements regarding the size of the	Directions for Use

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	treated area remain unchanged. At a minimum include pictograms, where applicable, to illustrate the following list of restrictions and directions for use: • do not use multiple canisters in a room • do not use in small confined areas • turn off ignition sources • remove or cover exposed food • air out the room before entering Include the following directions that prohibit use in closed, confined spaces: • "Do not use in small, enclosed spaces such as closets, cabinets or under counters or tables. Use of a fogger in an enclosed space may cause the product to explode, resulting in injury to people or damage to property." Include prominent headings using different font size or style (e.g., bold) in the directions, such as: • To Use This Product Correctly [before the standard language about small spaces and ignition sources] • Before you fog [cover food, remove pets, etc] • To Start Fogging [how to set up and activate] • Airing Out [how long] Include the following phrase in a prominent place in the directions and in boldface type: • "Vacate the treated house, individual apartment unit, or other structure immediately" In addition to the standard Precautionary Statements, add the following language to the Precautionary Statements section of the label: • "Breathing spray mist may be harmful."	

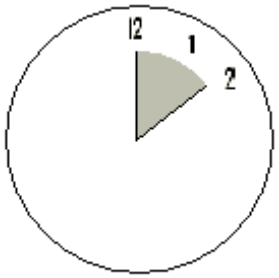
Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	Include the following statement in bold font in the Directions for Use: • "Does not control bed bugs" Include the phrase "Do Not Re-enter for X Hours" in a prominent place in the directions and in boldface type. Include a clock face pictogram shading the entry restriction immediately above or below this direction. Example:  Provide door knob hang tags at the point-of-sale with a space for customers to write-in when the entry restricted time has expired. • For example, the text on the hang tag could state: "Do not enter until [space for time] on [space for date]." Add the following statement to tell others of the treatment: • "Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for X hours." Include label statements in both English and Spanish on all indoor total release fogger product labels. Verify that the Spanish language text is a true and accurate translation of the English text and submit verification statement to EPA. Include both language versions of the labeling on the	

Table 12. Summary of Labeling Changes for Tetramethrin		
Description	**Amended Labeling Language**	**Placement on Label**
	product container. Note: EPA is working to develop more general guidance for non-English pesticide labeling. If companies are interested in substituting a different language on product labels, in place of Spanish, please submit a rationale for such substitution along with the alternate label language.	

Appendix A. Non-Food and Non-Feed Use Patterns Subject to the Reregistration of Tetramethrin

Use Profile (Application Method)	Maximum Application Rate			
	% Active Ingredient (% a.i.)	Volume-based	Area-based	Space-based
General Indoor[A] and Outdoor Spray[B] (Trigger Pump Sprays, Low Pressure Hand Wand, Back Pack Sprayer)	0.20	0.02 lb ai/gal solution	0.00002 lb ai/ft^2	0.000002 lb ai/ft^3
Aerosol Cans (Indoor & Outdoor Spray)	0.35	0.035 lb ai/gal solution	0.000035 lb ai/ft^2	0.0000035 lb ai/ft^3
Indoor Total Release Fogger[A]	0.54	n/a	n/a	6 oz can / 4,600 ft^3
Animal Treatment (Aerosol Can)	0.063	n/a	n/a	n/a
Outdoor Jet Sprays (intended for wasp and hornet use only)	0.20	1-2 sec burst	n/a	n/a
Outdoor Fogging Devices[BC]	0.10	n/a	0.0000001 lb ai/ft^2	1.25E-08 lb ai/ft^3

[A] Use sites include but are not limited to: commercial, industrial, institutional, and residential locations; agricultural structures and equipment; eating establishments; animal kennels and sleeping quarters; empty greenhouses; hospitals.

[B] Use sites include but are not limited to: commercial, industrial, institutional, and residential locations; compost piles; ornamental plants; patios; paths.

[C] Excludes RTU fogging devices.

