United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-99-012 September 1999

Reregistration Eligibility Decision (RED)

Sulfotepp

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case which includes the active ingredient sulfotepp. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative **Robbi Farrell (703) 308-8065.**

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

INSTRUCTIONS FOR RESPONDING TO THE REGISTRATION ELIGIBILITY DECISION (RED)

You may submit comments by mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify the docket control number in the subject line on the first page of your response. The docket control number is found in the **Federal Register** notice announcing the availability of this RED. The case number for this RED is **OPP-34146B.**

Do not submit any information that you consider to be Confidential Business Information (CBI). You may claim information that you submit to EPA in response to this RED as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under "FOR FURTHER INFORMATION CONTACT" in the **Federal Register** notice announcing the availability of this RED.

Submission Formats

Paper**:** 3 copies

Disk**:** Electronic submissions are accepted in WordPerfect 6.1/8.0 or ASCII file format. Avoid the use of special characters and any form of encryption.

E-Mail**:** Send to "opp-docket@epa.gov." Electronic submissions are accepted in WordPerfect 6.1/8.0 or ASCII file format. Avoid the use of special characters and any form of encryption. Electronic comments may also be filed online at many Federal Depository Libraries.

Delivery

Mail**:** Submit your written comments or disk to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person or by courier**:** Deliver your written comments or disk to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

REREGISTRATION ELIGIBILITY DECISION

Sulfotepp

LIST A

CASE 0338

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION PROGRAM

Table of Contents

List of Acronyms

a.i.	Active Ingredient
Agency	U.S. Environmental Protection Agency
EPA	U.S. Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act of 1996
HED	Health Effects Division
MOE	Margin of Exposure
MP	Manufacturing Use Product
MRID	Master Record Identification Number
MSHA	Mine Safety and Health Administration
NIOSH	National Institute of Occupational Safety and Health
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
OVR	Organic-Vapor-Removing
PHED	Pesticide Handlers Exposure Database
PPE	Personal Protective Equipment
PR	Pesticide Reregistration
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
SCBA	Self-Contained Breathing Apparatus
TRAC	Tolerance Reassessment Advisory Committee
USDA	U.S. Department of Agriculture
WPS	Worker Protection Standard

Executive Summary

This document and the process used to develop it are the results of a pilot process to facilitate greater public involvement and participation in the U.S. Environmental Protection Agency (EPA or the Agency) reregistration decisions on organophosphate pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The idea of using such an open process was discussed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body which is advising the Agency on implementing the new provisions of the FQPA. The organophosphate pesticides are the pilot project for this initiative.

EPA has completed its review of public comments, and has revised the risk assessment and developed risk management proposals for sulfotepp. The risk assessment is based on review of the available data supporting the use patterns of currently registered products and new information received during the 60-day public comment period. After considering the risk identified in the assessment associated with the use of sulfotepp, EPA has developed a reregistration eligibility decision for sulfotepp.

Sulfotepp is a restricted use, organophosphate insecticide/acaricide used on greenhouse ornamentals, including carnations, chrysanthemums, geraniums, gladiolus, poinsettias, snapdragons, azaleas, and roses. Sulfotepp is used to control whitefly prior to shipment of plants, which is important for ensuring that plants are pest-free when shipped as mandated by intrastate, interstate, and international requirements. Sulfotepp was first registered in the U.S. in 1951. The available usage data suggests that approximately 5,800 pounds of active ingredient (a.i.) are applied per year. However, use has declined recently to approximately1,000-3,000 pounds a.i. per year, primarily due to increased use of imidacloprid as a non-organophosphate alternative for whitefly treatment in poinsettias.

EPA's human health risk assessment for sulfotepp indicates that there is concern for workers during application as well as in postapplication tasks such as watering, cutting, harvesting, sorting, and packing. Because proper use of sulfotepp requires that the greenhouse in which it is used be sealed, ecological risks are not of concern. Sulfotepp is not used on any food and poses no dietary risk. Current labels, however, do not prohibit its use in residential greenhouses by certified applicators. There are reported incidents in residential areas resulting from leakage of sulfotepp from treated commercial greenhouses.

