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Reregistration Eligibility Decision for Tau-fluvalinate

Reregistration Eligibility Decision (RED) for Tau-fluvalinate

List A

Case No. 2295

Approved by: _____

Debra Edwards, Ph.D., Director
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Date: _____

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GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
ANLA	American Nursery and Landscape Association
AR	Anticipated Residue
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC	Engineering Control
ECD	Electron Capture Detection
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GC	Gas Chromatography
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC50	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.
LD50	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
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
g/g	Micrograms Per Gram
g/L	Micrograms Per Liter
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
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NIOSH	National Institute of Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NR	Not Required

NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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Executive Summary

EPA has completed its reregistration eligibility determination and tolerance reassessment decision for the pesticide tau-fluvalinate. There is one tolerance being reassessed for tau-fluvalinate. The risk assessments, which are summarized below, are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. The Agency has determined that products containing tau-fluvalinate are eligible for reregistration provided that data and regulatory needs are addressed and labels are amended accordingly. The decision is discussed fully in this document.

Tau-fluvalinate is a broad-spectrum insecticide/miticide in the pyrethroid class of pesticides. It is registered for a single food use (beehives/honey) and several non-food uses, including ornamentals (outdoor and container-grown, greenhouse, interior plantscapes, dip for cuttings), building surfaces/perimeters, ant mounds and certain crops (carrots and brassica/cole crops) grown for seed. Tau-fluvalinate was first registered in one of its earlier forms, racemic fluvalinate, in 1983. With an estimated 11,000 pounds of active ingredient (a.i.) used per year, it has minimal domestic usage. The majority of the usage is in commercial greenhouses and on outdoor field- and container-grown ornamentals. The residential uses are very limited (approximately 600 pounds a.i. annually on spot application to ant mounds and outdoor building perimeters), and no homeowner applications are allowed. Therefore, there is little potential for residential exposure.

EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the pyrethroid class of pesticides. Although all pyrethroids interact with sodium channels, there are multiple types of sodium channels, and it is currently unknown whether they have similar effects on all channels. In addition, we do not have a clear understanding of effects on key downstream neuronal function, e.g., nerve excitability, nor do we understand how these key events interact to produce their compound-specific patterns of neurotoxicity. There is ongoing research by both the EPA's Office of Research and Development and the pyrethroid registrants to evaluate the differential biochemical and physiological actions of pyrethroids in mammals. This research is expected to be completed by 2007. When the results of this research are available, the Agency will make a determination of common mechanism of toxicity as a basis for assessing cumulative risk.

Overall Risk Summary

Tau-fluvalinate dietary risks from food and drinking water sources are low and not of concern to the Agency. Although tau-fluvalinate is labeled for use in residential areas, neither a residential handler estimate nor a residential post-application estimate was necessary, because there is little potential for exposures from these uses. For ecological risks, tau-fluvalinate exceeds the Agency level of concern (LOC) for acute and chronic risk to aquatic organisms, and exceeds the Agency LOC for chronic risk to mammals. Risk to terrestrial invertebrates may also be a concern, because tau-fluvalinate is highly toxic to bees. There is uncertainty, however, surrounding the aquatic organism toxicity values used in this assessment. Exposure concentrations in the available studies were either not measured or were inconsistent. The acute toxicity studies for all aquatic species were classified as supplemental because of the apparent

rapid decline of the test material in the static studies, most likely due to adsorption of tau-fluvalinate to the glass chambers. In addition, the chronic studies had analytical variability. The Agency intends to issue a data call in (DCI) requiring additional data to address this area of uncertainty.

Dietary Risk – Food and Drinking Water

The acute dietary risk estimates for the U.S. general population and all population subgroups are less than 6% of the acute population adjusted dose (aPAD). The Agency's level of concern (LOC) is 100% of the aPAD, and therefore, acute dietary risk estimates are below the Agency's LOC. Similarly, the chronic aggregate risk estimates for the U.S. general population and all population subgroups are less than 1% of the chronic population adjusted dose (cPAD) and, therefore, below the Agency's LOC.

Residential Risk

Although tau-fluvalinate is labeled for use in residential areas, neither a residential handler estimate nor a residential post-application estimate was necessary since there is little potential for exposure from these uses. Tau-fluvalinate may be applied, primarily by spot application, in residential areas to outdoor building surfaces/perimeters and ant mounds by commercial applicators only (i.e., no homeowner applications are permitted).

Aggregate Risk

Aggregate risk refers to the combined risk from food, drinking water, and residential and any non-occupational (if applicable) exposures. In the case of tau-fluvalinate, the aggregate risk estimates only consider combined food and drinking water exposures because no residential uses are expected to contribute to chronic or acute exposures of this chemical. The acute aggregate risk estimates for the U.S. general population and all population subgroups are less than 6% of the aPAD and, therefore, below the Agency's level of concern. Similarly, the chronic aggregate risk estimates for the U.S. general population and all population subgroups are less than 1% of the cPAD and, therefore, below the Agency's level of concern

Occupational Risk

Workers can be exposed to tau-fluvalinate through mixing, loading, applying the pesticide, or re-entering treated sites. A dermal exposure assessment was not conducted, since dermal exposure to tau-fluvalinate is expected to be largely self-limiting due to the irritation that occurs on contact with the pyrethroid pesticide. Current labels require the use of chemical resistant gloves for all applicators and handlers.

The Agency has concern for inhalation margins of exposure below 100. All inhalation margins of exposure (MOEs) for tau-fluvalinate exceed 100 for all occupational handler scenarios assessed at baseline personal protective equipment (long sleeve shirt, long pants, shoes and socks), and are therefore, not of concern.

With the exception of the greenhouse uses, post-application inhalation exposure to tau-fluvalinate is expected to be minimal. Potential post-application inhalation exposure in greenhouses will be mitigated by the ventilation requirements of the Worker Protection Standard (WPS). For these reasons, a post-application inhalation exposure assessment was not deemed necessary for tau-fluvalinate. However, to confirm that the established restricted-entry interval (REI) of 12 hours is adequate, the Agency is requiring the registrant to conduct an inhalation post-application exposure study.

Ecological Risk

The Agency has conducted a screening-level ecological and environmental risk assessment for the registered uses of tau-fluvalinate. Based on the available data, the Agency has identified potential acute and chronic risks of concern to aquatic organisms and chronic risks of concern to mammals. There is also a concern for non-target terrestrial invertebrates. The screening-level risk assessment does not indicate a risk concern for birds.

There is significant uncertainty with the risk estimations due to the uncertainty surrounding the toxicity values used in this assessment. The toxicity data for all aquatic species were classified as supplemental due to the likely adsorption of tau-fluvalinate to the glass chambers. The toxicity of tau-fluvalinate could be greater than indicated by the assessment. The Agency is requiring additional data to address this area of uncertainty.

While there are slight estimated exceedence of the LOC for some terrestrial and aquatic species, and uncertainty surrounding the aquatic organism toxicity values, the ecological risk associated with the use of tau-fluvalinate is expected to be limited based on its use pattern, amount used, and toxicity profile. The majority of the outdoor uses of tau-fluvalinate are in nurseries, which generally are not present in large contiguous acreages. Moreover, much of the use in nurseries is for containerized plants, and applications in nurseries are made by hand wand. Although the groundboom application method for tau-fluvalinate is prohibited for nurseries, the modeling the Agency uses is based on the use of a groundboom; thus, the Agency's current environmental modeling capabilities are limited in being able to quantitatively refine exposure estimates to aquatic organisms. While it is recognized that hand wand application is more targeted than the groundboom application method, resulting in less runoff and off-target drift, these differences can not be quantified. Therefore, the scenarios assessed based on the use of groundboom applications of tau-fluvalinate may over-estimate the exposure to fish and aquatic invertebrates.

Endangered Species

Based on available screening-level information for tau-fluvalinate, there is a potential concern for acute and chronic effects on listed freshwater fish and invertebrates, and for acute effects on listed estuarine/marine fish. There is also potential concern for chronic effects on listed mammals should exposure actually occur. Potential risks to listed insects can not be precluded given that tau-fluvalinate is highly toxic to honeybees (acute contact LD_{50} is 0.2 μg/bee). The Agency currently does not have data to quantify risks for tau-fluvalinate at the screening-level and can not preclude potential direct effects to plants or chronic effects to

estuarine/marine invertebrates. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

Tolerance Reassessment

There is one tolerance for tau-fluvalinate currently listed in 40 CFR §180.427 (a) for honey. Based on the available data, the established tolerance for honey will be reduced from 0.05 ppm to 0.02 ppm.

Additional Information

The RED document and technical supporting documents for tau-fluvalinate are also available to the public through EPA's electronic public docket system, EPA Dockets, under docket identification (ID) number OPP-2005-0230. In addition, the tau-fluvalinate RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

EPA intends to issue a data call in (DCI) for additional data necessary to address areas of uncertainty and to confirm the conclusions of this RED for the active ingredient tau-fluvalinate.

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals.

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

regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative/.

This document presents EPA's human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for tau-fluvalinate. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides the regulatory history and a profile of the use and usage of the chemical. Section III gives an overview of the human health and environmental effects risk assessments based on data and other information received. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary as outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The risk assessments and other supporting documents for tau-fluvalinate are available in the Public Docket, under docket number OPP-2005-0230, and on the Agency's web page, http://www.epa.gov/edockets/.

II. Chemical Overview

A. Regulatory History

Tau-fluvalinate was first registered in the United States in 1983 to Zoecon Corporation for non-food uses. In 1986, the registration was extended for use on cotton and coffee; however, these uses were subsequently rescinded. In 1990, tau-fluvalinate was the first chemical approved for use in beehives. Its continued use in apiary strips, which are placed in empty beehives, is its only currently registered food use. In 1999, a special local need (SLN) registration was supported for carrots grown for seed in California. In 2004, a second SLN registration was added for brassica/cole crops grown for seed, also in California.

Tau-fluvalinate is one form of racemic fluvalinate, which consists of four active diastereoisomers. The product was initially registered under the name "Fluvalinate," and all four diastereoisomers were used in the product formulation. Later, chemical advances altered the product to include only the two diastereoisomers found to be insecticidally active, thus rendering a "half-resolved" version. It was renamed tau-fluvalinate in 1994 to reflect this change. In 1997, the manufacturer chose to support the half-resolved technical only and did not continue to support the registration of the racemic fluvalinate.

Ownership of the active ingredient changed twice since it was first registered by Zoecon Corporation in 1983. Later that year, fluvalinate assumed new ownership under Sandoz Agro, Incorporated. In 1997, the registration was transferred to Wellmark International. Data call-ins were issued in 1991, 1995, and 1998 for aquatic toxicity data, residue and exposure data, and neurotoxicity data, respectively.

B. Chemical Identification

Common Name: Tau-fluvalinate

Trade Names: Mavrik Aquaflow®, Zoecon Apistan Strip RF-318®

Chemical Name: Cyano-(3-phenoxyphenyl)methyl *N*-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate

Chemical Class: Pyrethroid

Case Number: 2295

CAS Registry Number: 102851-06-9

OPP Chemical Code: 109302

Molecular Weight: 502.9 g/mole

Empirical Formula: $C_{26}H_{22}ClF_3N_2O_3$

Basic Manufacturer: Wellmark International

Tau-fluvalinate is viscous, yellow oil with a boiling point of 164°C. Tau-fluvalinate degrades rapidly under aerobic conditions but is persistent under anaerobic conditions. It is highly immobile, non-bioaccumulative, and non-volatile. Tau-fluvalinate has low solubility in water (12 ug/l at 20°C), and the vapor pressure is 1.0×10^{-7} torr at 25°C.

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 tau-fluvalinate eligible for reregistration is contained in Appendix A.

Type of Pesticide: Insecticide/miticide

Target Organism: Aphids, whiteflies, mites, thrips, caterpillars, beetles, mealybugs, root weevils, *Lygus* bugs, and *Varroa* mites

Mode of Action: Tau-fluvalinate is a synthetic pyrethroid that acts to inhibit sodium channel modulators. In general, the pyrethroids share similar modes of action and work by keeping open the sodium channels in neuronal membranes. Pyrethroids affect both the peripheral and central nervous systems of the insect. They initially stimulate nerve cells to produce repetitive discharges and eventually cause paralysis.

Use Sites:

Food: Empty beehives
Non-Food: Eugenia, pepper trees, greenhouses, flower and foliage cuttings, interior

landscapes, and ornamentals. Special local need (SLN) registration in CA only for carrot and brassica/cole crops grown for seed

Residential: Building perimeters and ant mounds (commercial applicators only)

Public Health: No public health uses

Use Classification: General use

Formulation Types: Flowable concentrate and impregnated strips (bee hives)

Application Methods: Tau-fluvalinate application methods include aerial (in California for the SLN uses on carrot and brassica/cole crops grown for seed), dipping, spray, fogger, and outdoor perimeter treatment. Spoon or mound drench methods are used for ant mound treatments.

Application Rates: Tau-fluvalinate is labeled for use on greenhouse (non-food) plants, outdoor and interior ornamentals, Eugenia and pepper trees, and mound drenches at 0.34 lb a.i./A. It is labeled for use on brassica/cole and carrot crops grown for seed in California at 0.15 lb a.i./A, on flower and foliage cuttings at 5.0 fl oz/100 gal (as a dip), and on building perimeters at 3 tsp/5 gal/1000 sq ft. Its use in beehives is labeled as one strip for each five combs or less in each bee chamber.

Application Timing: Applications of tau-fluvalinate to carrot and brassica/cole crops grown for seed are made at bloom. Applications to plant and flower cuttings are typically made in the fall, and to nursery stock in the spring.

D. Estimated Usage of Pesticide

Based on Agency data, the average total annual domestic usage of tau-fluvalinate is approximately 11,000 pounds active ingredient (a.i.). The predominant usage is in California, Florida, and Texas. The highest usage, in pounds a.i., is on field and container-grown ornamentals (43%), followed by commercial greenhouses (35%), apiary beehives (13%), and perimeter treatments/outside surfaces (5%). The SLN use on carrots and brassica/cole crops grown for seed in California represents approximately 2% of the tau-fluvalinate use.