Appendix B. Data Supporting Guideline Requirements for Tetramethrin

Data Supporting Guideline Requirements for the Reregistration of Tetramethrin		
Guideline Number	**Study Description**	**Citation(s)**
PRODUCT CHEMISTRY		
830.1550	Product Identity and Composition	Required
830.1600	Description of Materials Used	Required
830.1620	Description of Production Process	Required
830.1670	Discussion of Formation of Impurities	Required
830.1700	Preliminary Analysis	Required
830.1750	Certified Limits	Required
830.1800	Enforcement Analytical Method	Required
830.6302	Color	Required
830.6303	Physical State	Required
830.6304	Odor	Required
830.6313	Stability	Required
830.7000	pH	Required
830.7050	UV/Visible Absorption	Required
830.7200	Melting Point	Required
830.7220	Boiling Point	Required
830.7300	Density	Required
830.7370	Dissociation Constant	Required
830.7550 830.7570	Octanol / Water Partition Coefficient	Required
830.7840 830.7860	Solubility	Required
830.7950	Vapor Pressure	Required
ECOLOGICAL EFFECTS		
850.1010	Aquatic Invertebrate Acute	41609609
850.1025	Oyster Acute Toxicity Test	Data gap
850.1035	Mysid Acute Toxicity Test	Data gap
850.1045	Penaeid Acute Toxicity Test	Data gap
850.1055	Bivalve Acute Toxicity Test	Data gap
850.1075	Fish Acute Toxicity	
	Freshwater	41609608, 41609607
	Estuarine / Marine	Data gap
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	Data gap
850.1350	Aquatic Invertebrate Life Cycle (Marine)	Data gap
850.1400	Fish Early Life-Stage (Freshwater and Marine)	Data gap
850.1500	Fish Full Life-Cycle (Freshwater and Marine)	Data gap
850.1710	Oyster BCF	Data gap

Data Supporting Guideline Requirements for the Reregistration of Tetramethrin		
Guideline Number	**Study Description**	**Citation(s)**
850.1730	Fish BCF	Data gap
850.1850	Aquatic Food Chain Transfer	Data gap
850.2100	Avian Acute Oral Toxicity	41609604
850.2200	Avian Subacute Dietary Toxicity	41609605, 41609606
850.2300	Avian Reproduction Toxicity	Data gap
850.2400	Wild Mammal Toxicity	00063574, 00161842
850.3020	Honey Bee Acute Contact Toxicity	41609613
850.3030	Residues on Foliage Honeybee Toxicity	41940801
850.3040	Honeybee Feeding Toxicity Test	Data gap
850.4100	Seedling Emergence and Growth	Data gap
850.4150	Vegetative Vigor	Data gap
850.4400	Aquatic Plant Growth	Data gap
850.4500	Algal Plant Toxicity	Data gap
850.4550	Algal Plant Toxicity	Data gap
TOXICOLOGY		
870.1100	Acute Oral Toxicity	42146405
870.1200	Acute Dermal Toxicity	00063574, 40276101
870.1300	Acute Inhalation Toxicity	Required
870.2400	Acute Eye Irritation	41609611
870.2500	Acute Dermal Irritation	Required
870.2600	Skin Sensitization	Required
870.3100	90-Day Oral Toxicity in Rodents	42146404
870.3150	90-Day Oral Toxicity in Non-rodents	42146403, 41698902
870.3200	21/28 -Day Dermal Toxicity	41995004
870.3465	90-Day Inhalation Toxicity	42012101, 41995003
870.3700	Prenatal Developmental Toxicity	Required 42189202, 41995005, 00114369, 00114370
870.3800	Reproduction and Fertility Effects, 2-Generation Reproduction	00114371, 00137656, 00137658, 00161842
870.4100	Chronic Toxicity	41723301, 40009401, 40280401, 00156488, 40007501, 41723302, 42189301, 44083501
870.4200	Carcinogenicity	41723301, 40009401, 40280401, 00156488, 40007501, 41723302
870.4300	Combined Chronic Toxicity/Carcinogenicity	00158951, 40276301, 44096001
870.5265	Gene Mutation (Ames assay)	40276001, 40275801
870.5385	Bone Marrow Chromosomal Aberration Test	40275901, 42414401, 42414402, 42414403
870.5550	Unscheduled DNA Synthesis in mammalian cells in culture	40778401, 40275801
870.6200	Neurotoxicity Screening battery	
(a)	Acute Neurotoxicity	Required 42601501, 42601502, 43152701
(b)	Subchronic Neurotoxicity	Required

Data Supporting Guideline Requirements for the Reregistration of Tetramethrin		
Guideline Number	**Study Description**	**Citation(s)**
870.6300	Developmental Neurotoxicity Study	Required
870.7485	Metabolism and Pharmacokinetics	42448901, 42448902
	Special Study – motor activity in male and female mice post-natally exposed by inhalation	44222801
ENVIRONMENTAL FATE		
835.1230	Leaching and Adsorption / Desorption	41995007, 42212901
835.1410	Laboratory Volatility	Data gap
835.2120	Hydrolysis	41995006
835.2240	Photodegradation in Water	00164634, 43773401
835.2370	Photodegradation in Air	Data gap
835.2410	Photodegradation on Soil	Data gap
835.4100	Aerobic Soil Metabolism	42563301
835.4200	Anaerobic Soil Metabolism	Data gap
835.4300	Aerobic Aquatic Metabolism	Data gap
835.4400	Anaerobic Aquatic Metabolism	Data gap
835.6100	Terrestrial Field Dissipation	42622401, 42622402
835.6200	Aquatic (Sediment) Dissipation	Data gap
835.6400	Combination and Tank Mixes Dissipation	Data gap
835.7100	Ground Water Monitoring	Data gap
835.8100	Field Volatility	Data gap

Appendix C. Technical Support Documents

Additional documentation in support of the Tetramethrin RED is maintained in the OPP Regulatory Public Docket, located in Room S-4400 One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP Docket room or viewed and/or downloaded via the Internet at http://www.regulations.gov. The Agency's documents in support of this RED include the following:

1. Daiss, B. Tetramethrin Health Effects Division's Risk Assessment for Reregistration Eligibility Decision. June 18, 2008.