The database for sulfotepp is incomplete. The registrants have been unable to support the data requirements for reregistration and have signed an agreement for voluntary cancellation. The cancellation will take effect September 30, 2002, with an existing stocks provision in effect until September 30, 2004. The registrants have agreed to request interim label amendments to address risks of concern posed by the use of sulfotepp. For occupational risk, labels must be amended to

increase the level of personal protective equipment for workers, specify the sequence of application procedures, strengthen ventilation requirements and reentry intervals for postapplication workers, restrict use to commercial greenhouses, and restrict use in greenhouses with attached structures. To address risk to bystanders outside of treated structures, a 100-foot buffer zone around a greenhouse where sulfotepp is applied is required.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether 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 both FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), but does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document and the process used to develop it are the results of a pilot process to facilitate greater public involvement and participation in the reregistration decisions on organophosphate pesticides. As part of the Agency's effort to involve the public in the implementation of FQPA, the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The idea of using such an open process was discussed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body which is advising the Agency on implementing the new provisions of the FQPA. The organophosphate pesticides are the pilot project for this initiative.

This document presents the Agency's risk management decision for sulfotepp. The Agency is requesting public comments on this Reregistration Eligibility Document (RED) for sulfotepp during a 60-day time period, as announced in a Notice of Availability published in the *Federal Register*.

This document consists of five sections. Section I contains the regulatory framework for reregistration as well as a description of the process developed by TRAC for public comment on science policy issues for organophosphate pesticides. Section II provides a profile of the usage of the chemical. Section III gives an overview of the human health risk assessment resulting from public comments and other information. Section IV presents the Agency's risk management/reregistration eligibility decision. Section V summarizes required label changes based on the risk mitigation measures outlined in Section IV. Finally, an Appendix lists all related documents and how to access them. The complete risk assessment is not included in this document, but is available on the Agency's web page (www.epa.gov/oppsrrd1/op), and in the Public Docket.

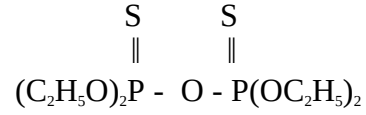
II. CHEMICAL OVERVIEW

A. Regulatory History

Sulfotepp was first registered in the United States in 1951 for use as an insecticide/ acaricide. A Registration Standard was issued in September, 1988. Data Call-Ins (DCIs) issued in June 1991, August 1993, and October 1995 required additional data for sulfotepp. Currently, 2 sulfotepp products are registered.

B. Chemical Identification

- **Chemical Structure:**



- **Common Name:** Sulfotepp
- **Chemical Name:** Tetraethyl thiodiphosphate (0,0,0,0-tetraethyl dithiopyrophosphate)
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 3689-24-5
- **OPP Chemical Code:** 079501
- **Empirical Formula:** $C_8H_{20}O_5P_2S_2$
- **Molecular Weight:** 322.3
- **Trade and Other Names:** Bladafum, Sulfotep
- **Technical Registrants:** Plant Products Corporation (8241-11) and Fuller System, Inc. (1327-39)
- **Special Local Need 24(c) Registrant:** Glad-A-Way Gardens (8241-4-AA; CA89005900)

C. Use Profile

The following information is based on the currently registered uses of sulfotepp with an overview of use sites and application methods.

Type of Pesticide: Acaricide/Insecticide

Summary of Use Sites:

Food: None.

Residential: None.

Public Health: None.

Other Nonfood: Products containing sulfotepp are intended for indoor (greenhouse) use only, by certified commercial applicators. Sulfotepp-containing products may be used on carnations, chrysanthemums, geraniums, gladiolus, poinsettias, snapdragons, azaleas, and roses in bloom, as well as gladiolus tissue culture material, bulblets and corms.

Target Pests: Red spider mites, thrips, whiteflies, aphids, soft-brown scale, mealybugs.

Formulation Types Registered: Plant Products Corp. formulates and distributes the end-use product Plantfume 103® (8241-10). The special local need permit issued by the State of California is associated with Plantfume 103®. Fuller System, Inc. formulates the end-use product Fulex Dithio Smoke® (1327-38). End-use product is formulated as impregnated material in smoke generators (canisters) containing 14-15% active ingredient.

Method and Rates of Application:

Equipment: Smoke-generating canister (containing product), sparkler and ignitor.