III. Summary of Tau-fluvalinate Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents, and supporting information listed below and in Appendix C, were used to formulate the safety finding and regulatory decision for tau-fluvalinate. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2005-0230 and may also be accessed through the Agency's website at http://www.epa.gov/edockets/. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2005-0230. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

- *Tau-Fluvalinate Reregistration Eligibility Decision Document. Residue Chemistry Considerations,* February 22, 2005
- *Tau-Fluvalinate Reregistration Eligibility Decision. Product Chemistry Considerations,* February 22, 2005
- *Tau-fluvalinate Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision,* March 11, 2005
- *Revised, Corrected Tau-Fluvalinate. Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision Document,* July 26, 2005
- *Review of Fluvalinate Incident Reports,* March 14, 2005
- *Tau-fluvalinate: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). D321911; S. Stanton; September 29, 2005*
- *Environmental Fate and Ecological Risk Assessment for Tau-fluvalinate.* M. Corbin and P. Hurley*;* July 11, 2005
- *Tier II Estimated Environmental Concentration for the Use of Tau-fluvalinate for Apiary Uses, Carrots for Seed (24-C SLNs), Building Perimeters, Nurseries, Ornamentals, Indoor Landscapes and Honey for the Human Health Drinking Water Risk Assessment,* February 3, 2005

A. Human Health Risk Assessment

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

1. Toxicity of Tau-fluvalinate

The Agency has reviewed all human health toxicity studies submitted for tau-fluvalinate and has determined that the toxicological database is sufficient for reregistration. Further details on the toxicity of tau-fluvalinate can be found in the *Tau-fluvalinate: Revised HED Chapter of the Reregistration Eligibility Decision Document*. The residue of concern for risk assessment purposes in all commodities and drinking water consists of parent tau-fluvalinate only.

a. Toxicity Profile

Tau-fluvalinate is a pyrethroid insecticide of the type II class. Tau-fluvalinate is moderately acutely toxic, being classified in Toxicity Category II for oral toxicity and Category III for dermal toxicity. Tau-fluvalinate is not a primary irritant to either the eye (Toxicity Category III) or skin (Toxicity Category IV) and is not a dermal sensitization agent. While Category IV for skin irritation denotes mild irritation, this categorization may seem incongruous with the "pyrethroid reaction" that occurs on contact with this chemical, which will be discussed in further detail later in this document. The categorization for acute skin irritation will be revisited following receipt of product acute toxicity data in response to the product-specific data call in (PDCI). The acute toxicity profile for tau-fluvalinate is summarized in Table 1.

Table 1. Acute Toxicity Profile - Tau-fluvalinate				
Guideline No.	**Study Type**	**MRID(s) (Year)**	**Results**	**Toxicity Category**
870.1100	Acute oral - rat	0094103 (1982)	LD_{50}[a] = 282 (218-365) mg/kg -males LD_{50} = 261 (194-353) mg/kg - females.	II
870.1200	Acute dermal - rabbit	41597301 (1998)	LD_{50} > 2000 mg/kg	III
870.1300	Acute inhalation - rat	Not applicable[b]		
870.2400	Acute eye irritation -rabbit	00144622 (1984)	Slight conjunctival discharge observed one hour post instillation. Conjunctival swelling and redness noted for up to three days.	III
870.2500	Acute dermal irritation -rabbit	00144623 (1984)	Primary irritation index = 0.8 (mild or slight irritation)	IV
870.2600	Skin sensitization - guinea pig	41889714 (1990)	Not a sensitizer	Not applicable

a. The dose that can be expected to cause death in 50% of the test animals when administered by the route indicated.
b. A study is not required because tau-fluvalinate is a viscous, non-volatile liquid with a vapor pressure of less than 1×10^{-7} torr at 25°C.

b. FQPA Safety Factor Determination

The Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

The toxicology database for tau-fluvalinate is adequate for FQPA safety factor (SF) considerations and includes acceptable reproductive and developmental toxicity studies. A clear No Observed Adverse Effects Level (NOAEL) and Lowest Observed Adverse Effect Level (LOAEL) were established by the developmental rabbit study and the 2-generation reproductive study in rats. In the rat reproductive study, the fetal anomalies (tremors during lactation in both litters, decrease in pup weight in F2 generation and slightly lower litter size) were seen only at the highest dose tested (9.53/10.51 mg/kg/day for males/females), and they were observed in the presence of maternal toxicity (skin ulcerations). These effects are considered a qualitative increase in susceptibility of low concern.

Based on a review of both hazard and exposure data, the Agency has reduced the special FQPA SF to 1X. The dietary food exposure assessment utilizes conservative assumptions,

including tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assumptions, chronic exposures/risks will not be underestimated. Furthermore, the dietary drinking water assessment utilizes values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations.

c. Toxicological Endpoints for Risk Assessment

The toxicological endpoints used in the human health risk assessment for tau-fluvalinate are listed in Table 2. A 100X uncertainty factor (UF) is used to account for interspecies extrapolation and intraspecies variability (10X and 10X, respectively).

Table 2. Toxicological Doses and Endpoints for Tau-fluvalinate for Use in Human Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)	Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
Tau-fluvalinate Dietary Exposures			
Acute Dietary (general population)	NOAEL = 0.5 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF = 1X Total UF = 100X Acute RfD = 0.005 mg/kg/day	aPAD = $\frac{\text{Acute RfD}}{\text{FQPA SF}}$ aPAD = 0.005 mg/kg/day	LOAEL = 1 mg/kg/day. Clinical signs in the rat chronic feeding study coupled with a LOAEL of 2 mg/kg/day based on excessive grooming and bulging eyes in the subchronic neurotoxicity study.
Chronic Dietary (general population)	NOAEL = 0.5 mg/kg/day UF = 100X (inter and intraspecies) FQPA SF = 1X Total UF = 100X cRfD = 0.005 mg/kg/day	cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$ cPAD = 0.005 mg/kg/day	LOAEL = 1 mg/kg/day. Clinical signs in the rat chronic feeding study coupled with a LOAEL of 2 mg/kg/day based on excessive grooming and bulging eyes in the subchronic neurotoxicity study.
Tau-fluvalinate Dermal Exposures			
Dermal - all intervals	No endpoint selection. Dermal exposure should be self-limiting because of the dermal reactions resulting from contact with product. The issue of dermal exposure can be best addressed by labeling to avoid contact with skin and instructions to wash the affected area immediately following contact.		

Table 2. Toxicological Doses and Endpoints for Tau-fluvalinate for Use in Human Risk Assessments			
Exposure Scenario	**Dose, Uncertainty Factors (UFs), and Safety Factors (SFs)**	**Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)**	**Study and Toxicological Effects**
Tau-fluvalinate Inhalation Exposures			
Inhalation (Short- and Intermediate-Term)	NOAEL = 0.5 mg/kg/day UF = 100X (inter and intraspecies) Total UF = 100X 100% inhalation absorption assumed	Occupational MOE = 100	LOAEL = 1 mg/kg/day. Clinical signs in the rat chronic feeding study coupled with a LOAEL of 2 mg/kg/day based on excessive grooming and bulging eyes in the subchronic neurotoxicity study.

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

As a type II pyrethroid, tau-fluvalinate causes the "pyrethroid reaction," a specific type of dermal irritation following contact. The "pyrethroid reaction" may be one manifestation of the chemical's ability to act on nerve endings. The "pyrethroid reaction" is unlike the primary dermal irritation assessed in acute or subchronic dermal irritation studies. In humans, the pyrethroid reaction is characterized by tingling sensations and/or itching, often severe, upon contact with the chemical. Dermal exposure to tau-fluvalinate is expected to be largely self-limiting due to the "pyrethroid reaction"; therefore, no dermal toxicity endpoint was selected.

No incidental oral endpoint was selected, since there are no residential, recreational or institutional uses likely to result in incidental oral exposure to tau-fluvalinate. Cancer endpoints were not selected, since no evidence of carcinogenicity was seen in rat and mouse carcinogenicity studies with tau-fluvalinate, and the available mutagenicity/genetic toxicity data do not indicate a concern. Tau-fluvalinate may be classified as "not likely to be a human carcinogen."

2. Dietary Exposure and Risk

a. Exposure Assumptions

Acute and chronic dietary (food and drinking water) risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™), Version 2.00/2.02, and the Lifeline Model Version 2.0, which use food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The Tier 1 acute analysis assumed 100% crop treated and reassessed tolerance-level residues of 0.02 ppm in honey. Tau-fluvalinate is not registered for any other food uses.

Drinking water exposure to pesticides can occur through surface and ground water contamination. The Agency considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or monitoring data, if available and of sufficient quality, to

estimate those exposures. Tau-fluvalinate is highly immobile (K_d values between 853 and 1,708 with corresponding K_{oc} values between 110,000 and 370,000, respectively) and practically insoluble in water (2.4 ppb at 25°C), indicating a low potential for significant residues in drinking water. Nevertheless, tau-fluvalinate is registered for outdoor, non-food uses (including carrots and brassica/cole crops grown for seed, ornamentals, and building perimeters) that could potentially result in residues in surface or ground water.

Estimated drinking water concentrations (EDWCs) were incorporated in the dietary screening-level assessment using the 1 in 10 year annual peak (acute) concentration, and the 1 in 10 year annual mean (chronic) concentration, for surface water generated by the PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System).

b. Estimated Drinking Water Concentration

To estimate concentrations of tau-fluvalinate in surface water or ground water, modeling was used in the absence of surface water or ground water monitoring data. In the case of tau-fluvalinate, because higher Tier II scenarios were available for modeling of the labeled use for tau-fluvalinate on carrots grown for seed and ornamentals, drinking water exposure assessments were completed using Tier II model predictions. For tau-fluvalinate, the estimated drinking water concentrations from surface water sources were calculated using Tier II PRZM and EXAMS. Three scenarios were modeled for tau-fluvalinate use: carrots in Florida, vegetables in California, and ornamentals in Oregon. The California coastal vegetable scenario was modeled for comparison with the Florida scenario and represents a general vegetable scenario in an area where carrots are likely grown in California (SLN registration is for carrots grown for seed). The two scenarios together provide a reasonable exposure scenario for the SLN use. The vegetable scenarios were modeled with aerial application at a rate of 0.15 lbs. a.i./A for two applications, five days apart. The ornamental scenario was modeled with ground application at a rate of 0.34 a.i./A for 12 applications, 14 days apart. PRZM/ EXAMS modeling was performed with index reservoir (IR) scenarios and percent cropped area (PCA) adjustment factors. The estimated ground water concentrations were calculated using the Tier I SCI-GROW (Screening Concentration In Ground Water) model. The higher PRZM-EXAMS EDWCs for surface water were used for the acute and chronic dietary analyses. The modeling results are summarized in Table 3. Risks from exposure to tau-fluvalinate in drinking water are further discussed in the section titled "Aggregate Exposure and Risk."

Table 3. Summary of Drinking Water Concentrations for Tau-fluvalinate

Exposure Duration	Surface Water, ppb	Ground Water, ppb
Acute	1.31	0.0025
Chronic (Non-cancer)	0.65	0.0025

c. Population Adjusted Dose

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

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

Estimated dietary (food) risks less than 100% of the PAD, either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The aPAD is the dose at which a person could be exposed at any given day with no adverse health effects expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime with no adverse health effects expected.

d. Dietary (Food and Drinking Water) Risk Estimates

The dietary exposure and risk estimates resulting from intake of food and water with residues of tau-fluvalinate were determined for the general U.S. population and all sub-population groups. Nearly all of the estimated dietary exposure to tau-fluvalinate is from drinking water. Estimated dietary exposure to tau-fluvalinate from food represents between less than 0.01% to 0.06% (children, 1-2 yrs. old) of the total estimated exposure. No cancer dietary exposure assessment was conducted because studies indicate that there is no carcinogenic concern from tau-fluvalinate exposure.

Acute. The acute dietary exposure estimates using the DEEM-FCID model were less than 6% of the aPAD for the U.S. population and all population subgroups. Tau-fluvalinate acute dietary exposure (food + drinking water) at the 95th percentile was estimated at 0.000069 mg/kg/day for the U.S. population (1.4% of the aPAD) and 0.000257 mg/kg/day (5.1% of the aPAD) for the most highly exposed population subgroup (All Infants). Estimated acute exposures at the 95th percentile using the Lifeline model were consistent with the DEEM-FCID results (1.2% of the aPAD for the U.S. population and 3.9% of the aPAD for infants). Table 4 summarizes the dietary exposure and risk.

Chronic. The chronic dietary exposure estimates using the DEEM-FCID model were less than 1% of the cPAD for the U.S. population and all population subgroups. Tau-fluvalinate chronic dietary exposure (food + drinking water) was estimated at 0.000014 mg/kg/day for the U.S. population (0.3% of the cPAD) and 0.000045 mg/kg/day (0.9% of the cPAD) for the most highly exposed population subgroup (All Infants). Estimated chronic exposures using the Lifeline model were consistent with the DEEM-FCID results (0.2% of the cPAD for the U.S. population and 0.8% of the cPAD for infants). See Table 4 for a summary of the dietary exposure and risk for tau-fluvalinate.

Table 4. Summary of Dietary Exposure and Risk for Tau-fluvalinate								
Population Subgroup	Acute Dietary (95th Percentile)[1]				Chronic Dietary			
	DEEM-FCID™		Lifeline		DEEM-FCID™		Lifeline	
	Dietary Exposure (mg/kg)	% aPAD	Dietary Exposure (mg/kg)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000069	1.4	0.000060	1.2	0.000014	<1	0.000010	<1
All Infants (< 1 year old)	0.000257	5.1	0.000197	3.9	0.000045	<1	0.000038	<1
Children 1-2 years old	0.000109	2.2	0.000126	2.5	0.000021	<1	0.000020	<1

1. Acute exposure is reported at the 95th percentile since it was a Tier 1 dietary assessment and assumed 100% crop treated and tolerance-level residues.

4. Residential and Non-Occupational Exposure

Although tau-fluvalinate is labeled for use in residential areas, neither a residential handler estimate nor a residential post-application estimate was required, since there is little potential for exposure from these uses. Tau-fluvalinate may be applied in residential areas to building surfaces/perimeters and ant mounds by commercial applicators only (i.e., no homeowner applications are permitted). There are no wide-area treatments, such as broadcast applications on home lawns that would result in significant post-application exposure to adults or children.

5. Aggregate Exposure and Risk

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

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from the following major sources or pathways: food, drinking water and, if applicable, residential or other non-occupational exposures. In the case of tau-fluvalinate, the aggregate risk estimates only consider combined food and drinking water exposures because no residential uses are expected to contribute to chronic or acute exposures of this chemical. Estimated food and drinking water exposures were aggregated using the Dietary Exposure Evaluation Model (DEEM-FCID™) and Lifeline dietary exposure analyses.