2. Crowley, M. Tetramethrin: Phase IV Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision. June 13, 2008.

3. Eckel, W. et al. Revised Environmental Fate and Ecological Risk Assessment for the Re-registration Eligibility Decision on Tetramethrin. February 5, 2008.

4. Abdel-Saheb, I. Revised Drinking Water Assessment for Tetramethrin Use as a Rapid Knockdown Agent Against Flying and Crawling Insects. February 5, 2008.

5. Crowley, M. HED Review of "Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Supplemental Assessment for Indoor Space Spray" (EPA MRID 47713101). April 27, 2009.

6. Daiss, B. Tetramethrin: Benchmark Dose Analysis of Toxicity Endpoint for Incidental Oral Exposure. January 6, 2010.

7. Crowley, M. HED Review of "Evaluation of Potential Human Health Risks Associated with Residential Uses of Tetramethrin: Revised Supplemental – Short-Term Oral Benchmark Dose Analysis" (EPA MRID 47921601). February 25, 2010.

Appendix D. Bibliography

In addition to the studies listed in Appendix B, this bibliography contains additional citations considered to be part of the database supporting the reregistration decision for Tetramethrin.

In addition to the MRID study references listed in Appendix B, this bibliography contains the expanded study citations as well as additional literature considered to be part of the database supporting the reregistration decision for Tetramethrin.

MRID	Citation Reference
63574	Miyamoto, J.; Kadota, T.; Kohda, H. (1977) Acute Oral and Dermal Toxicities of Neopynamin in Mice and Rats. (Unpublished study received Apr 21, 1978 under 10308-1; prepared by Sumitomo Chemi- cal Co., Ltd., Japan, submitted by Sumitomo Chemical Co., Ltd., Baltimore, Md.; CDL:233835-A)
114369	Sato, T.; Narama, K. (1982) Reproduction Test of Neopynamin: Part 2. Teratology Study in Rats: Doc. Code IT-01-0076. (Transla- tion; unpublished study received Sep 20, 1982 under 10308-1; prepared by Sumitomo Chemical Co., Ltd., Japan, submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:248342-B)
114370	Sato, T.; Narama, K. (1982) Reproduction Test of Neopynamin: Part 3. Teratology Study in Rabbits: Doc. Code IT-01-0077. (Transla- tion; unpublished study received Sep 20, 1982 under 10308-1; prepared by Sumitomo Chemical Co., Ltd., Japan, submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:248342-C)
114371	Sato, T.; Tagawa, G.; Narama, K. (1982) Reproduction Test of Neo- pynamin: Part 4. Perinatal and Postnatal Study in Rats: Doc. Code IT-01-0078. (Translation; unpublished study received Sep 20, 1982 under 10308-1; prepared by Sumitomo Chemical Co., Ltd., Japan, submitted by Sumitomo Chemical Co., Ltd., Balti- more, MD; CDL:248342-D)
131413	Gabriel, K. (1981) Guinea Pig Contact Dermal Irritation/Sensitization--Buehler Method: TL-2252: Project No. 81-2354A. (Unpublished study received Sep 19, 1983 under 1021-1492; prepared by Biosearch, Inc., submitted by McLaughlin Gormley King Co., Minneapolis, MN; CDL:251313-E)
137656	Hazleton Laboratories America, Inc. (1980) One-generation Reproduc- tion Study--Rats: Neo-Pynamin: Individual Animal Data: Project No. 343-106; IT-01-0081. (Unpublished study received Apr 30, 1982 under 10308-1; submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:247530-A)
137658	Rutter, H. (1974) One-generation Reproduction Study--Rats: Neo-Pyn- amin: Project No. 343-106; IT-41-0042. Final rept. (Unpub- lished study received Apr 30, 1982 under 10308-1; prepared by Hazleton Laboratories, Inc., submitted by Sumitomo Chemical Co., Ltd., Baltimore, MD; CDL:247530-C)
156488	Pence, D. (1986) Chronic Toxicity Study in Rats: Neopynamin Technical: Addendum to Final Report: Project No. 343-117. Unpublished study prepared by Hazleton Laboratories America, Inc. 575 p.
158951	Cox, R. (1986) Combined Chronic Toxicity and Oncogenicity Study in Mice: Neopynamin: Final Report: Project No. 343-136. Unpublish- ed study prepared by Hazleton Laboratories America, Inc. 4980 p.