Method and Rate: Sulfotepp is applied by inserting the sparkler provided into the product container and igniting the sparkler. A smoke containing the active ingredient is dispersed from the container upon ignition. Maximum application rate is .0033 pound of active ingredient (a.i.) per 1,000 cubic feet.

Timing: Sulfotepp may be applied every three days until the greenhouse is pest-free.

Use Classification: Restricted-use for all use sites.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for use of sulfotepp. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The available usage data suggests that approximately 5,800 pounds a.i. of sulfotepp were applied per year in the period 1991 to 1994. However, use has declined in recent years to approximately 1,000-3,000 pounds a.i. per year, primarily due to emergence of imidacloprid as a non-organophosphate alternative for mid-season use.

E. Benefits of Sulfotepp

Sulfotepp remains the most effective treatment for whitefly on ornamentals at the end of the growing season. As a smoke, it effectively penetrates areas where eggs are deposited. In addition, the smoke does not result in discoloration of foliage as would a wet application. This makes it attractive for use just before shipment of plants from the greenhouse. Sulfotepp also plays a role in integrated pest management. (Sutherland and Wise, 1997)

III. OVERVIEW OF SULFOTEPP RISK ASSESSMENT

Following is a summary of EPA's human health risk findings and conclusions for the organophosphate pesticide sulfotepp, as fully presented in the document, "Human Health Risk Assessment: Sulfotepp," dated June 30, 1999. This risk assessment for sulfotepp was placed into the Public Docket on June 30, 1999, opening a 60-day public comment period on risk management for this pesticide. The risk assessment presented here forms the basis of the mitigation measures agreed to by the Agency and the registrants, and for the Agency's reregistration eligibility decision for sulfotepp.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessment for sulfotepp in September, 1998 (Phase 2 of the TRAC process). No significant substantive comments were received that resulted in major revisions to the human health risk assessment.

1. Dietary and Drinking Water Risk

Sulfotepp has no food uses, and is used in sealed greenhouses only. Therefore, dietary and drinking water exposures are not expected.

2. Residential Risk

There are currently no registered homeowner products for sulfotepp. However, current labels do not prohibit application in residential greenhouses by certified commercial applicators. The Agency believes this represents a potential risk to residents. In addition, residential (bystander) exposures have occurred when sulfotepp has leaked from treated commercial greenhouses and exposed bystanders in nearby residential areas. The Agency and registrants have agreed to label amendments that will address both of these scenarios for potential residential risk.

3. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, or applying a pesticide, and by postapplication activities in treated areas. Occupational handlers of sulfotepp include certified commercial applicators who apply sulfotepp and re-enter a greenhouse to operate ventilation equipment. Postapplication workers include those who water, pack, prepare for shipment or otherwise handle treated plants. Occupational risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Effect Level (NOEL). For workers entering a treated site, Restricted Entry Intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to reenter.

a. Factors Forming the Basis for Occupational Handler Risk Assessments

No guideline or otherwise acceptable chemical-specific handler exposure data have been submitted to the Agency. Available data in the Pesticide Handlers Exposure Database (PHED) do not reflect the use patterns of sulfotepp. This occupational risk assessment was based on the limited toxicology data submitted, published sources, and on assumptions drawn from similar acutely toxic organophosphate pesticides.

Due to the significant lack of data, sulfotepp has not been reviewed by the Agency's Health Effects Division (HED) Hazard Identification Committee. This Committee evaluates toxicological data for adequacy, establishes endpoints and doses for risk assessment, and most significantly for sulfotepp, establishes MOEs for risk assessment and regulatory purposes. An MOE of 100 or greater is generally considered adequate by the Agency for both the short- and intermediate-term dermal and inhalation risk assessments. This includes a 10-fold safety factor for interspecies variability, and a 10-fold safety factor for intraspecies variability. When data gaps exist, MOEs much higher than 100 are typically used to account for greater uncertainty. Due to the lack of acceptable data for sulfotepp, HED has not determined an MOE that is considered adequate.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protective equipment (PPE). The Agency typically evaluates all exposures with

minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario. If MOEs from the lowest tier are less than 100, MOEs are calculated using increasing levels of risk mitigation [PPE and engineering controls (EC)]. The **current labels** for sulfotepp require handlers to wear a respirator, long pants, long-sleeved shirt, socks, and shoes. The levels of protection that formed the basis for calculations of exposure from sulfotepp activities include:

Baseline: Long-sleeved shirt, long pants, socks and shoes
Minimum PPE: Baseline scenario + half-face or full-face organic-vapor-removing (OVR) respirator
Maximum PPE: Baseline scenario + self-contained breathing apparatus (SCBA)

The inhalation NOEL was established at 1.94 mg/m^3, based on a subchronic rat inhalation study (Kimmerle and Klimmer, 1974). The endpoint is based on significant inhibition of plasma and red blood cell cholinesterase.