Acute and Chronic Aggregate Risk

As presented in Table 4, the acute aggregate risk estimates for the U.S. general population and all population subgroups are less than 6% of the aPAD and, therefore, below the Agency's level of concern. Similarly, the chronic aggregate risk estimates for the U.S. general population and all population subgroups are less than 1% of the cPAD and, therefore, below the Agency's level of concern

6. Occupational Risk

Occupational risk for all exposure scenarios are measured by a margin of exposure (MOE), which determines how close the occupational exposure comes to a NOAEL or LOAEL. The target MOE for tau-fluvalinate is 100, which is based on the standard uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. MOEs greater than 100 do not exceed the Agency's level of concern.

Occupational handlers are those who mix, load, or apply the pesticide. Occupational handler assessments are conducted using increasing levels of protection. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach (going from minimal to maximum levels of protection) in an attempt to assess reduction in exposure achieved by each protective measure. The lowest tier is represented by the baseline clothing scenario (i.e., single layer clothing, socks, and shoes), followed by, if MOEs are of concern, increasing levels of risk mitigation, such as personal protective equipment (PPE) and engineering controls (EC). Tau-fluvalinate labels currently require applicators and handlers to wear long-sleeved shirts, long pants, chemical-resistant gloves, shoes and socks, and a NIOSH-approved respirator. For occupational risk, the Agency also considers the possibility of post-application exposure to workers entering treated areas for activities such as scouting, irrigation, etc.

Tau-fluvalinate exposure occurs in a variety of patterns. Occupational handlers may be exposed during mixing, loading and/or applying the pesticide using aerial, groundboom, high/low-pressure hand wand, or fogging equipment and during flagging operations for spray applications. This is an upper-bound assessment, which presents handler risk estimates for both short- (1 to 30 days) and intermediate-term (1 month to 6 months) exposure durations. No long-term exposure (>6 months) is expected from applications of tau-fluvalinate.

For more information on the assumptions and calculations of potential risks to workers handling tau-fluvalinate or working in tau-fluvalinate-treated areas, see the *Revised, Corrected Tau-Fluvalinate. Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision Document,* dated July 26, 2005, which is available in the public docket OPP-2005-0230.

a. Occupational Toxicity

Dermal exposure to tau-fluvalinate is expected to be largely self-limiting due to the specific type of dermal irritation that occurs on contact with the pesticide as a result of the

characteristic "pyrethroid reaction," which is characterized by tingling sensations and/or itching, often severe, upon contact with the chemical. Therefore, no toxicity endpoint for dermal exposure to tau-fluvalinate has been selected. However, a screening level assessment was conducted, based on the NOAEL of 100 mg/kg/day from the 21/28-day dermal toxicity study in rabbits. In this study, minimal irritation effects were seen at the 100 mg/kg/day dose with indications of the "pyrethroid reaction" only at the higher doses (500 and 2000 mg/kg/day). The Agency believes the issue of dermal exposure can be best addressed by labeling to avoid contact with skin and instructions to wash the affected area immediately following contact. Currently approved end-use product labels include adequate precautionary labeling and protective equipment requirements (long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks and a NIOSH-approved respirator) to mitigate risk from dermal exposure.

Even though the volatility of this chemical is low, both short- and intermediate-term inhalation exposure may occur based on the registered use patterns of tau-fluvalinate. As presented in Table 2, an endpoint for short- and intermediate-term inhalation exposure has been selected based on the NOAEL of 0.5 mg/kg/day from the rat chronic feeding study and the rat subchronic neurotoxicity study, and assuming a 100% inhalation absorption factor. The inhalation target MOE is 100; MOEs greater than 100 are not of concern to the Agency.

b. Occupational Handler Risk

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. The Agency evaluated occupational inhalation exposures for uses on carrots and brassica/cole crops grown for seed, outdoor and indoor ornamentals, outdoor perimeter treatments (structures, buildings, etc), greenhouses, and ant mounds. The remaining uses (beehives, greenhouse fog treatment, and cut flowers/cuttings) were not evaluated, as explained below:

- In the case of the treated strips used in beehives, an outdoor use, the Agency believes that inhalation exposure to tau-fluvalinate impregnated in the strips will be minimal due to its low vapor pressure (10^{-7} torr), and dermal exposure will be limited by the required use of chemical-resistant gloves.

- In the case of cut flowers/cuttings, the Agency believes that the high-pressure hand wand greenhouse scenario would be a comparable, protective estimate of exposure to tau-fluvalinate through this use.

- In the case of greenhouse fog treatments, the Agency does not have data with which to estimate possible tau-fluvalinate exposures through this use. Potential exposure is expected to be low due to the low volatility and rapid degradation of this chemical. Nevertheless, the Agency intends to address this area of uncertainty by requiring the registrant to submit occupational exposure data for greenhouse exposure scenarios (post-application inhalation exposure; OPPTS Guideline 875.2500).

The eight major exposure scenarios identified, based on use sites, formulations, and various equipment that may be used for tau-fluvalinate applications, are as follows:

1. Mix/load: Liquids to support aerial application on carrots/brassica,
2. Application: Aerial spray application on carrots/brassica,
3. Application: Groundboom spray application on carrots/brassica,
4. Flagger: To support aerial application on carrots/brassica,
5. Mix/load/application on non-agricultural outdoor areas, structures, buildings etc. (high-pressure hand wand),
6. Mix/load/application for greenhouses (high-pressure hand wand),
7. Mix/load/application for outdoor ornamentals (low-pressure hand wand), and
8. Mix/load/application for ant mounds (low-pressure hand wand).

Because no chemical specific data and/or studies were submitted for this chemical, PHED V1.1 has been used to assess the exposure scenarios for tau-fluvalinate. Occupational handler assessments are conducted using increasing levels of protection. In the case of tau-fluvalinate, inhalation MOEs for all assessed occupational exposure scenario are above 100 at baseline PPE (long-sleeved shirt, long pants, socks and shoes, and no respirator). See Table 5 for a summary of occupational inhalation risk estimates with baseline level of PPE (long sleeve shirt, long pants, shoes, and socks) for all scenarios, except for aerial applications, which were assessed using engineering controls (enclosed cockpit). Current labels require additional levels of PPE for applicators and all other handlers, including gloves and an NIOSH approved respirator for both indoor and outdoor applications. Estimated occupational handler MOEs for all exposure scenarios are greater than 100 and are, therefore, not of concern.

Table 5. Inhalation Occupational Exposures and Risks of Tau-fluvalinate

Exposure Scenario (Scenario #)	Inhalation Unit Exposure (µg/lb ai)	Crop	Application Rate[a]	Daily Area Treated	Inhalation Dose (mg/kg/day)	Inhalation MOE[b]
Mixer/Loader						
Mixing/Loading Liquids for Aerial application (1)	1.2	Carrots & brassica crop group grown for seed	0.15 lb ai per acre	350 Acres per day	0.0009	560 (Baseline)[c]
Applicator						
Sprays for Aerial application (2)	0.068	Carrots & brassica crop group grown for seed	0.15 lb ai per acre	350 Acres per day	0.000051	9800 (Engineering controls)[d]
Sprays for Groundboom Application (3)	0.74	Carrots & brassica crop group grown for seed	0.15 lb ai per acre	80 acres per day	0.00013	3900 (Baseline)

Table 5. Inhalation Occupational Exposures and Risks of Tau-fluvalinate						
Exposure Scenario (Scenario #)	**Inhalation Unit Exposure (µg/lb ai)**	**Crop**	**Application Rate[a]**	**Daily Area Treated**	**Inhalation Dose (mg/kg/day)**	**Inhalation MOE[b]**
Flagger						
Flagging for Sprays application (4)	0.35	Carrots & brassica crop group grown for seed	0.15 lb ai per acre	350 Acres per day	0.00026	1900 (Baseline)
Mixer/Loader/App						
Mixing/Loading/ Applying Liquids for High-Pressure Hand wand application (5)	120	Non-agricultural areas; non-residential/ industrial outdoor areas; buildings, structures.	0.0016 lb ai per gallon	1000 Gallons per day	0.0027	180 (Baseline)
Mixing/Loading/ Applying Liquids for High-Pressure Hand wand application (6)	120	Greenhouses	0.0016 lb ai per gallon	1000 Gallons per day	0.0027	180 (Baseline)
Mixing/Loading/ Applying Liquids for Low-pressure Hand wand application (7)	30	Outdoor ornamentals	0.0016 lb ai per gallon	40 Gallons per day	0.000027	18000 (Baseline)
Mixing/Loading/ Applying Liquids for Low-pressure Hand wand application (8)	30	Ant mounds	0.0016 lb ai per gallon	40 Gallons per day	0.000027	18000 (Baseline)

a. Application rates are the maximum application rates determined from EPA registered labels for tau-fluvalinate.
b. Inhalation MOE= 0.5 mg/kg/day (oral NOAEL) /Daily Inhalation Dose. Target MOE is 100.
c. Baseline level of protection consists of long sleeve shirt, long pants, shoes, and socks.
d. Closed cockpits are assumed for aerial applications.

c. Occupational Post-Application Risk

Post-application dermal exposure to tau-fluvalinate is expected to be largely self-limiting due to the irritation that occurs on contact with the pesticide as a result of the characteristic "pyrethroid reaction." Therefore, post-application dermal exposure and risk were not quantitatively assessed.

With the exception of the greenhouse uses, post-application inhalation exposure to tau-fluvalinate is expected to be minimal. Potential post-application inhalation exposure in greenhouses will be mitigated by the ventilation requirements of the Worker Protection Standard (WPS). For these reasons, a post-application inhalation exposure assessment is not necessary for

tau-fluvalinate. However, to confirm that the established restricted-entry interval (REI) of 12 hours is adequate, the Agency will require the registrant to conduct an inhalation post-application exposure study (OPPTS Guideline 875.2500).

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), Poison Control Centers, the California Department of Pesticide Regulation, the National Pesticide Telecommunications Network (NPTN), and the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR).

From the available incident data, it is apparent that tau-fluvalinate exposure can lead to mild or moderate irritation of eyes and skin. Commonly reported systemic effects include headache, nausea and breathing difficulty. Many of the incidents reported in California were related to the pesticide's use in greenhouses. In addition, beekeepers nationwide have reported dermal or other allergic-type reactions. In a comparison of Poison Control Centers' data for tau-fluvalinate and other pesticides, tau-fluvalinate was found to be as likely to cause minor symptoms as other pesticides in the database, but much less likely to cause serious effects requiring hospitalization or critical care.

B. Environmental Risk Assessment

The Agency has conducted a screening level risk assessment for the use of tau-fluvalinate on ornamentals in outdoor nurseries, greenhouses, and shade houses, for use on Eugenia/pepper trees, empty beehives, building perimeters, interior landscapes, ant mounds and for selected SLN use on carrots and brassica/cole crops grown for seed. The Agency's screening level assessment was conducted using all available acceptable and supplemental data submitted in conjunction with acceptable ecotoxicity data from the open literature. Based on the available data, the Agency has identified potential acute and chronic risks of concern for aquatic organisms and chronic risks of concern to mammals. There is also a concern for non-target terrestrial invertebrates. Based on the available data, the screening level risk assessment does not indicate a concern for birds.

There is significant uncertainty with the risk estimations for aquatic organisms due to the uncertainty surrounding the toxicity values used in this assessment. The acute toxicity studies for all aquatic species were classified as supplemental because of the apparent rapid decline of the test material in the static studies, most likely due to adsorption of tau-fluvalinate to the glass chambers. The chronic studies had analytical variability. These factors suggest that the toxicity of tau-fluvalinate could be greater than indicated. The Agency intends to require additional toxicity data to address this area of uncertainty. Basing ecological risk assessment on high-intensity use scenarios, high drift conditions, and 1–in-10 year peak concentrations, model estimates are expected to provide relatively high estimates of tau-fluvalinate concentrations in vulnerable water bodies. Additional analysis suggests that while spray drift is a significant

component of the total exposures for aquatic organisms in general, the effectiveness of spray drift buffers cannot be further evaluated by current modeling techniques.

A summary of the Agency's risk assessment is presented below. More detailed information associated with the environmental risk from the use of tau-fluvalinate can be found in the *Environmental Fate and Ecological Risk Assessment for Tau-fluvalinate*, dated July 11, 2005, which is available on the internet and in the public docket.

1. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure associated with tau-fluvalinate use. Tau-fluvalinate is expected to degrade rapidly under aerobic conditions but be persistent under anaerobic conditions. Tau-fluvalinate is also expected to be highly immobile, non-bioaccumulative, and non-volatile. Given this profile, the main routes of exposure from use of tau-fluvalinate are expected to be due to runoff and spray drift. Since this synthetic pyrethroid has a high organic carbon partitioning coefficient (K_{oc}), and other pyrethroids are known to accumulate in sediment in aquatic systems, the Agency has considered this route of exposure as well.

2. Ecological Risk Estimations

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target terrestrial and aquatic organisms. The estimated environmental concentrations (EECs) are used to calculate risk quotients (RQs). An RQ is the estimated ratio of exposure concentration to the toxicity endpoint. The calculated RQs use the EECs that are based on maximum single application rates for tau-fluvalinate, which would yield the maximum tau-fluvalinate exposure estimates. The RQ is then compared to the Level of Concern (LOC) to determine if exposure to tau-fluvalinate and its degradates would pose a risk to non-target organisms. Table 6 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 6. Agency's LOCs and Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Restricted Use - there is potential for acute risk, but may be mitigated through restricted use classification.	0.2	0.1	N/A
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

3. Risk to Aquatic Organisms

Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are typically not the same as the values used to assess human dietary exposure from drinking water sources.

For exposure to fish and aquatic invertebrates, EPA considers surface water and sediment. The Tier II PRZM-EXAMS model was used to estimate surface water concentrations of tau-fluvalinate, which were also used to derive EECs to measure potential exposures to freshwater aquatic organisms in surface water. Sediment and pore water EEC values are derived by incorporating elements of equilibrium partitioning theory into the PRZM/EXAM model. The maximum single application rates of 0.15 lb a.i./A and 0.34 lb a.i./A were used for modeling California carrots and Oregon ornamentals, respectively. The selected PRZM/EXAM scenarios are used to represent all registered outdoor uses. Indoor uses, use on apiary strips, and use on ant mounds are not expected to result in significant aquatic exposures. Table 7 lists the aquatic EECs for tau-fluvalinate.