MRID	Citation Reference
161842	Pence, D.; Wolfe, G.; Kulwich, B. (1986) Two-generation Reproduction Study in Rats: Neopynamin Forte: Final Report: Project No. 343-147. Unpublished study prepared by Hazleton Labo- ratories America, Inc. 418 p.
164634	Chen, Y.; Casida, J. (1970) Photodecomposition of pyrethrin I, allethrin, phthalthrin, and dimethrin modifications in the acid moiety. Pyrethum Post 10(3):7-16.
40007501	Cox, R. (1986) Chronic Toxicity Study in Rats, Neopynamin Techni- cal: Addendum III to Final Report: Hazleton Project No. 343-117. Unpublished study prepared by Hazleton Laboratories America, Inc. 7 p.
40009401	Cox, R. (1986) Two-year Dietary Administration in the Rat: Neo Pynamin: Addendum 1: Final Report: Project No.: 343-107. Unpub- lished study prepared by Hazleton Laboratories America, Inc. 831 p.
40275701	Suzuki, H.; Miyamoto, J. (1975) Mutagenicity of Some Synthetic Pyrethroids in Bacterial Test System: Laboratory Project ID: ET-50-0024. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 14 p.
40275801	Ding, C.; Yu, Y.; Zhang, J.; et al. (1985) Genotoxicity of tetramethrin in mammalian cells and salmonella typhimuriam. Journal of the Zhejiang Univ. of Medicine 14(1):1-4.
40275901	Kogiso, S.; Hara, M.; Yoshitake, A.; et al. (1986) In vivo Chromo- somal Aberration Test of Neopynamin in Mouse Bone Marrow Cells: Laboratory Project ID: IT-60-0197. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 12 p.
40276001	Kogiso, S.; Yamada, F.; Hara, M.; et al. (1987) Reverse Mutation Test of Neopynamin in Salmonella typhimurium and Escherichia coli: Lab Project No.: IT-70-0205. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 18 p.
40276101	Suzuki, T.; Sako, H.; Okuno, Y.; et al. (1987) Acute Dermal Toxicity of Neopynamin in Rabbits: Lab Project No.: IT-70-0207. Unpublished study prepared by Takarazuka Research Center. 17 p.
40276301	Cox, R. (1987) Combined Chronic Toxicity and Oncogenicity Study in Mice: Neopynamin Technical: Amendment to Final Report (IT-71- 0210). Unpublished study prepared by Hazleton Laboratories America, Inc. 1487 p.
40280401	Cox, R.; Jones, S. (1987) Historical Control Data for Liver Adenoma Incidence among Mice, and Supporting Information: Hazleton Product No. 343-107. Unpublished study prepared by Hazleton Laboratories America, Inc. 53 p.
40778401	Kogiso, S. (1988) In vitro Unscheduled DNA Synthesis (UDS) Assay of Neopynamine in Rat Hepatocytes: Study No. 1280. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 54 p.
41054701	Knarr, R.D. (1988) Exposure of Applicators to Propoxur During Trigger-Pump Spray Application of a Liquid Product. Unpublished study prepared by Mobay Corporation. 195 p.
41609604	Culotta, J. et al. (1990) Neo-Pynamin: An Acute Oral Toxicity Study with the Bobwhite: (IW-01-0008): Final Report: Lab Project Number: IW/01/0008. Unpublished study prepared by Sumitomo Chemical Company. 17 p.
41609605	Long, R. ; Hoxter, K. ; Smith, G. (1990) Neo-Pynamin: A Dietary LC50 Study with the Northern Bobwhite: Lab Project Number: 166/133. Unpublished study prepared by Sumitomo Chemical Company. 54 p.