The NOEL of 0.014 mg a.i./kg/day from a subchronic dog feeding study (Hoffman and Schilde, 1975) was used for the intermediate-term dermal endpoint. The endpoint is based on inhibition of plasma and red blood cell cholinesterase.

Due to the lack of sulfotepp dermal and oral toxicity data, the short-term dermal NOEL was established by using the ratio of the short- and intermediate-term NOELs of similar toxic organophosphate pesticides, and applying it to the intermediate-term NOEL for sulfotepp. The Agency assumes 100% dermal absorption for sulfotepp, based on data showing that sulfotepp penetrates the skin in amounts sufficient to induce systemic toxicity. The short- term dermal NOEL for sulfotepp was, therefore, estimated to be 0.14 mg a.i./kg/day.

b. Occupational Risk Characterization

i. Applicator Scenarios and Risks

Based on the use patterns, two pesticide handler scenarios were identified: opening/lighting of canisters; and reentering fumigated greenhouses to open vents and dispose of canisters. Note that reentry to open vents is considered a handler task under the Worker Protection Standard (WPS). Both handler scenarios are assumed to involve only short-term exposure. The same individual could perform both of these tasks; however, this assessment does not combine the risk from these two scenarios.

For handlers, dermal exposures are assumed to be small, infrequent and of short duration relative to exposures from inhalation. Potential dermal exposure is limited to possible contact with the sulfotepp formulated product while opening the canisters and inserting the sparkler, in the event of an accidental spill, and possible contact with residue on the outside of a spent

canister. Because these exposures are expected to be negligible when compared with the estimated inhalation exposure and the potentially high air concentrations of sulfotepp during handling activities, only inhalation exposures and risks were estimated for handlers.

Two air concentrations (exposure levels) were used in the risk assessment. The first, 2.7 mg a.i./m^3, was taken from a study by Williams et al. (1980) in which a greenhouse having a volume of 450 m^3 was fumigated using two cans each containing 11 g formulated product. Air concentration levels were measured approximately four hours after the start of fumigation and before opening the vents to aerate. This level, 2.7 mg a.i./m^3, was selected to represent a reasonable level possibly encountered by applicators igniting the canisters or persons entering to activate the ventilation system. The second, 52.5 mg a.i./m^3, was estimated to be the maximum air concentration possible, assuming that during fumigation all of the active ingredient in the canister enters the greenhouse air at the label application rate and is uniformly distributed throughout the greenhouse. Inhalation risks are summarized in Table 1 below.

Table 1. Occupational Handlers' Inhalation Risks from Sulfotepp

Level of Protection	Air Concentration (mg ai/m^3)	Inhalation MOE (0.5 hr/1 hr)
Baseline (no respirator)	52.5	0.3/0.2
	2.7	6/3
Half-face OVR respirator	52.5	3/2
	2.7	65/32
Full-face OVR respirator	52.5	17/8
	2.7	320/160
SCBA	52.5	3,300/1,700
	2.7	65,000/32,000

ii. Postapplication Scenarios and Risk

Two postapplication scenarios were identified: entry to perform watering or other routine low exposure tasks and entry to perform harvesting, transferring, or other high exposure tasks.

For postapplication exposure, both dermal and inhalation exposures were assessed. Based on the Williams study referenced above, inhalation exposures were calculated from air concentrations after ventilation (including off-gassing after watering), monitored continuously for 48 hours and air concentrations measured 18 days after fumigation.