Table 7. EECs of Tau-fluvalinate In Surface Water and Benthic Pore Water

Surface Water Concentration (μg/L)				
Crop	**Number of Applications (Intervals)**	**1/10 Year Peak Annual**	**1/10 Year 21-Day Average**	**1/10 Year 60-Day Average**
CA carrots	2 (5 day)	0.46	0.19	0.09
OR ornamental	12 (14 day)	0.25	0.16	0.14
Benthic Pore Water Concentration (μg/L)				
	96 Hour	**21 Day**	**60 Day**	**90 Day**
CA carrots	0.019	0.019	0.018	0.016
OR ornamentals	0.039	0.038	0.037	0.036

The Agency's current environmental modeling capabilities are limited in being able to quantitatively refine exposure estimates to aquatic organisms. Tau-fluvalinate is typically applied by hand wands to ornamental plants and in nurseries, while the use of the groundboom application method for ornamental crops and in nurseries is not permitted for tau-fluvalinate. The modeling the Agency uses assumes that the drift and runoff potential from groundboom and hand wand application methods are the same. However, it is recognized that hand wand application is more targeted, resulting in less of the pesticide being available for potential runoff, and less drift with associated potential for off-target exposures. Furthermore, applicators using hand wands do not treat large contiguous acreages in a short time frame as is typical for tractor mounted groundbooms. Although these differences cannot be quantified, the estimated RQs based on the use of groundboom applications may over-estimate the risk to non-target organisms.

The only uses of tau-fluvalinate approved for aerial applications are the SLN registrations on carrots and brassica/cole crops grown for seed in CA. Current labels limit aerial applications to within 150 feet of aquatic water bodies. The Agency used the AgDRIFT model to assess the amount of drift expected when a 150 foot buffer is applied, and the results indicate a reduction in EECs by approximately 20%. However, the estimated RQs are based on EECs that did not consider this 150 foot buffer.

As discussed previously, tau-fluvalinate, being a pyrethroid, has a tendency to adsorb to glass. Since adherence to the glass test chambers and rapid photolysis are likely, and only nominal concentrations were provided, it is likely that the acute LC_{50}s are lower than reported. The toxicity values fall within the range established by the five other pyrethroid studies found in the ecotoxicity database, which may suggest that the RQs are unlikely to change significantly based on new data. However, this is an uncertainty that needs to be addressed, which is why the Agency intends to require additional data.

The acute RQs for freshwater fish and freshwater invertebrates slightly exceed the Agency's LOC of 0.5. Acute RQs for marine/estuarine fish and invertebrates are below the Agency LOC, except for *Mysid* shrimp, which has an RQ of 23 under the California carrot scenario because of the higher toxicity value for this species. The acute risks from tau-fluvalinate for both freshwater and marine/estuarine organisms are outlined in Table 8.

Table 8. Fish and Invertebrate Acute Risk Estimates

Test Species	Crop	EEC (ppb)	EC_{50}/LC_{50}[1]	Toxicity Classification	RQ[2]
Freshwater					
Fish *(Carp)*	CA carrots	0.46	0.35	Highly toxic	1.3
Fish *(Carp)*	OR ornamental	0.25	0.35	Highly toxic	0.7
Invertebrate *(Red swamp crayfish)*	CA carrots	0.46	0.31	Highly toxic	1.5
Invertebrate *(Red swamp crayfish)*	OR ornamental	0.25	0.31	Highly toxic	0.8
Marine/Estuarine					
Fish *(Sheepshead minnow)*	CA carrots	0.46	10.8	Slightly toxic	0.04
Fish *(Sheepshead minnow)*	OR ornamental	0.25	10.8	Slightly toxic	0.02
Invertebrate *(Mysid shrimp)*	CA carrots	0.46	0.02	Very highly toxic	23.0

Table 8. Fish and Invertebrate Acute Risk Estimates					
Test Species	**Crop**	**EEC (ppb)**	**EC_{50}/LC_{50}[1]**	**Toxicity Classification**	**RQ[2]**
Invertebrate *(Mysid shrimp)*	OR ornamental	0.25	0.02	Very highly toxic	12.5
Invertebrate *(Eastern oyster)*	CA carrots	0.46	12	Slightly toxic	0.04
Invertebrate *(Eastern oyster)*	OR ornamental	0.25	12	Slightly toxic	0.02

1. A statistically derived concentration that can be expected to cause death in 50% of test animals.
2. Acute Risk Quotients are calculated using the following formula: EEC/LC_{50}. Acute LOC = 0.5.

Following chronic exposure to tau-fluvalinate, risks to freshwater and marine/estuarine fish and aquatic-phase amphibians slightly exceed the Agency's LOC. Chronic RQs range from 3.9 for marine/estuarine fish (ornamentals) to 1.4 for freshwater fish (carrots). Chronic RQs for freshwater invertebrates also exceed the Agency's LOC. Chronic RQs for marine/estuarine invertebrates were not calculated due to a lack of data. The Agency intends to require chronic toxicity data to address this area of uncertainty. The chronic risk from tau-fluvalinate for both freshwater and marine/estuarine organisms is outlined in Table 9.

Table 9. Fish and Invertebrate Chronic Risk Estimates					
Test Species	**Crop**	**EEC (ppb)**	**NOEC[1]**	**Study Effects**	**RQ[2]**
Freshwater					
Fish *(Fathead minnow)*	CA carrots	0.09	0.064	Growth of juvenile fish affected and decreased survival (at higher concentrations)	1.4
Fish *(Fathead minnow)*	OR ornamental	0.14	0.064		2.2
Invertebrate *(Daphnid)*	CA carrots	0.19	0.044	Decrease in length and mean number of offspring/adult/reproductive day and decreased survival (at higher concentrations)	4.3
Invertebrate *(Daphnid)*	OR ornamental	0.16	0.044		3.6
Marine/Estuarine					
Fish *(Sheepshead minnow)*	CA carrots	0.09	0.036	Diminished reproductive capacity and growth	2.5
Fish *(Sheepshead minnow)*	OR ornamental	0.14	0.036		3.9

1. No observed effect level.
2. Chronic LOC for aquatic organisms is 1.

Since sediment bound tau-fluvalinate could present a toxicity risk for benthic aquatic life and aquatic ecosystems in general, this risk concern was also assessed. Aquatic invertebrate

studies were used as surrogates for benthic organisms. The acute RQs exceed the LOC of 0.5 using the mysid shrimp EC_{50} value, but do not exceed the LOC using the oyster or red swamp crayfish toxicity values. These studies indicate that there is some uncertainty associated with the acute risk to benthic organisms. Table 10 provides a range of acute RQs for benthic organisms.

Table 10. Acute Risk Quotient for Benthic Organisms Using Surrogate Values for Tau-fluvalinate

Test Species	Crop	EEC (ppb)	EC_{50}[1]	RQ[2]
Freshwater				
Red swamp crayfish	CA carrots	0.019	0.31	0.06
Red swamp crayfish	OR ornamental	0.039	0.31	0.12
Marine/Estuarine				
Eastern oyster	CA carrots	0.019	12.0	0.002
Eastern oyster	OR ornamental	0.039	12.0	0.003
Mysid shrimp	CA carrots	0.019	0.02	0.95
Mysid shrimp	OR ornamental	0.039	0.02	1.95

1. A statistically derived concentration that can be expected to cause death in 50% of test animals.
2. LOC = 0.5 for acute risk to aquatic organisms.

For chronic risk to benthic organisms, the estimated 21-day EEC pore water values of 0.019 (carrots) and 0.038 µg/L (ornamentals) were used to estimate the chronic RQs. The NOEC value of 0.044 µg/L was used as a surrogate, yielding chronic RQ values of 0.43 and 0.86 for carrots and ornamentals, respectively. The chronic RQs for benthic organisms do not exceed the chronic LOC of 1, and are not tabulated in this section.

4. Risk to Terrestrial Organisms

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972), as modified by Fletcher *et al.* (1994). Residue estimates are based on a nomogram that relates food item residues to pesticide application rates. Terrestrial maximum and mean EECs for non-granular formulations were derived using the highest labeled application rates (0.34 lbs a.i./A for ornamentals and 0.15 lbs a.i./A for carrots/cole crops grown for seed). The shortest interval (5 days) between applications was used for carrots/cole crops grown for seed, and the typical interval (14 days) between applications was used for ornamentals.

a. Birds

Tau-fluvalinate is classified as practically non-toxic to birds. All of the acute and chronic RQs are below the LOCs for birds for both the California carrot and the Oregon ornamental scenarios. Table 11 summarizes the risk to birds using maximum EECs following both acute and chronic exposure, based on an acute LC_{50} of 5627 ppm and a chronic NOEC of 900 ppm.

Acute sublethal effects were observed in both mallard ducks and bobwhite quail at levels below the acute LD/LC_{50}s and at levels below which mortality was observed. Lethargy and slightly lower body weight gain and food consumption were noted, with lethargy as the most sensitive endpoint. The lowest level at which lethargy was observed was 398 mg/kg body weight (bw) in a dose-based study, which was the lowest dose tested in that particular study. With the highest predicted dose at 370 mg/kg bw/day (EEC of 325 ppm), lethargy may occur with small birds eating short grass. The chronic studies did not indicate any sublethal effects.

Table 11. Avian Acute and Chronic Risk Quotients for Tau-fluvalinate [a]

Use/Application Method	Food Items	Maximum EEC (ppm)[b]	Acute RQ (EEC/ LC_{50})	Chronic RQ (EEC/ NOEC)
CA carrots (vegetable as surrogate)/ Foliar	Short grass	68.61	0.01	0.08
	Tall grass	31.44	0.01	0.03
	Broadleaf plants/small insects	38.59	0.01	0.04
	Fruits, pods, seeds, and large insects	4.29	<0.01	<0.01
OR Ornamentals/ Foliar	Short grass	325.90	0.06	0.36
	Tall grass	148.91	0.03	0.17
	Broadleaf plants/small insects	182.75	0.03	0.20
	Fruits, pods, seeds, and large insects	20.31	<0.01	0.02

a. Avian acute LOC = 0.5; chronic LOC = 1.
b. Estimated environmental concentrations predicted using 1st-order degradation model based on foliar dissipation.

b. Mammals

Tau-fluvalinate is slightly toxic to mammals on an acute basis. Using maximum EEC values and the most sensitive toxicity endpoint established by a rat acute oral study (LD_{50} = 1402 mg/kg), none of the RQs exceed the Agency's LOC of 0.5 for terrestrial animals. Table 12 summarizes the acute risk to mammals.

Table 12. Mammalian Acute Risk Quotients of Tau-fluvalinate						
Use/App. Method	**Body Weight (g)**	**Mammalian Acute Risk Quotient**				
		Short Grass	**Tall Grass**	**Broadleaf Plants/Small Insects**	**Fruits/pods/ large insects**	**Seeds**
CA carrots (vegetable as surrogate)/ foliar	15	0.02	0.01	0.01	<0.01	<0.01
	1000	0.01	<0.01	<0.01	<0.01	<0.01
OR ornamentals/ foliar	15	0.10	0.05	0.06	0.01	<0.01
	1000	0.05	0.02	0.03	<0.01	<0.01

Tau-fluvalinate is classified as very highly toxic to mammals on a chronic basis. However, given the limited outdoor use of tau-fluvalinate, both in terms of total pounds applied and geographic extent, terrestrial exposure to tau-fluvalinate is expected to be limited. Chronic RQs calculated from a rat reproduction study with a dietary NOEC of 25 ppm are based on tremors in offspring, decrease in pup weight, and slightly lower litter size. The chronic RQs range from 0.08 for the carrot scenario with mammals eating fruits, pods, large insects, and/or seeds, to 13.0 for the ornamental scenario with mammals eating short grass. Table 13 contains the chronic RQs for terrestrial mammals, using both maximum and mean EECs.

Table 13. Chronic RQs for Mammals Exposed to Tau-fluvalinate				
Use/Application Method	**RQ Value Range = Mean EECs to Maximum EECs**			
	Short Grass	**Tall Grass**	**Broadleaf Plants/Insects**	**Fruits/pods/large insects/seeds**
CA carrots (vegetable as surrogate) / Foliar	0.97 – 2.74	0.41 – 1.26	0.51 – 1.54	0.08 – 0.17
OR ornamentals / Foliar	4.6 – 13.0	1.95 – 5.96	2.44 – 7.31	0.38 – 0.81

5. Non-Target Insects

Available information suggests that terrestrial insects will likely be adversely affected by tau-fluvalinate use. The Agency currently does not estimate risk quotients for terrestrial non-target insects. However, an appropriate label statement is required to protect foraging honeybees when the LD_{50} is less than 11 μg/bee. For tau-fluvalinate, the acute contact toxicity study to honeybees indicates that the LD_{50} is 0.2 μg/bee. This classifies tau-fluvalinate as highly toxic to honeybees. The impregnated strip formulation is used in beehives to treat *Varroa* mites when bees are not present.

6. Non-Target Plant Exposure and Risk

Assessment of risk could not be conducted for plants, although efficacy information in indicates that tau-fluvalinate may not be significantly toxic to terrestrial plants. Studies on nonvascular aquatic plants were found in the open literature on two degradates of tau-fluvalinate. These studies indicate probable low risk to nonvascular aquatic plants; thus the requirement for plant toxicity data is reserved at this time.

7. Ecological Incidents

Incident information was searched on the Ecological Incident Information System (EIIS) database and no incident data has been reported.

8. Risk to Federally Listed Endangered and Threatened Species

Based on a screening-level assessment, tau-fluvalinate will have no direct acute or chronic effect on listed avian species. However, there is some evidence that suggests there is a potential for sublethal effects to avian species. The screening level assessment further indicates there is a potential concern for direct effects to a variety of taxa, should exposure actually occur at modeled level. These are as follows:

- Freshwater fish – exceeds acute and chronic LOCs for California carrots and nationwide ornamentals
- Marine/estuarine fish – exceeds chronic LOC for California carrots and nationwide ornamentals
- Freshwater invertebrates – exceeds acute and chronic LOCs for California carrots and nationwide ornamentals
- Marine/estuarine invertebrates – exceeds acute LOC (*Mysid*) for California carrots and nationwide ornamentals
- Mammals – exceeds acute LOC for small mammals feeding on short grass for nationwide ornamentals. Exceeds chronic LOC for all size mammals (short and tall grass, broadleaf plants and small insects for California carrots and nationwide ornamentals); all size mammals (fruits, pods and large insects for nationwide ornamentals); and small mammals feeding on seeds for nationwide ornamentals.

As a pyrethroid, tau-fluvalinate has a tendency to adsorb to glass. Thus, there is uncertainty surrounding the data that was used to determine toxicity to aquatic organisms, and it is possible that calculated risks to aquatic species may be underestimated. Additional data is being required to address this uncertainty. Because of this uncertainty, we can not currently preclude the possibility of effects to aquatic species. Although the Agency expects tau-fluvalinate to pose an acute risk to nontarget insects because tau-fluvalinate is highly toxic to honeybees (acute contact LD_{50} is 0.2 μg/bee), an assessment method for estimating the risk to bees is not yet available; therefore, we can not preclude the possibility of potential effects to listed insect species. The Agency currently does not have data to quantify risks for tau-fluvalinate at the screening-level and can not preclude potential direct effects to plants or chronic effects to estuarine/marine invertebrates. Finally, the Agency can not preclude the potential for indirect effects to listed species that may be dependent upon taxa that experience direct effects

from the use of tau-fluvalinate. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

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 tau-fluvalinate as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing tau-fluvalinate.