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41609608	Bowman, J. ; Gormley, M. (1990) Acute Flow-Through Toxicity of Neo- Pynamin to Rainbow Trout (Oncorhynchus mykiss): Lab Project Number: IW/01/0011. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., 189 p.
41609609	Burgess, D. (1990) Acute Flow-through Toxicity of Neo-Pynamin to Daphnia magna: Lab Project Number: IW/01/0009. Unpublished Study Prepared by Analytical Bio-Chemistry Laboratories, Inc., 176 p.
41609611	Nakanishi, T. (1990) Primary Eye and Skin Irritation Tests with Neo-Pynamin in Rabbits: Lab Project Number: IT/00/0217. Unpublished study prepared by Biochemistry and Toxicology Laboratory. 20 p.
41609613	Hoxter, K. ; Smith, G. ; Jaber, M. (1990) Neo-Pynamin: An Acute Contact Toxicity Study with the Honey Bee: Lab Project Number: 1W/01/0012. Unpublished study prepared by Sumitomo Chemical Co. Ltd. 13 p.
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41723301	Cox, R. (1974) Two-Year Dietary Administration in the Rat, Part A: Final Report, Neo-Pynamin: Lab Project Number: 343-107. Unpub- lished study prepared by Technology Services Group, Inc. 262 p.
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41995004	Osheroff, M. (1991) 21-Day Dermal Toxicity Study in Rats with Neo- Pynamin: Final Report: Lab Project Number: 343/232. Unpublished study prepared by Hazleton Laboratories America, Inc. 206 p.
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41995006	Katagi, T.; Mikami, N.; Matsuo, M.; et al. (1991) Hydrolysis of Trans-Neo-Pynamin in Buffered Aqueous Solutions: Lab Project Number: HYD90001: HYD91001. Unpublished study prepared by Sumi- tomo Chemical Co., Ltd, Environmental Health Science Lab. 127 p.

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41995007	Yoshimura, J.; Mikami, N.; Matsuo, M.; et al. (1991) Adsorption and Desorption of Tetramethrin in Water-Soil Suspension Systems: Lab Project Number: ADS91001. Unpublished study prepared by Sumitomo Chemical Co., Ltd, Environ. Health Science Lab. 60 p.
42012101	Kawaguchi, S. (1991) Three-Month Inhalation Toxicity Study of Neo- Pynamin in Rats: Lab Project Number: 2189. Unpublished study prepared by Sumitomo Chem. Co. 1055 p.
42146401	Suzuki, T.; Kohda, H.; Misaki, Y.; et al. (1981) Acute and Sub- acute Inhalation Toxicity Studies of NeoPynamin Forte in Rats: Lab Project Number: IT-10-0144. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 78 p.
42146402	Hosokowa, S.; Hiromori, T.; Seki, T.; et al. (1981) Additional 6 Month Sub-chronic Toxicity Study of Neo-Pynamin Forte in Rats : Lab Project Number: IT-10-0140. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 61 p.
42146403	Hosokowa, S.; Hiromori, T.; Seki, T.; et al. (1981) Six-month Subchronic Toxicity Study of Neo-Pynamin Forte in Rats: Lab Project Number: IT-00-0139. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 97 p.
42146404	Hosokowa, S. (1982) One Month Oral Subacute Toxicity Study with Neo-Pynamin Forte in Rats: Lab Project Number: IT-20-0188. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 65 p.
42146405	Kohda, H.; Misaki, Y.; Suzuki, T. (1981) Acute Oral Subcutan- eous, Intraperitoneal and Dermal Neo-Pynamin Forte in Rats and Mice: Lab Project Number: IT-00-0086. Unpublished study pre- pared by Sumitomo Chemical Co., Ltd. 38 p.
42189202	Robinson, K.; Washer, G.; Noveroske, J. (1991) An Oral Range- Finding Teratology Study of Neo-Pynamin in the Rat: Lab Project Number: 95219. Unpublished study prepared by Bio-Research Labs., Ltd. 520 p.
42189301	Dalgard, D. (1991) Chronic Toxicity Study in Dogs with Neo- Pynamin: IT-11-0242: Lab Project Number: 343-235. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 406 p.
42212901	Yoshimura, J.; Mikami, N.; Matsuo, M.; et al. (1992) Aged Column Leaching Study of ?carbon 14|-Tetramethrin in Soil: Lab Project Number: LEA91001. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 81 p.
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42414402	Murli, H. (1992) Bone Marrow Toxicity Study for In vivo Murine Bone Marrow Cytogenetics Assay with Neo-Pynamin: Final Report: Lab Project Number: 12400-1-459IP: IT-21-0253. Unpublished study prepared by Hazleton Washington, Inc. 21 p.
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42448902	Shiba, K. (1992) Metabolism of (1RS,cis)-Tetramethrin in Rats: Lab Project Number: 2557: IM-20-0016. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 382 p.
42563301	Yoshimura, J.; Mikami, N.; Matsuo, M. (1992) Aerobic Soil Metabolism Study of (Carbon 14)-(1RS)-trans-Tetramethrin: Lab Project Number: SOI90001. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 209 p.
42601501	Robinson, K.; Benjamin, W.; Noveroske, J. (1992) An Acute Study of the Potential Effects of Orally Administered Neo-Pynamin on Behavior and Neuromorphology in Rats: Lab Project Number: 97137. Unpublished study prepared by Bio-Research Labs, Inc. 609 p.
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42622401	Ver Hey, M. (1992) A Terrestrial Field Dissipation Study with Tetramethrin (Neo-Pynamin) Applied for Control of Insects in Plants (California Field Study): Lab Project Number: SUMITOMO-1150. Unpublished study prepared by Colorado Analytical Research & Development Corp. 397 p.
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43261603	Woollen, B.; Marsh, J.; Thornley, K. (1992) Cypermethrin: Pharmacokinetics in Man Following A Single Dermal Dose: Lab Project Number: CTL/R/1077. Unpublished study prepared by Zeneca Central Toxicology Lab. 40 p.
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44083501	Walker, M. (1996) 52-Week Toxicity Study in Dogs with Neo-Pynamin: Final Report: Lab Project Number: CHV 343-249: IT-0276: 343-249. Unpublished study prepared by Corning Hazleton Inc. 456 p.
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46188602	Non-Dietary Exposure Task Force (NDETF) Study Volume 2. Post-Application Deposition Measurements for Pyrethrins & Piperonyl Butoxide Following Use of a Total Release Indoor Fogger.
46188613	NDETF Volume 13. Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation to DSS Wetted Hands Following a Single Hand Press.
46188618	NDEFT Volume 18. Measurement of Air Concentration, Dermal Exposure, and Deposition of Pyrethrin and Piperonyl Butoxide Following the Use of an Aerosol Spray.
46188623	NDETF Volume 23. Post-Application Deposition Measurements for Permethrin & Piperonyl Butoxide Following Use of a Total Release Indoor Fogger.
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Appendix E. Tetramethrin Acute Mammalian Toxicity Batching