The Agency has completed its assessment of the dietary, residential, occupational, and ecological risk associated with the use of pesticide products containing the active ingredient tau-fluvalinate. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of tau-fluvalinate to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that tau-fluvalinate-containing products are eligible for reregistration provided that label amendments are made as outlined in Section V. In addition, the Agency intends to require data to confirm some risk conclusions discussed in Section III. Appendix A summarizes the uses of tau-fluvalinate 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 tau-fluvalinate, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of tau-fluvalinate, the Agency has determined that tau-fluvalinate products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of tau-fluvalinate. If all changes outlined in this document are incorporated into the product labels, then all current risks for tau-fluvalinate will be adequately mitigated for the purposes of this determination.

B. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to tau-fluvalinate is within its own "risk cup." An aggregate assessment was conducted for

exposures through food and drinking water. Residential uses were not considered in the aggregate assessment, because they are not expected to contribute to chronic or acute exposures of this chemical. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for tau-fluvalinate meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and drinking water.

b. Determination of Safety to U.S. Population

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

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for tau-fluvalinate, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of tau-fluvalinate residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of tau-fluvalinate, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been reduced to 1X for tau-fluvalinate, because there are no residual uncertainties for pre- and/or post-natal toxicity.

2. Endocrine Disruptor Effects

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

in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). There were no indications based on the animal studies submitted for registration purposes that indicate that tau-fluvalinate affects the estrogen, androgen, or thyroid or other hormone systems. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, tau-fluvalinate may be subject to additional screening and/or testing.

3. Cumulative Risks

The FFDCA, as amended by the FQPA, requires that 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." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually.

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

D. Tolerance Reassessment Summary

Current Tolerances Under 40 CFR §180.427 (a)

A tolerance is established at 40 CFR §180.427 (a) under the name "Fluvalinate" for residues of "(alpha *RS* , 2R)-fluvalinate [(*RS*)-alpha-cyano-3-phenoxybenzyl (*R)*-2-[2-chloro-4-(trifluoromethyl)anilino]-3-methylbutanoate" in/on honey at 0.05 ppm. "Fluvalinate" is the common name for the racemic mixture of the 4 isomers of cyano-(3-phenoxyphenyl)methyl N-[2-chloro-4-(trifluoromethyl)phenyl]-valinate (CAS name). "Tau-fluvalinate" is the term for the half resolved mixture (2 of the 4 isomers). The tolerance expression should be revised to reflect the correct common name and the CAS name as follows: "Tolerances are established for

residues of the insecticide *tau*-fluvalinate [cyano-(3-phenoxyphenyl)methyl N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate]."

The nature of the residue in honey is adequately understood. The registered use does not involve the direct application of tau-fluvalinate to honey, but involves the possible transfer of secondary residues from tracking by the bee colony as they make contact with the insecticide strips. Therefore, the Agency has determined that only the parent compound, tau-fluvalinate *per se*, is the residue of concern. Adequate data are available to reassess the established tolerance for honey at the same level. However, based on the available data, the established tolerance may be reduced from 0.05 ppm to 0.02 ppm, as presented in Table 14.

Table 14. Current Tolerances for Tau-fluvalinate under 40 CFR § 180.427(a)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Honey	0.05	0.02	N/A

No CODEX maximum residue levels (MRLs) have been established for either fluvalinate or tau-fluvalinate.

Residue Analytical Methods (GLN 860.1340)

The reregistration requirements for residue analytical methods are fulfilled. A gas chromatography (GC) with electron capture detection (ECD) method is available for the enforcement of tolerances for residues of tau-fluvalinate in honey. This method has been for forwarded to FDA for publication in the Pesticide Analytical Manual (PAM) Volume II. This method has a limit of detection of 0.01 ppm. Residue data for honey were collected using this GC/ECD enforcement method.

E. Regulatory Rationale

The Agency has determined that tau-fluvalinate is 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 tau-fluvalinate.

1. Human Health Risk

There are no tau-fluvalinate human health dietary (food and drinking water), residential, or aggregate (dietary and residential) risks of concern, based on currently registered use patterns and screening-level assessments. Moreover, this assessment is protective of the general U.S. population and all population subgroups, including infants and young children.

Occupational risk estimates are also low and are not of concern. However, as a type II pyrethroid, tau-fluvalinate causes the "pyrethroid reaction," a specific type of dermal irritation following contact. The "pyrethroid reaction" is unlike the primary dermal irritation assessed in

acute or subchronic dermal irritation studies. Dermal assessments are conducted to determine the systemic effects resulting from exposure to a chemical. The "pyrethroid reaction," while irritating, is not systemic in nature, thus a quantitative dermal assessment was not conducted. Dermal exposure to tau-fluvalinate is expected to be self-limiting due to the "pyrethroid reaction" that occurs on contact with the chemical. Incident data suggests that there have been minor, dermal reactions resulting from contact with the insecticidal strips used in beehives. The Agency believes that the issue of dermal exposure is effectively addressed by labeling to avoid contact with skin and instructions to wash the affected area immediately following contact. Language to this effect has been added to the label amendments, which are summarized in Table 16. Furthermore, the current label restrictions that require the use of chemical-resistant gloves for applicators and handlers, of both the insecticidal strips and liquid formulations, will be maintained.

Although the inhalation MOEs exceed 100 for all occupational scenarios at baseline level of protection (long sleeve shirt, long pants, shoes and socks, and no respirator), tau-fluvalinate labels also currently require respirators for applicators and all other handlers for both indoor and outdoor applications. Tau-fluvalinate may have a special problem with regard to the unknown consequences resulting from the property of this chemical to cause the "pyrethroid reaction" once the respiratory tract is exposed to the chemical. In particular, persons with asthma and emphysema may be especially sensitive. Prevention of possible respiratory hazard associated with the "pyrethroid reaction" will be accomplished by maintaining the current label requirement for the use of respirators for those product uses where spray mists or other potentially respirable atmospheres containing tau-fluvalinate occur. In addition, to confirm that the established restricted-entry interval (REI) of 12 hours is adequate, the Agency will require the registrant to conduct an inhalation post-application exposure study (OPPTS Guideline 875.2500).

2. Environmental Risk

The Agency has conducted a screening-level ecological and environmental risk assessment for the registered uses of tau-fluvalinate. Based on the available data, the Agency has identified potential acute and chronic risks of concern to aquatic organisms and chronic risks of concern to mammals. There is also a concern for non-target terrestrial invertebrates. However, the screening-level risk assessment does not indicate a risk concern for birds. The use pattern for tau-fluvalinate suggests that the potential risks are likely to be limited to those geographic areas where the chemical is used the most; however, use data is limited and does not allow for further refinement for the non-SLN uses. The following states were identified as major nursery production states, though not necessarily main use areas for tau-fluvalinate: California, Oregon, Michigan, Florida, Pennsylvania, and Texas.

As a pyrethroid, tau-fluvalinate has a tendency to adsorb to glass. Since adherence to the glass test chambers and rapid photolysis are likely, and only nominal concentrations were provided, it is likely that the acute LC_{50}s are lower than reported. The toxicity values fall within the range established by the five other pyrethroid studies found in the ecotoxicity database, which may suggest that the RQs are unlikely to change significantly based on new data. However, this is an uncertainty that needs to be addressed, which is why the Agency will be requiring additional data.

While there are estimated exceedences of the LOC for some terrestrial and aquatic species, the ecological risks associated with the use of tau-fluvalinate is expected to be limited based on its use pattern and toxicity profile. Tau-fluvalinate is not a widely used chemical. Of the estimated 11,000 pounds active ingredient used on average per year, approximately half is applied outdoors. The remaining indoor uses, such as use in greenhouses, interior landscapes and others, do not result in environmental exposure. The amount of tau-fluvalinate used for the SLN registration for carrots and brassica/cole crops grown for seed accounts for approximately 2% of the total pounds of tau-fluvalinate applied annually. The majority of the remaining outdoor uses are in nurseries, which generally are not present in large contiguous acreages. Moreover, much of the use in nurseries is for containerized plants, and label use directions prohibit use of broadcast applications in nurseries, which is expected to limit the amount of potential exposure from runoff and drift.

a. Fish and Aquatic Invertebrate Risk

The Agency has low acute and chronic risk concerns for freshwater and estuarine/marine organisms exposed to tau-fluvalinate via runoff or drift. The Agency completed a high-end, screening level assessment using maximum labeled rates for tau-fluvalinate.

The Agency's current environmental modeling capabilities are limited in being able to quantitatively refine exposure estimates to aquatic organisms. Tau-fluvalinate is typically applied by hand wands in nurseries, and the use of the groundboom application method for ornamental crops and in nurseries is not permitted for tau-fluvalinate. The modeling the Agency uses assumes that the drift and runoff potential from groundboom and hand wand application methods are the same. However, it is recognized that hand wand application is more targeted, resulting in less of the pesticide being available for potential runoff, and less drift with associated potential for off-target exposures. Furthermore, applicators using hand wands do not treat large contiguous acreages in a short time frame as is typical for tractor mounted groundbooms. Although these differences can not be quantified, the estimated RQs based on the use of groundboom applications may over-estimate the risk to fish and aquatic invertebrates.

Runoff is also reduced in nurseries by their waste-water containment programs, which results in further reduced risk to aquatic organisms. While there are currently no national studies that can be used to quantify the effects of nursery waste-water containment practices, these practices have proven effective in reducing risk to non-target species. According to the American Nursery and Landscape Association (ANLA), container nurseries use a variety of methods to control water runoff from nursery operations, including grassed waterways, sediment control ponds, constructed wetlands, and irrigation runoff water recycling ponds. The practice of retaining water onsite is being driven by two factors: 1) the Clean Water Act and states' regulatory efforts regarding non-point pollution control and storm water management, and 2) water shortages that are appearing in various sections of the US, such as Florida, where nurseries need to insure a consistent supply of irrigation water. Furthermore, the ANLA reports that all new container nursery operations under development are being designed for zero or minimum offsite water discharge.

The only uses of tau-fluvalinate approved for aerial applications are the SLN registrations on carrots and brassica/cole crops grown for seed in CA. Seed producing carrots are usually grown in semi-arid areas where rain fall and humidity is low, which should limit exposure to aquatic organisms. In addition, current labels limit aerial applications to within 150 feet of aquatic water bodies. The Agency used the AgDRIFT model to assess the amount of drift expected when a 150 foot buffer is applied, and the results indicate a reduction in EECs by approximately 20%. However, the estimated RQs are based on EECs that did not consider this 150 foot buffer. Therefore, actual RQs for aquatic organisms may be slightly lower.

Data will be required to address uncertainty surrounding the aquatic organism toxicity values. As a pyrethroid, this chemical has a tendency to adsorb to glass. Since adherence to the glass test chambers and rapid photolysis are likely, and only nominal concentrations were provided, it is possible that the acute LC_{50}s are lower than reported. The toxicity values fall within the range established by the five other pyrethroid studies found in the ecotoxicity database, which suggests that the RQs may not change significantly based on new data; however, this is an uncertainty that needs to be addressed.

b. Avian Risk

There are no risks of concern for avian species. Tau-fluvalinate is practically non-toxic to birds, and estimated acute and chronic RQs based on maximum EECs were less than all LOCs. However, it is possible some sublethal effects may occur in birds under maximum labeled use scenarios.

c. Mammalian Risk

There are no acute mammalian risk concerns, but there are low chronic risk concerns for small mammals under certain scenarios. The terrestrial organism risk assessment is based on maximum labeled rates, which sources indicate are at times twice the amount typically applied in the field. Uncertainties in the environmental fate data, specifically, lack of data on interception and subsequent dissipation from foliar surfaces, and a lack of data on aerobic aquatic metabolism, results in the use of default assumptions in the modeling parameters. The default assumptions are upper-bound estimates, yielding a high-end risk assessment.

As noted previously, the hand wand application method used in nurseries is expected to limit exposure through runoff and drift, and the 150 foot buffer zones required for aerial applications (only on SLN registrations for carrots and brassica/cole crops grown for seed), will also reduce drift. Based on these factors, risk estimates to terrestrial organisms may be over-estimated.

d. Terrestrial and Aquatic Plant

Assessment of risk to plants could not be conducted due to a lack of acceptable toxicity data for tau-fluvalinate. However, efficacy information in the open literature indicates a probable low risk to both terrestrial and nonvascular aquatic plants; thus the requirement for plant toxicity data is reserved at this time.

e. Non-Target Insects

The Agency expects tau-fluvalinate poses an acute risk to nontarget insects because tau-fluvalinate is highly toxic to honeybees (acute contact LD_{50} is 0.2 μg/bee). However, the Agency does not assess risk to bees using RQs, because a screening level RQ assessment method for estimating the risk to bees is not available.

At this time, the Agency is not requiring additional measures to reduce potential exposure and risk to nontarget organisms from the use of tau-fluvalinate, based on the factors discussed above. These factors include the limited amount of the pesticide being applied outdoors and potentially available for off-target exposure; the likely overestimate of potential predicted risk due to limitations in the Agency's assessment methods to reflect the risk associated with the predominant application method (hand wand); and uncertainties associated with the aquatic toxicity data resulting from the tendency of chemicals of this type to adsorb to glass. The Agency is requiring additional data to address the uncertainties associated with the toxicity to aquatic organisms and will review these data to evaluate whether mitigation measures are warranted. The Agency intends to conduct further review of tau-fluvalinate as part of its Registration Review program, which is required to determine whether pesticides continue to meet the standard for registration. Because tau-fluvalinate is a synthetic pyrethroid, it is proposed to be reviewed along with other synthetic pyrethroids in years four to six of the Registration Review program. The proposed schedule and further details on the Registration Review program can be found by accessing the Agency's website at http://www.epa.gov/oppsrrd1/registration_review/index.htm.

F. 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 tau-fluvalinate. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

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

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As

part of the reregistration process, the EPA will continue to work with all interested parties on this important issue.

Because of the low risks associated with the use of tau-fluvalinate, as summarized in this document, and the existing buffer zone restrictions for aerial applications, the Agency concludes that spray drift mitigation is not needed as part of the reregistration eligibility determination. Thus, no additional mitigation to address human health and environmental risks from spray drift is warranted.

V. What Registrants Need to Do

The Agency has determined that tau-fluvalinate is eligible for reregistration provided that the required label amendments are made. To address Agency regulatory needs, the registrant will be required to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Table 16. The Agency intends to issue Data Call-In (DCIs) Notice requiring product specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. Below are the label amendments that the Agency intends to require for tau-fluvalinate to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

Table 15. Guideline Requirements for Tau-fluvalinate

Data Requirement	Old Guideline Number	New OPPTS Guideline No.
Post-application inhalation exposure	133-4	875.2500
90-Day Inhalation Toxicity (reserved)	82-4	870.3465
UV/Visible Absorption	N/A	830.7050
Freshwater fish acute LC50	72-1	850.1075
Estuarine/marine fish acute LC50 (sheepshead minnows)	72-3 (a)	850.1075
Freshwater invertebrate acute EC50 (daphnia)	72-2	850.1010
Estuarine/marine acute LC50 (shrimp)	72-3 (c)	850.1035
Freshwater invertebrate life cycle (daphnia)	72-4	850.1300

Freshwater fish early life stage *(reserved)*	72-4 (a)	850.1400
Estuarine/marine invertebrate life cycle, shrimp *(reserved)*	72-3 (b)	850.1350
Estuarine/marine acute EC50, mollusk *(reserved)*	72-3 (b)	850.1025
Whole sediment acute, freshwater *(reserved)*	None	850.1735
Whole sediment acute, marine *(reserved)*	None	850.1740
Terrestrial plant toxicity, seedling emergence (Tier 1 only) *(reserved)*	122-1 (a)	850.4100
Terrestrial plant toxicity, vegetative vigor (Tier 1 only) *(reserved)*	122-1 (b)	850.4150
Vascular (*lemna gibba*) Aquatic Plant Toxicity Test (Tier 1 only) *(reserved)*	122-2	850.4400
Vascular (*lemna gibba*) Aquatic Plant Toxicity Test (Tier II only) *(reserved)*	123-2	850.4400
Aquatic Plant Toxicity Test using *lemna* spp. (Tier 1 only) *(reserved)*	122-2	850.5400
Aquatic Plant Toxicity Test using *lemna* spp. (Tier II only) *(reserved)*	123-2	850.5400

The Agency does not have data with which to estimate possible tau-fluvalinate exposures through the use of greenhouse fog treatments; therefore, a post-application exposure study (OPPTS Guideline 875.2500) will be required. This is confirmatory data, specific to tau-fluvalinate, which will be used to confirm that post-application greenhouse inhalation exposures are minimal and that the ventilation requirement under the WPS adequately protects post-application workers. Should the results of the post-application exposure study indicate that post-application inhalation exposures may be of concern, additional data might be required. Thus, a 90-Day Inhalation Toxicity test (OPPTS Guideline 875.3465) is being reserved pending the outcome of the post-application exposure study.

The Agency will require acute toxicity studies on freshwater and marine/estuarine fish and invertebrates. For marine/estuarine invertebrates, the acute study for shrimps is being required. Since the current data indicate that the shrimp are more sensitive, the acute study on mollusks is on reserve. The mollusk study is reserved in the event that other information becomes available indicating mollusks are more sensitive than current data suggests. The chronic freshwater fish study is on reserve because the Agency already has data from a chronic marine/estuarine fish study. When the acute data for freshwater and marine/estuarine fish is received, acute to chronic ratios can be used to estimate chronic toxicity to freshwater fish. The freshwater fish chronic study is reserved in the event that irresolvable uncertainty arises from efforts to estimate toxic levels using the acute to chronic ratio. A chronic freshwater invertebrate (daphnia) study is being required, while a chronic marine/estuarine invertebrate study on shrimp is on reserve. As previously explained, once the acute data for daphnia and shrimp are received, acute to chronic ratios can be used to estimate chronic toxicity to marine/estuarine invertebrates. The chronic study with daphnia is reserved in the event that unacceptable uncertainty arises from efforts to estimate toxic levels using the acute to chronic ratio. The whole sediment freshwater and marine/estuarine studies are on reserve until data is received from the other acute freshwater and marine/estuarine invertebrate studies. The plant studies are reserved pending the publication new testing guidelines (40 CFR 8158), and are intended to be required upon publication.

2. Labeling for Manufacturing-Use Products

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 labeling contained in Table 16.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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 16. 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 16 describes how language on the labels should be amended.

Table 17. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an insecticide for the following uses: perimeter treatments to include outdoor surfaces, containerized nursery stock, woody and herbaceous ornamentals, ant mound treatments, greenhouse application, indoor ornamentals, flower and foliage cuttings, and the Special Local Needs (SLN) registration for use on carrots and brassica/cole crops grown for seed in California;"	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public 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 Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements
End-Use Products Intended for Occupational Use (WPS and non-WPS)		
Other Precautionary Statements	"If workers enter the treated area and/or contact treated surfaces: - pesticide residues that get on their skin may cause itching or irritation that can be severe, and - they should avoid skin contact with treated foliage and/or surfaces, and - they should wash the affected skin immediately if irritation begins to occur."	Precautionary Statements following First Aid Statements
PPE Requirements Established by the RED for liquid (FlC)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" [registrant inserts	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language**	**Placement on Label**
formulations	correct material(s)]. For more information, follow instructions in Supplement Three of PR Notice 93-7. "If you want more options, follow the instructions for category" [registrant inserts A, B, C, D, E, F, G or H] "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks, -chemical-resistant gloves, and - A NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N** R, P, or HE filter." * Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil. See engineering controls for additional requirements.	
PPE Requirements Established by the RED for impregnated strip (IMPR) formulation.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" [registrant inserts correct material(s)]. For more information, follow instructions in Supplement Three of PR Notice 93-7. "If you want more options, follow the instructions for category" [registrant inserts A, B, C, D, E, F, G or H] "on an EPA chemical-resistance category selection chart." "All handlers must wear chemical-resistant gloves."	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements for all formulations	"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 Requirements for liquid formulations only	"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language**	**Placement on Label**
Engineering Controls for Aerial Applications for Section 24(c) labels only	Enclosed Cockpits "Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6) and must wear long-sleeve shirt, long pants, shoes, and socks. Chemical-resistant gloves and respirator need not be worn."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Optional Use by Handlers for Section 24(c) labels only	Engineering Control Statement for Optional Use (WPS Only) "Engineering Controls: When applicators use an enclosed cab in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR170.240(d)(5)], the handler PPE requirements may be reduced or modified as specified in the WPS."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Recommendations for all products	"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Additional User Safety Recommendations for liquid formulations only	"Users should remove clothing/ PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Restricted-entry Interval for WPS for liquid formulations only	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Reentry Personal Protective Equipment for liquid formulations only	"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 soil, plants, or water, is: -coveralls, -chemical-resistant gloves made of any waterproof material, -shoes plus socks."	Directions for Use, Agricultural Use Requirements Box

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language**	**Placement on Label**
General Application Restrictions for liquid formulations only	"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."	Place in the Directions for Use directly above the Agricultural Box, if there is one, otherwise place in the Directions for Use under General Precautions and Restrictions.
General Application Restrictions for liquid formulations	"Do not apply this product through any type of irrigation system. Not for broadcast use in nurseries. Not for use on sod farms, on grass grown for seed, or on golf course turf. Do not apply this product by aerial application. "	Place in the Directions for Use directly after the Agricultural Box, if there is one, otherwise place in the Directions for Use under General Precautions and Restrictions.
Application Restrictions for 24(c) labels	"Aerial application is permitted. Do not apply by ground within 25 feet or by air within 150 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, and commercial fish ponds."	Directions for Use under General Precautions or Restrictions and/or Application Instructions
Environmental Hazards Statements Required by the RED and Agency Label Policies for liquid formulations	"This pesticide is toxic to fish and aquatic organisms. 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. Drift and runoff from treated areas may be hazardous to fish and aquatic organisms in adjacent aquatic sites. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements: Hazards to Humans and Domestic Animals
Spray Drift Label Language for 24(c) labels	"SPRAY DRIFT MANAGEMENT" "Avoiding spray drift at the application site is the responsibility of the applicator and the grower. The interactions of many equipment and weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions." "For aerial applications:" "The boom length must not exceed 70% of the wingspan or 85% of the rotor blade diameter." "Do not make any type of application into temperature inversions." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind."	Directions for Use under General Precautions or Restrictions and/or Application Instructions

Table 17. Labeling Changes Summary Table		
Description	**Amended Labeling Language**	**Placement on Label**
	"Use the largest droplet size consistent with pest control. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure." "Spray should be released at the lowest height consistent with good pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided." "For Aerial and Ground Applications:" "Make aerial or ground applications when the wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph. Avoid applications when wind gusts approach 15 mph." "Risk of exposure to aquatic areas can be reduced by avoiding growth of vegetative filter strip." "Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of increased spray drift to aquatic areas." "Applicators must follow all state and local pesticide drift requirements regarding application of tau-fluvalinate. Where states have more stringent regulations, they must be observed." "All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers or surrogates".	

VI. Appendices

Appendix A. Use Patterns Eligible for Reregistration for Tau-fluvalinate								
Application Timing Application Equipment Application Type	**Formulation**	**Maximum Single Application Rate**	**Maximum No. Of Applications per Year**	**Maximum Seasonal Rate**	**Pre-harvest Interval (days)**	**Application Interval (days)**	**Reentry Interval**	**Limitations**
Beehives (empty)								
when needed impregnated strip insecticidal strip	IMPR	1 strip / brood chamber	NS	NS	NS	42	NS	
Carrots and brassica/cole								
foliar aircraft, ground sprayer low volume spray	FLC	0.15 lb ai/A	NS	NS	NS	5	12 hr	SLN for CA state, for seed only
Perimeter treatments								
when needed low-pressure ground sprayer crack and crevice, outdoor general surface spray	FLC	0.0078 lb / 1000 sq ft	20	NS	NS	7	NS	
Ant mound treatments								
when needed spoon mound drench	FLC	0.0016 lb / mound	NS	NS	NS	NS	NS	
Containerized nursery stock and woody and herbaceous ornamentals - outdoors								
foliar fogger, sprayer broadcast, fog, spray	FLC	0.0078 lb / 1000 sq ft	16	NS	NS	7	12 hr	Except in CA
Eugenia and pepper trees- outdoors								
foliar fogger, sprayer broadcast, fog, spray	FLC	0.0078 lb / 1000 sq ft	16	NS	NS	14	12 hr?	Except in CA
Greenhouse applications								
foliar fogger, sprayer broadcast, fog, spray	FLC	0.0078 lb / 1000 sq ft	16	NS	NS	NS	12 hr	
Flower and foliage cuttings for dipping- indoors								
cutting dip tank dip treatment	FLC	0.0039 lb / minute	NS	NS	NS	NS	12 hr	

NS = Not Specified

Appendix B Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**	**Study Description**		
830.1550	61-1	Product Identity and Composition	All	41889701; 45598800
830.1600	61-2A	Description of Materials Used to Produce the Product	All	00076684; 00076685; 00128515; 41889701; 45598800
830.1620	61-2B	Description of Production Process	All	00076684; 00076685; 00128515; 41889701; 45598800
830.1670	61-2B	Formation of Impurities	All	00076684; 00076685; 00128515; 41889701; 41889702; 44701401; 45598800
830.1700	62-1	Preliminary Analysis	All	00076684; 00076685; 00128515; 41889702; 44701401; 45598801
830.1750	62-2	Certification of Limits	All	41889701; 41889702; 45598800
830.1800	62-3	Analytical Method	All	41889702; 45598801
830.6302	63-2	Color	All	41889703
830.6303	63-3	Physical State	All	41889704
830.6304	63-4	Odor	All	41889705
830.6313	63-13	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	All	41889713; 44694101
830.7000	63-12	pH	All	41889712
830.7050	N/A	UV/Visible Absorption	All	Data Gap
830.7220	63-6	Boiling Point/Boiling Range	All	41889706
830.7300	63-7	Density	All	41889707
830.7550	63-11	Partition Coefficient, Shake Flask Method	All	41889711; 44694101
830.7840	63-8	Water Solubility: Column Elution Method; Shake Flask Method	All	41889708; 44694101
830.xxxx	N/A	Solvent Solubility	All	41889709; 44694101

Appendix B Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
830.7950	63-9	Vapor Pressure	All	41889710; 44694101
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	A, B	00085444; 00104671
850.2200	71-2A	Avian Dietary Toxicity - Quail	A, B	00094601; 00079964
850.2200	71-2B	Avian Dietary Toxicity - Duck	A, B	00104672; 00079965
850.2300	71-4A	Avian Reproduction - Quail	A, B	00149824
850.2300	71-4B	Avian Reproduction - Duck	A, B	00149825
850.1075	72-1	Freshwater Fish Acute Toxicity - Bluegill	A, B	00094599 (supplemental); 00079962 (supplemental); 00094600 (supplemental); 00094596 (supplemental); Data Gap
850.1075	72-1	Freshwater Fish Acute Toxicity – Carp	A, B	00150125 (supplemental); Data Gap
850.1075	72-1	Freshwater Fish Acute Toxicity - Rainbow Trout	A, B	00079961 (supplemental); 00094598 (supplemental); Data Gap
850.1010	72-2A	Invertebrate Toxicity	A, B	00094597 (supplemental); 00079960 (supplemental); 00127995 (supplemental); Data Gap
850.1075	72-3A	Estuarine/Marine Fish Acute Toxicity	A, B	00155450 (supplemental); 00160766 (supplemental); Data Gap
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B	00160767 (supplemental); Data Gap
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp	A, B	00127994 (supplemental); Data Gap
850.1400	72-4	Freshwater Fish Early Life Stage Toxicity – Fathead Minnow	A, B	00127996 (supplemental); Data Gap
850.1350	72-4B	Estuarine/Marine Invertebrate Chronic Toxcitiy- *Mysid* Shrimp	A, B	Data Gap