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 3, 2008

MEMORANDUM

SUBJECT: Tetramethrin [PC Codes 069003], Acute Mammalian Toxicity Batching Appendix for Tetramethrin RED Document.

FROM: Marianne Lewis, Biologist **[sign. M.Lewis 12/3/08]**
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

TO: Monica Wait, CRM
Reregistration Branch III
Special Review and Reregistration Division (7508P)

Attached is the batching appendix for Tetramethrin. Please let me know if you have any questions regarding this document.

EPA'S BATCHING OF TETRAMETHRIN PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing TETRAMETHRIN as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to

participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Many products containing TETRAMETHRIN have been previously batched in the PBO, Pyrethrins, & MGK 264 REDs. If a TETRAMETHRIN product registration number cannot be found in the following tables, please refer to the batching appendices for PBO, Pyrethrins, & MGK 264. One hundred and thirty eight products have been found which contain TETRAMETHRIN as the active ingredient, and have not been previously batched in the PBO, Pyrethrins, & MGK 264 REDs. These products have been placed into seventeen batches and a No Batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percentage Active Ingredient
	10308-1	95.0
	73049-145	95.0
	73049-258	100.0

Batch 2	EPA Reg. No.	Percentage Active Ingredient
	270-356	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	1021-177	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	2517-76	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	9444-165	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	28293-215	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015

Batch 3	EPA Reg. No.	Percentage Active Ingredient
	192-196	Tetramethrin: 0.400 Phenothrin: 0.300

		Pyriproxyfen: 0.015
	1021-1622	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	2724-663	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	40849-55	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015
	68543-23	Tetramethrin: 0.400 Phenothrin: 0.300 Pyriproxyfen: 0.015

Batch 4	EPA Reg. No.	Percentage Active Ingredient
	4822-436	Tetramethrin: 0.50 Cypermethrin: 0.15
	9688-254	Tetramethrin: 0.10 Cypermethrin: 0.60

Batch 5	EPA Reg. No.	Percentage Active Ingredient
	769-584	Tetramethrin: 0.20 Esfenvalerate: 0.10
	9444-145	Tetramethrin: 0.20 Esfenvalerate: 0.10

Batch 6	EPA Reg. No.	Percentage Active Ingredient
	1021-1715	Tetramethrin: 0.20 Permethrin: 0.20
	8848-83	Tetramethrin: 0.20 Permethrin: 0.20

Batch 7	EPA Reg. No.	Percentage Active Ingredient
	73049-313	Tetramethrin: 0.20 Permethrin: 0.50
	73049-314	Tetramethrin: 0.10 Permethrin: 0.25
	73049-328	Tetramethrin: 0.20 Permethrin: 0.50

Batch 8	EPA Reg. No.	Percentage Active Ingredient

	73049-436	Tetramethrin: 0.10 Permethrin: 0.10
	73049-437	Tetramethrin: 0.20 Permethrin: 0.20

Batch 9	EPA Reg. No.	Percentage Active Ingredient
	2724-533	Tetramethrin: 0.40 Permethrin: 0.30
	8845-67	Tetramethrin: 0.40 Permethrin: 0.30

Batch 10	EPA Reg. No.	Percentage Active Ingredient
	192-153	Tetramethrin: 0.286 Permethrin: 0.572
	239-2535	Tetramethrin: 0.050 Permethrin: 0.100
	2724-541	Tetramethrin: 0.050 Permethrin: 0.100
	2724-547	Tetramethrin: 0.050 Permethrin: 0.100
	8845-84	Tetramethrin: 0.050 Permethrin: 0.100
	46515-21	Tetramethrin: 0.029 Permethrin: 0.057
	46515-30	Tetramethrin: 0.029 Permethrin: 0.057
		Tetramethrin: 0.40 Permethrin: 0.30

Batch 11	EPA Reg. No.	Percentage Active Ingredient
	4822-271	Tetramethrin: 0.200 Permethrin: 0.200
	4822-423	Tetramethrin: 0.119 Permethrin: 0.124
	4822-533	Tetramethrin: 0.200 Permethrin: 0.200

Batch 12	EPA Reg. No.	Percentage Active Ingredient
	1021-1780	Tetramethrin: 0.20 Phenothrin: 0.20
	1021-1806	Tetramethrin: 0.15 Permethrin: 0.15

Batch 13	EPA Reg. No.	Percentage Active Ingredient
	478-101	Tetramethrin: 0.20 Phenothrin: 0.20
	498-160	Tetramethrin: 0.20 Phenothrin: 0.20
	8845-68	Tetramethrin: 0.20 Phenothrin: 0.20
	46813-10	Tetramethrin: 0.20 Phenothrin: 0.20

Batch 14	EPA Reg. No.	Percentage Active Ingredient
	1021-1775	Tetramethrin: 0.2000 Phenothrin: 0.2000
	1021-1808	Tetramethrin: 0.2000 Phenothrin: 0.2000
	2724-540	Tetramethrin: 0.0500 Phenothrin: 0.1000
	2724-542	Tetramethrin: 0.0286 Phenothrin: 0.0572
	2724-543	Tetramethrin: 0.05 Phenothrin: 0.10
	8845-83	Tetramethrin: 0.05 Phenothrin: 0.10

Batch 15	EPA Reg. No.	Percentage Active Ingredient
	2724-536	Tetramethrin: 0.2 Phenothrin: 0.4
	5887-118	Tetramethrin: 0.2 Phenothrin: 0.4

Batch 16	EPA Reg. No.	Percentage Active Ingredient
	192-184	Tetramethrin: 0.200 Phenothrin: 0.125
	498-156	Tetramethrin: 0.200 Phenothrin: 0.125
	506-140	Tetramethrin: 0.200 Phenothrin: 0.125
	1021-1649	Tetramethrin: 0.200 Phenothrin: 0.125
	3862-127	Tetramethrin: 0.200 Phenothrin: 0.125

	4313-87	Tetramethrin: 0.200 Phenothrin: 0.125
	5887-158	Tetramethrin: 0.200 Phenothrin: 0.125
	7405-71	Tetramethrin: 0.200 Phenothrin: 0.125
	7754-44	Tetramethrin: 0.200 Phenothrin: 0.125
	9444-181	Tetramethrin: 0.200 Phenothrin: 0.125
	10806-105	Tetramethrin: 0.200 Phenothrin: 0.125
	11623-38	Tetramethrin: 0.200 Phenothrin: 0.125
	40849-52	Tetramethrin: 0.200 Phenothrin: 0.125
	44446-54	Tetramethrin: 0.200 Phenothrin: 0.125
	46515-44	Tetramethrin: 0.200 Phenothrin: 0.125
	55809-3	Tetramethrin: 0.200 Phenothrin: 0.125
	68543-8	Tetramethrin: 0.200 Phenothrin: 0.125

Batch 17	EPA Reg. No.	Percentage Active Ingredient
	192-189	Tetramethrin: 0.20 Phenothrin: 0.20
	239-2523	Tetramethrin: 0.05 Phenothrin: 0.10
	239-2524	Tetramethrin: 0.20 Phenothrin: 0.20
	239-2525	Tetramethrin: 0.25 Phenothrin: 0.15
	478-93	Tetramethrin: 0.25 Phenothrin: 0.15
	498-114	Tetramethrin: 0.20 Phenothrin: 0.19
	499-355	Tetramethrin: 0.40 Phenothrin: 0.30
	506-157	Tetramethrin: 0.20 Phenothrin: 0.20
	706-83	Tetramethrin: 0.20 Phenothrin: 0.20
	769-609	Tetramethrin: 0.25