Appendix B Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
850.1300	72-4B?	Freshwater Invertebrate Chronic Toxicity - Daphnia	A, B	00127997 (supplemental); Data Gap
850.1500	72-5	Estuarine/Marine Fish Life Cycle	A, B	43753501; 00160768
850.1735	N/A	Whole Sediment Acute Toxicity (Invertebrates, Freshwater)	A, B	Data Gap
850.1740	N/A	Whole Sediment Acute Toxicity (Invertebrates, Marine)	A, B	Data Gap
850.4100	122-1A	Terrestrial Plant Toxicity, Seedling Emergence (Tier 1)	A, B	Data Gap
850.4150	122-1B	Terrestrial Plant Toxicity, Vegetative Vigor (Tier 1)	A, B	Data Gap
850.4400	122-2	Vascular Aquatic Plant Toxicity - *lemna gibba* (Tier 1)	A, B	Data Gap
850.5400	122-2	Aquatic Plant Toxicity- *lemna* spp. (Tier 1)	A, B	Data Gap
850.4400	123-2	Vascular Aquatic Plant Toxicity – *lemna gibba* (Tier II)	A, B	Data Gap
850.5400	123-2	Aquatic Plant Toxicity Test – *lemna* spp. (Tier II)	A, B	Data Gap
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B	41783901; 41996203
850.3030	141-2	Honey Bee Toxicity of Residues on Foliage	A, B	41996204
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity – Rat	A, B	0094103
870.1200	81-2	Acute Dermal Toxicity – Rabbit	A, B	41597301
870.2400	81-4	Acute Eye Irritation – Rabbit	A, B	00144622
870.2500	81-5	Acute Dermal Irritation - Rabbit	A, B	00144623
870.2600	81-6	Skin Sensitization – Guinea Pig	A, B	41889714

Appendix B Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
870.3100	82-1A	90-Day Oral Toxicity – Rodent	A, B	00094109 (Rat); 92069032 (Rat); 00094113 (Mouse)
870.3200	82-2	21/28-Day Dermal Toxicity – Rabbit	A, B	00094115; 92069034
870.3700	83-3	Prenatal Developmental Toxicity	A,B	44743301 (Rat); 0094112 (Rabbit); 92069038 (Rabbit)
870.3800	83-4	Reproduction and Fertility Effects – Rat	A, B	44596601
830.4100	83-1	Chronic Toxicity – Dog	A, B	44743201
870.4200	83-2b	Carcinogenicity – Mouse	A, B	00094889; 00128336; 00144628; 92069036
870.4300	83-5	Combined Chronic Feeding/ Carcinogenicity – Rats	A, B	00128334, 00128335
870.5100	84-2	Bacterial Reverse Mutation	A, B	00094116
870.5300	84-2 (?a)	Cytogenetics- Mouse Lymphoma Mutagenic Assay	A, B	00144625
870.5375	84-2 (B?)	Cytogenetics – Sister Chromatid Exchange In CHO cells.	A, B	00144626
870.5550	54-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	A, B	00145614
870.6200	81-7	Acute Neurotoxicity Screening Battery	A, B	43433901
870.6200	82-5	Subchronic Neurotoxicity Screening Battery – Rat	A, B	44900601
870.7485	85-1	General Metabolism	A, B	43214101; 42322301
870.7600	85-3	Dermal Penetration and Absorption	A, B	46266101
Special Studies	N/A	90 Day Dermal Study to Determine Mechanism of Dermal Lesions	A, B	00126175
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2500	133-4	Inhalation Exposure	A, B	Data Gap
870.3465	82-4	90-Day Inhalation Toxicity	A, B	Data Gap

Appendix B
Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate

REQUIREMENT			Use Pattern	CITATION(S)
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B	41597303; 45769201; 45769202
835.2240	161-2	Photodegradation – Water	A, B	ACC 072938; 41597305; 45769203
835.2410	161-3	Photodegradation – Soil	A, B	83757; 41597307; 45769201
835.4100	162-1	Aerobic Soil Metabolism	A, B	126102; 41889715; 45769201
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	41889715; 45769201
835.1230	163-1	Sediment and Soil Adsorption/Desorption	A, B	45769204
835.1240	163-1	Soil Column Leaching	A, B	45769204
850.1730	165-4	Bioaccumulation in Fish	A, B	92069044
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue – Plants	A, B	00160816; 41998801; 43122701
860.1300	171-4B	Nature of Residue – Livestock	A, B	00160815; 00162555; 43122702
860.1340	171-4C	Residue Analytical Method – Plants	A, B	00150616; 00159650; 40823002; 43214110; 43214112; 43254601; 43254602
860.1340	171-4D	Residue Analytical Method – Animals	A, B	00150616; 00159650
860.1380	171-4E	Storage Stability - Plants	A, B	41910302; 41923501
860.1480	171-4J	Magnitude of the Residue – Meat, Milk, Poultry, Eggs	A, B	00150616
860.1500	171-4K	Crop Field Trials (Coffee, Beans)	A, B	40053601; 42044201
860.1500	171-4K	Crop Field Trials (Cotton, Seed, and Gin Byproducts	A, B	00150616
860.1500	171-4K	Crop Field Trials (Honey)	A, B	41094001; 41094003; 41145801
860.1520	171-5	Processed Food/Feed (Coffee)	A, B	40053601; 42044201
860.1520	171-5	Processed Food/Feed (Cotton)	A, B	00150616
OTHER				

Appendix B Data Supporting Guideline Requirements for the Reregistration of Tau-fluvalinate				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
840.1100	201-1	Droplet Size Spectrum	A, B	Spray Drift Task Force
840.1200	202-1	Drift Field Deposition Evaluation	A, B	Spray Drift Task Force

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket contains the risk assessments and related documents as of October 28, 2005. The availability announcement will be published in the Federal Register. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: www.epa.gov/pesticides/reregistration. The following list details all documents related to the Tau-fluvalinate RED.

Health Effects Documents

1. *Tau-fluvalinate: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED).* D321911; S. Stanton; September 29, 2005
2. *Tau-Fluvalinate. RED - Reregistration Eligibility Decision Document. Residue Chemistry Considerations*. D300204; J. Morales; February 22, 2005
3. *Tau-Fluvalinate RED - Reregistration Eligibility Decision. Product Chemistry Considerations.* D311824; J. Morales; February 22, 2005
4. *Tau-fluvalinate Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision*. D300203; S. Stanton; March 11, 2005
5. *Tau-Fluvalinate. Corrected Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision Document (RED).* D300200; R. Travaglini; June 23, 2005
6. *Review of Fluvalinate Incident Reports*. D300199, J. Blondell, March 14, 2005

Biological and Economical Analysis Documents

1. *Assessment of tau-fluvalinate use on outdoor ornamentals, carrots grown for seed in California, and consideration of the benefits as proposed by the registrant of tau-fluvalinate.* 300218; W. Gross and D. Donaldson; October 4, 2005

Ecological Fate and Effects Documents

1. *Environmental Fate and Ecological Risk Assessment for Tau-fluvalinate.* M. Corbin and P. Hurley; July 11, 2005
2. *Tier II Estimated Environmental Concentration for the Use of Tau-Fluvalinate for Apiary Uses, Carrots for Seed (24-C SLNs), Building Perimeters, Nurseries, Ornamentals, Indoor Landscapes and Honey for the Human Health Drinking Water Risk Assessment.* D304067; M. Corbin; February 3, 2005

Additional Reference Documents

2. *Tau-fluvalinate Use Closure Memorandum*. K. Rothwell; October 21, 2004
3. *Tau-fluvalinate: Response to Registrant's Error Comments on EPA's Preliminary Risk Assessment for the Reregistration Eligibility Decision for Tau-fluvalinate.* D318467; S. Stanton; June 26, 2005

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

MRID#	Citation
72918	Baroid (19??) Efficacy Data (percent Required for Inhibition): Surflo-B18. (Unpublished study received Sep 27, 1972 under 17664-1; CDL:226770-B)
76684	Reuter, S. (1979) Purity Determination of Technical Fluvalinate. Method no. 146-1179-0AR dated Sep 1, 1979. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070093-C)
76685	Reuter, S. (1980) Purity Determination of Technical Fluvalinate by HPLC Internal Standard. Method no. 149-0380-0AR dated Mar 13, 1980. (Unpublished study received May 13, 1981 under 20954-EX- 1; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070093-D)
76691	Staiger, L.E.; Milligan, L.E.; Quistad, G.B.; et al. (1979) Hydrolytic Stability of Fluvalinate. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Al- to, Calif.; CDL:070094-A)
76692	Staiger, L.E.; Milligan, L.E.; Quistad, G.B.; et al. (1979) Aerobic Soil Metabolism of Fluvalinate. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070094-B)
77026	Reno, F.E.; Hoberman, A.M.; Mossburg, P.A.; et al. (1980) Pilot Teratology Study in Rats: ZR 3210 Technical: Project No. 777- 129. Final rept. (Unpublished study received May 13, 1981 under 20954-EX-18; prepared by Hazleton Laboratories America, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070097-A)

MRID#	Citation
77027	Hoberman, A.M.; Bristol, K.L.; Durloo, R.S.; et al. (1980) Teratology Study in Rats: ZR-3210 Technical: Project No. 777-130. Final rept. (Unpublished study received May 13, 1981 under 20954- EX-18; prepared by Hazleton Laboratories America, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070097-B)
77047	Misubishi Laboratories (1981) Result of Biological Tests of ZR- 3210: Carp. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070100-G)
77048	Wildlife International, Limited (1980) Final Report: Subacute Feeding--Reproduction Screening Bioassay--Bobwhite Quail: Project No. 102-108. (Unpublished study, including letter dated Aug 21, 1980 from R. Fink to Norma Jean Galiher, received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070100-H)
77049	Wildlife International, Limited (1981) Final Report: One-generation Reproduction Study--Bobwhite Quail: Project No. 102-109. (Unpublished study, including letters dated Oct 10, 1980 and Apr 10, 1981 from J.B. Beavers to Norma Jean Galiher, letter dated Nov 3, 1980 from P.H. Friedman to Norma Galiher, and letter dated Mar 24, 1981 from G. Milad to Norma Galiher, received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070100-I)
77050	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: One-generation Reproduction Study--Mallard Duck: Project No. 102-110. (Unpublished study, including letters dated Oct 10, 1980 and Apr 10, 1981 from J.B. Beavers to Norma Jean Galiher, letter dated Nov 3, 1980 from P.H. Friedman to Norma Galiher, and letter dated Mar 24, 1981 from G. Milad to Norma Galiher, received May 13, 1981 under 20954-EX-18; prepared by Wildlife International, Ltd., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070100-J)
77052	Atkins, L. (1981) Field Trials on Cotton and Alfalfa and Foliage Residue Trials To Assess Toxicity to Honeybees: Mavrik 2E. Final rept. (Unpublished study received May 13, 1981 under 20954-EX-18; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070100-L)
79947	Dean, W.P.; Kalman, E.; Myer, J.; et al. (1979) Acute Oral Toxicity (LD50) Study in Rats: 322-033. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by International Re- search and Development Corp., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-B)
79958	Rushbrook, C.J.; Jorgenson, T.A. (1979) Acute Toxicity Studies of ZR-3210 2E Emulsifiable Concentrate: Acute Oral Toxicity--Rat; Acute Dermal Toxicity--Rabbit; Skin Irritation--Rabbit; Eye Irritation--Rabbit: SRI Project LSC-7182. (Unpublished study received Nov 27, 1979 under 20954-EX-13; prepared by SRI International, submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 241388-O)
79960	Buccafusco, R.J. (1979) Acute Toxicity of ZR-3210 Technical to the Water Flea (*Daphnia magna*) in Dilution Water Buffered to pH 6.5: Report #BW-79-9-534. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by EG & G, Bionomics, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-Q)
79961	Buccafusco, R.J.; Ziencina, M. (1979) Acute Toxicity of ZR-3210 Technical to Rainbow Trout (*Salmo gairdneri*) in Dilution Water Buffered to pH 6.5: Report #BW-79-9-535. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by EG & G, Bionomics, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-R)
79962	Buccafusco, R.J.; Stiefel, C. (1979) Acute Toxicity of ZR-3210 Technical to Bluegill (*Lepomis macrochirus*) in Dilution Water Buffered to pH 6.5: Report #BW-79-9-533. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by EG & G, Bionomics, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-S)

MRID#	Citation
79963	Atkins, E.L. (1979) Letter sent to Brooks Bauer dated Oct 15, 1979 Summary sheets and dosage-mortality curves for ZR-3210 (pyrethroid) and permethrin. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by Univ. of California--Riverside, Citrus Research Center and Agricultural Experiment Station, Dept. of Entomology, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-T)
79964	Fink, R.; Beavers, J.B.; Grimes, J.; et al. (1979) Final Report: Eight-day Dietary LC50--Bobwhite Quail: Project No. 102-105. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by Wildlife International Ltd. and Washington College, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-V)
79965	Fink, R.; Beavers, J.B. (1979) Final Report: Eight-day Dietary LC50--Mallard Duck: Project No. 102-106. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; prepared by Wildlife International Ltd., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-W)
79966	Kious, C. (1979) Letter sent to Keith S. Pike dated Aug 28, 1979: Small scale bee poisoning tests with honey bee. (Unpublished study, including letter dated Sep 21, 1979 from K.S. Pike to Brooks, received Nov 27, 1979 under 20954-EX-13; prepared by Washington State Univ., Irrigated Agriculture Research and Extension Center, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-X)
83757	Staiger, L.E.; Milligan, L.E.; Quistad, G.B.; et al. (1979) Photodegradation of Fluvalinate. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070094-C)
83757	Staiger, L.E.; Milligan, L.E.; Quistad, G.B.; et al. (1979) Photodegradation of Fluvalinate. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070094-C)
85444	Fink, R.; Beavers, J.B.; Grimes, J.; et al. (1979) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 102-107. (Unpublished study, including letter dated Oct 10, 1979 from N.J. Galiher to File, received Nov 27, 1979 under 20954-EX-13; pre- pared by Wildlife International Ltd. and Washington College, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:241388-U)
94100	Hansen, K.L.; Hewett, T.A.; Beck, L.S.; et al. (1981) Comparative Acute Oral LD50 Toxicity Study: Racemic ZR-3210 Technical: Project No. 1654-D. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Elars Bioresearch Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070660-B)
94102	Hansen, K.L.; Hewett, T.A.; Beck, L.S.; et al. (1981) Comparative Acute Oral LDI50^ Toxicity Study: Half-resolved ZR-3210 Technical: Project No. 1654-D. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Elars Bioresearch Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070661-B)
94103	Rushbrook, C.J.; Jorgensen, T.A. (1980) Acute Toxicity Studies of ZTS-0017--a New Formulation of ZR-3210: Acute Oral Toxicity (LD50) of ZTS-0017--Rat; Acute Oral Toxicity (LD50) of ZTS-0017--Mouse: Project LSC-7182, Compound Report No. 26. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by SRI International, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070661-C)
94103	Rushbrook, C.J.; Jorgensen, T.A. (1980) Acute Toxicity Studies of ZTS-0017--a New Formulation of ZR-3210: Acute Oral Toxicity (LD50) of ZTS-0017--Rat; Acute Oral Toxicity (LD50) of ZTS-0017--Mouse: Project LSC-7182, Compound Report No. 26. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by SRI International, submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070661-C)
94105	Mecler, F.J. (1981) 14 Day Range Finding Study in Mice: ZR3210 Half Resolved Fluvalinate and ZR3210 Racemic Fluvalinate: LBI Project No. 22070. Rev. final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070661-E)