		Phenothrin: 0.15
	1021-1587	Tetramethrin: 0.25 Phenothrin: 0.15
	1021-1588	Tetramethrin: 0.20 Phenothrin: 0.20
	1021-1667	Tetramethrin: 0.20 Phenothrin: 0.20
	1021-1862	Tetramethrin: 0.10 Phenothrin: 0.10
	2724-529	Tetramethrin: 0.25 Phenothrin: 0.20
	2724-530	Tetramethrin: 0.25 Phenothrin: 0.15
	2724-537	Tetramethrin: 0.20 Phenothrin: 0.20
	2724-545	Tetramethrin: 0.20 Phenothrin: 0.20
	2724-597	Tetramethrin: 0.25 Phenothrin: 0.15
	2724-604	Tetramethrin: 0.20 Phenothrin: 0.20
	2724-615	Tetramethrin: 0.20 Phenothrin: 0.40
	2915-59	Tetramethrin: 0.20 Phenothrin: 0.20
	5887-123	Tetramethrin: 0.20 Phenothrin: 0.19
	5887-159	Tetramethrin: 0.25 Phenothrin: 0.15
	7056-99	Tetramethrin: 0.25 Phenothrin: 0.15
	8845-63	Tetramethrin: 0.25 Phenothrin: 0.15
	8848-38	Tetramethrin: 0.20 Phenothrin: 0.20
	8848-42	Tetramethrin: 0.40 Phenothrin: 0.30
	9688-54	Tetramethrin: 0.20 Phenothrin: 0.40
	10088-116	Tetramethrin: 0.25 Phenothrin: 0.15
	10806-41	Tetramethrin: 0.25 Phenothrin: 0.14
	10807-61	Tetramethrin: 0.20 Phenothrin: 0.20
	10807-182	Tetramethrin: 0.25

		Phenothrin: 0.15
	11623-11	Tetramethrin: 0.20 Phenothrin: 0.20
	11715-82	Tetramethrin: 0.20 Phenothrin: 0.20
	28293-160	Tetramethrin: 0.40 Phenothrin: 0.30
	40849-4	Tetramethrin: 0.20 Phenothrin: 0.20
	40859-46	Tetramethrin: 0.20 Phenothrin: 0.40
	46515-40	Tetramethrin: 0.25 Phenothrin: 0.15
	46515-43	Tetramethrin: 0.20 Phenothrin: 0.20
	64240-23	Tetramethrin: 0.25 Phenothrin: 0.15

No Batch	EPA Reg. No.	Percentage Active Ingredient
	478-126	Tetramethrin: 0.2 Permethrin: 0.4
	706-109	Tetramethrin: 0.200 Phenothrin: 0.125
	769-931	Tetramethrin: 0.25 Phenothrin: 0.15
	769-938	Tetramethrin: 0.284 Resmethrin: 0.120
	769-939	Tetramethrin: 2.84 Resmethrin: 2.96
	1021-1384	80.0
	1021-1386	Tetramethrin: 8.9 Phenothrin: 8.9
	1021-1387	Tetramethrin: 12.5 Phenothrin: 7.5
	1021-1437	Tetramethrin: 8.0 Phenothrin: 16.0
	1021-1505	Tetramethrin: 12.30 Phenothrin: 9.23
	1021-1613	Tetramethrin: 0.20 Esfenvalerate: 0.03
	1021-1640	Tetramethrin: 10.00 Phenothrin: 6.26
	1021-1652	Tetramethrin: 10.01 Esfenvalerate: 1.57
	1021-1659	Tetramethrin: 8.89

		Permethrin: 8.90
	1021-1856	Tetramethrin: 0.05 Cypermethrin: 0.05
	2724-538	Tetramethrin: 12.0 Phenothrin: 3.83
	2724-599	Tetramethrin: 0.40 Phenothrin: 0.23 Butoxypolypropylene glycol: 51.92
	4822-513	Tetramethrin: 0.35 Permethrin: 0.10 Allethrin: 0.10
	4822-514	Tetramethrin: 0.3 Permethrin: 0.1
	7056-185	Tetramethrin: 0.2 Permethrin: 0.2
	10807-191	Tetramethrin: 0.2 Esfenvalerate: 0.1
	73049-233	Tetramethrin: 25.0 Resmethrin: 10.6
	73049-255	Tetramethrin: 0.250 Resmethrin: 0.106
	73049-260	Tetramethrin: 26.64 Resmethrin: 5.85
	73049-262	Tetramethrin: 0.25 Resmethrin: 0.25
	73049-264	Tetramethrin: 16.67 Resmethrin: 7.06
	73049-265	Tetramethrin: 20.84 Resmethrin: 20.84
	73049-315	Tetramethrin: 16.0 Resmethrin: 40.0
	73049-434	Tetramethrin: 10.0 Permethrin: 10.0