MRID#	Citation
94109	Lang, P.L.; Brewer, L.; Kopplin, J.R.; et al. (1981) 13-week Dietary Toxicity Study in Rats with Half-resolved ZR-3210 Technical (Fluvalinate): 322-047. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by International Research and Development Corp., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070659-B)
94111	Wolfe, G.W.; Phipps, R.B.; Durloo, R.S. (1981) Pilot Teratology Study in Rabbits: Half-resolved ZR-3210 Technical (Fluvalinate): Project No. 777-136. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Hazleton Laboratories America, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070663-B)
94112	Wolfe, G.W.; Pruett, D.K.; Durloo, R.S. (1981) Rabbit Teratology Study: Half-resolved ZR-3210 Technical (Fluvalinate): Project No. 777-137. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Hazleton Laboratories America, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070663-C)
94112	Wolfe, G.W.; Pruett, D.K.; Durloo, R.S. (1981) Rabbit Teratology Study: Half-resolved ZR-3210 Technical (Fluvalinate): Project No. 777-137. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Hazleton Laboratories America, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070663-C)
94113	Goldsmith, L.A.; Weir, R.J. (1981) Thirteen Week Dietary Toxicity Study in Mice with Half-resolved ZR 3210 Technical (Fluvalinate): Project No. 22088. Final rept. Includes method no. 01-22088 dated Jun 5, 1981 and method dated Dec 18, 1980. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070663-D; 070664)
94113	Goldsmith, L.A.; Weir, R.J. (1981) Thirteen Week Dietary Toxicity Study in Mice with Half-resolved ZR 3210 Technical (Fluvalinate): Project No. 22088. Final rept. Includes method no. 01-22088 dated Jun 5, 1981 and method dated Dec 18, 1980. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070663-D; 070664)
94115	Hansen, R.L.; Hewett, T.A.; Beck, L.S.; et al. (1981) Subchronic 21-day Dermal Toxicity Study: ZR 3210 Technical: Project No. 1675-F. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Elars Bioresearch Laboratories, Inc. and Westpath Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070664-B)
94116	Jagannath, D.R.; Goode, S. (1980) Mutagenicity Evaluation of ZR 3210 ZTS 0016 in the Ames salmonella Microsome Plate Test: LBI Project No. 20988. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070664-C)
94117	Rundell, J.O.; Guntakatta, M. (1980) Evaluation of ZR 3210 Technical (ZTS-0016) in the in vitro~Transformation of Balb/3T3 Cells Assay: LBI Project No. 20992. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070664-D)
94118	Rundell, J.O.; Guntakatta, M. (1980) Evaluation of ZR 3210 Technical (ZTS-0016) in the in vitro Transformation of Balb/3T3 Cells Assay with Activation by Primary Rat Hepatocytes: LBI Project No. 20992. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Litton Bionetics, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070664-E)
94119	Mayhew, D.A.; Abbott, L.; Altringer, L.; et al. (1981) Acute Oral Toxicity Study in Albino Rats with Mavrik^(R)I 2E ZPA 1457: WIL- 80203. Final rept. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by WIL Research Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070664-F)
94596	Forbis, A.D.; Boudreau, P.; McKee, M.J.; et al. (1981) Dynamic Acute Toxicity of Fluvalinate to Bluegill Sunfish (*Lepomis macrochirus*): Flow-through Acute Toxicity Final Report #27157. (Unpublished study, including letters dated May 18, 1981 from P. Boudreau to Norma Jean Galiher and Jun 11, 1981 from P. Boudreau and A.D. Forbis to Norma Jean Galiher, received Feb 4, 1982 under 20954-19; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070665-E)

MRID#	Citation
94597	Boudreau, P.; Forbis, A.D. (1981) Acute Toxicity of Half-resolved Fluvalinate Technical to *Daphnia magna*: Static Acute Bioassay Report #27723. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070665-F)
94598	Griffen, J.; Thompson, C.M. (1981) Acute Toxicity of Half-resolved Fluvalinate Technical to Rainbow Trout (*Salmo gairdneri*): Static Acute Bioassay Report #27722. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Analytical Bio- Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070665-G)
94599	Griffen, J.; Thompson, C.M. (1981) Acute Toxicity of Half-resolved Fluvalinate Technical to Bluegill Sunfish (*Lepomis macro chirus*): Static Acute Bioassay Report #27721. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070665-H)
94600	Griffen, J.; Thompson, C.M. (1981) Acute Toxicity of Half-resolved Fluvalinate Technical to Bluegill Sunfish (*Lepomis machro chirus)* Using a Sandy Loam Soil Substrate: Static Acute Bio-assay Report #28106. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL: 070665-I)
94601	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Eight-day Dietary LC50--Bobwhite Quail: Half-resolved ZR-3210 Technical: Project No. 102-111. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Wildlife International Ltd., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070666-A)
94603	Boudreau, P.; Forbis, A.D. (1981) Acute Toxicity of Mavrik 2E Half- resolved to *Daphnia magna*: Static Acute Bioassay Report #27726. (Unpublished study, including letter dated Jul 1, 1981 from J.P. Brown to Alan Forbis, received Feb 4, 1982 under 20954-19; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070666-C)
94604	Thompson, C.M.; Griffen, J. (1981) Acute Toxicity of Mavrik 2E Half-resolved to Rainbow Trout (*Salmo gairdneri*): Static Acute Bioassay Report #27725. (Unpublished study, including letter dated Jul 1, 1981 from J.P. Brown to Alan Forbis, received Feb 4, 1982 under 20954-19; prepared by Analytical Bio- Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070666-D)
94605	Griffen, J.; Thompson, C.M. (1981) Acute Toxicity of Mavrik 2E Half-resolved to Bluegill Sunfish (*Lepomis machrochirus*): Static Acute Bioassay Report #27724. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Analytical Bio- Chemistry Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070666-E)
94889	International Research and Development Corporation (1981) Two Year Dietary Toxicity and Oncogenicity Study in Mice with Half- resolved ZR-3210 Technical (Fluvalinate): Study No. 322-048. (Unpublished study, including letter dated Nov 20, 1981 from N.J. Galiher to Franklin D.R. Gee, received Dec 2, 1981 under 20954-EX-19; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070515-A)
104671	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Acute Oral LD50--Bobwhite Quail: Half-resolved ZR-3210 Technical: Project No. 102-113. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Wildlife International Ltd., submitted by Zoecon Corp, Palo Alto, Calif.; CDL:070665-J)
104672	Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1981) Final Report: Eight-day Dietary LC50--Mallard Duck: Half-resolved ZR-3210 Technical: Project No. 102-112. (Unpublished study received Feb 4, 1982 under 20954-19; prepared by Wildlife International Ltd., submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070665-K)
116648	Zoecon Corp. (1982) Summary of Bee Toxicity Data for Fluvalinate Technical and Mavrik 2E Insecticide. (Compilation; unpublished study received Oct 20, 1982 under 20954-EX-19; CDL:248634-A)

MRID#	Citation
118398	Hansen, K.; Billings, B.; Hepler, D.; et al. (1982) Acute Oral Toxicity Study: Mavrik 2F (Half-resolved): Project No. 1767-D. Final rept. (Unpublished study received Nov 10, 1982 under 20954- 123; prepared by Elars Bioresearch Laboratories, Inc., submitted by Zoecon Corp., Palo Alto, CA; CDL:248822-C)
126102	Staiger, L.; Quistad, G. (1982) Degradation and Movement of Fluvalinate in Soil. (Unpublished study received Feb 8, 1983 under 20954-115; submitted by Zoecon Corp., Palo Alto, CA; CDL:249513-B)
126102	Staiger, L.; Quistad, G. (1982) Degradation and Movement of Fluvalinate in Soil. (Unpublished study received Feb 8, 1983 under 20954-115; submitted by Zoecon Corp., Palo Alto, CA; CDL:249513-B)
126102	Staiger, L.; Quistad, G. (1982) Degradation and Movement of Fluvalinate in Soil. (Unpublished study received Feb 8, 1983 under 20954-115; submitted by Zoecon Corp., Palo Alto, CA; CDL:249513-B)
126175	Goldenthal, E.; Lang, P. (1982) Pilot Study to Examine Skin Lesion Etiology: Half-resolved ZR-3210 Tech: 322-051. (Unpublished study received Mar 1, 1983 under 20954-EX-19; prepared by International Research and Development Corp., submitted by Zoecon Corp., Palo Alto, CA; CDL:249604-C)
126180	Staiger, L.; Quistad, G. (1982) Metabolism of 14C Fluvalinate Applied Dermally on Rats: Report No. 3760-1A-06-82. (Unpublished study received Mar 1, 1983 under 20954-EX-19; submitted by Zoecon Corp., Palo Alto, CA; CDL:249604-H)
127994	Ward, S.; Brown, J. (1982) Acute Toxicity of Half-resolved Fluvalinate Technical to *Mysid Shrimp* ...: Report No. BP-82-4-28. (Unpublished study received May 9, 1983 under 20954-EX-19; pre- pared by EG & G Bionomics, submitted by Zoecon Corp., Palo Alto, CA; CDL:250141-B)
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45769201	Doran, T. (2002) Response to "Fluvalinate: Status of Studies Proposed for Support of Reregistration", (Internal EPA Memo, Dated April 3, 2002 from Kylie Rothwell, Special Review and Reregistration Division): Lab Project Number: 0201-WE. Unpublished study prepared by North Coast RegSci, LLC. 12 p.
45769202	Ekdawi, M. (1991) Fluvalinate--Addendum to a Previous Hydrolysis Study: Lab Project Number: 480605: 14: 480605-14. Unpublished study prepared by Sandoz Crop Protection Corporation. 32 p.
45769202	Ekdawi, M. (1991) Fluvalinate--Addendum to a Previous Hydrolysis Study: Lab Project Number: 480605: 14: 480605-14. Unpublished study prepared by Sandoz Crop Protection Corporation. 32 p.
45769203	Yu, C. (1991) Addendum to Photodegradation Study of Fluvalinate in Aqueous Solution: Addendum to Final Report: Lab Project Number: 480605: 9A: DP300681. Unpublished study prepared by Sandoz Crop Protection Corporation. 9 p.
45769203	Yu, C. (1991) Addendum to Photodegradation Study of Fluvalinate in Aqueous Solution: Addendum to Final Report: Lab Project Number: 480605: 9A: DP300681. Unpublished study prepared by Sandoz Crop Protection Corporation. 9 p.
45769204	Skinner, W.; Dennis, P. (1991) Adsorption-Desorption of Fluvalinate in Soil: Final Report: Lab Project Number: 480605: 16: DP-300687. Unpublished study prepared by Sandoz Crop Protection Corporation. 75 p.

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45769204	Skinner, W.; Dennis, P. (1991) Adsorption-Desorption of Fluvalinate in Soil: Final Report: Lab Project Number: 480605: 16: DP-300687. Unpublished study prepared by Sandoz Crop Protection Corporation. 75 p.
92069001	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00085444. Technical Fluvalinate Acute LD50 Test-Bobwhite Quail: Project 102-107.: 13 p.
92069002	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00104671. Fluvalinate Half Resolved Acute LD50 Test--Bobwhite Quail: Project 102-113. Prepared by WILDLIFE INTERNATIONAL. 12 p.
92069003	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00079964. Technical Fluvalinate: 8 Day Dietary LC50--Bobwhite Quail: Project 102-105.: 13 p.
92069004	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094601. Fluvalinate Half Resolved: 8 Day Dietary LC50--Bobwhite Quail: Project 102-111.: 14 p
92069005	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00079965. Fluvalinate Technical: Eight Day Dietary LC50--Mallard Duck: Project 102-106.: 13 p.
92069006	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00104672. Fluvalinate Half Resolved: Eight Day Dietary--Mallard Duck: Project 102-112.: 14 p.
92069007	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00149824. Fluvalinate Technical: One Generation Reproduction Study--Bobwhite Quail: Project 102-109.: 21 p
92069008	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00149825. Fluvalinate Technical: One Generation Reproduction Study--Mallard Ducks: Project 102-110.: 18 p.
92069009	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094599. Fluvalinate Half Resolved: Acute Toxicity--Bluegill Sunfish: Project 27721.: 11 p.
92069010	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094605. MAVRIK 2 E Acute Toxicity--Bluegill Sunfish: Project 27724.: 11 p.
92069011	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00154543. MAVRIK 2F Acute Toxicity--Bluegill Sunfish: Project BW-83-11-1511.: 12 p.
92069012	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094598. Fluvalinate Half Resolved: Acute Toxicity--Rainbow Trout: Project 27722.: 12 p
92069013	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094604. MAVRIK 2 E Acute Toxicity--Rainbow Trout--Project 27725.: 11 p.
92069014	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00154544. MAVRIK 2 F Acute Toxicity--Rainbow Trout: Project BW-83-11-1504.: 12 p.
92069015	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094597. Fluvalinate Half Resolved: Acute Toxicity--*Daphnia magna*: Project 27723.: 12 p.

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92069016	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00094603. MAVRIK 2 E Acute Toxicity--*Daphnia magna*: Project 27726.: 12 p
92069017	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00154546. MAVRIK 2 F Acute Toxicity--*Daphnia magna*: Project BW-83-11-1503.: 12 p.
92069018	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00155450. Fluvalinate Half Resolved: Acute Toxicity--Sheepshead Minnow: Project BW-85-12-1897.: 12 p.
92069019	Levin, A. (1990) Sandoz Crop Protection Corporation Phase 3 Summary of 00160767. Half-resolved Fluvalinate Technical: Acute Toxicity--Eastern Oyster Embryo/Larvae: Project BW-86-6-2058.: 12 p.

Appendix E. Generic Data Call-In (GDCI)

Appendix F. Product Data Call-In (PDCI)

Appendix G. EPA's Batching of Tau-fluvalinate Products for Meeting Toxicity Data Requirements for Reregistration

The Agency has determined that batching is not required; therefore, each product-specific data requirement should be addressed for each product separately.

Appendix H. List of Registrants Sent this Data Call-In notice

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173

Appendix I. List of Available Related Documents and Electronically Available Documents

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program--Storage and Disposal Statements
    b. 84-1 Clarification of Label Improvement Program
    c. 86-5 Standard Format for Data Submitted under FIFRA
    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

    Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
    b. EPA Form No. 8570-4, Confidential Statement of Formula
    c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The documents listed in Appendix C are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents may also be obtained by contacting the person listed on the respective Chemical Status Sheet.