Short- and intermediate-term risks were calculated. Intermediate-term risks were assessed because, in practice, two to three applications at three-day intervals are possible and workers may reasonably be expected to have daily exposures for more than a week, depending on how rapidly sulfotepp dissipates. To estimate the level of dermal exposure, the amount of residue available on the treated foliage was obtained from a study conducted in 1986 (CDFA, 1987). The levels from three sites (two poinsettia sites and one geranium site) were used for risk assessment purposes. In lieu of chemical-specific data showing how readily residues transfer from foliage to workers who contact the foliage, the Agency applies a standard transfer coefficient for low and high dermal exposure activities. Standard values are determined based on the limited data that are available to the Agency. For sulfotepp, a transfer coefficient of 1,000 was used for low exposure activities, and 10,000 for high exposure activities.

Results indicate that for total risk (combined dermal plus inhalation), short-term MOEs range from 1 for high-exposure activities to 14 for low exposure activities. Intermediate-term MOEs range from 0.3 to 7 (at all air concentration levels for both high and low exposure activities, respectively, up to 38 hours following fumigation). Current labeling allows reentry between two and 24 hours after fumigation, depending on how the greenhouse is ventilated. These MOEs represent a concern for all postapplication scenarios. Total risks for postapplication workers are summarized in Table 2 below.

Table 2. Postapplication Total Risks from Sulfotepp

Exposure Scenario		Total Short-Term MOE	Total Intermediate-Term MOE
Low exposure activity (tending)	15 hours after fumigation	2 - 10	1 - 3
	24 hours after fumigation	2 - 13	2 - 4
	38 hours after fumigation	2 - 14	2 - 7
High exposure activity (harvesting, preparing for shipping)	15 hours after fumigation	1 - 3	0.3
	24 hours after fumigation	2 - 4	0.5 - 0.6
	38 hours after fumigation	2 - 7	0.8 - 1

B. Ecological Effects Risk Assessment

Toxicity data for sulfotepp indicate that it is toxic to wildlife, fish, and aquatic invertebrates. Based on this information, the Agency presumes it is also toxic to birds. However, because sulfotepp is registered for indoor (greenhouse) use only, ecological exposure to sulfotepp is expected to be minimal (Grim, 1999).

IV. RISK MANAGEMENT & REREGISTRATION ELIGIBILITY DECISION

A. Risk Management Considerations

This section describes EPA's decisions for mitigating risks associated with sulfotepp use based on the Agency's human health risk assessment. The risk management decision for sulfotepp has been developed based on careful consideration of the human health risk assessment, apparent benefits, and the public comments received on the preliminary risk assessment. The Agency has also consulted with the registrants, the U.S. Department of Agriculture, and grower groups in developing its risk management decision.

B. Status of the Database for Sulfotepp

The database for sulfotepp is incomplete. Only one toxicity study, a subchronic feeding study in dogs (Hoffman and Schilde, 1975; MRID 43615401), has been determined to be acceptable for regulatory purposes. No acceptable sulfotepp-specific exposure studies have been submitted. Waivers have been granted for two fate studies. A waiver was also granted for

guideline study 133-4 (inhalation passive dosimetry exposure); however, the Agency has since determined that the inhalation data are critical to the occupational risk assessment.

The following data sets are incomplete: product chemistry, acute toxicity, specific organ/tissue toxicity, neurotoxicity, subchronic toxicity, chronic toxicity, general metabolism, and postapplication worker exposure. All outstanding studies are overdue except guideline studies 132-1(a) (foliar residue dissipation), and 133-3 (dermal passive dosimetry exposure), which were due by March 31, 2000. Because the registrants have elected to voluntarily cancel their registrations, these data will not be required.

Using the available data and making conservative assumptions to estimate risk, the Agency was able to estimate handler risk and to develop mitigation measures to address these risks. However, postapplication risk remains a concern. At a minimum, 21-day dermal toxicity, postapplication dermal exposure, postapplication inhalation exposure, and foliar dislodgeable residue dissipation data would have been required if this chemical were to be considered for reregistration.

C. Summary of Remaining Risks from Use of Sulfotepp at Current Label

The limited data available for sulfotepp indicates that risks to workers who apply sulfotepp, enter treated areas to ventilate, and work in treated areas or with treated plants, are of significant concern. Current labeling does not provide adequate protection for workers engaged in application activities. EPA and the registrants have agreed on label amendments for the end-use products that will mitigate these risks for application workers.

Risk to postapplication workers, i.e., workers involved in watering, harvesting, packing and shipping, are of concern to the Agency. As indicated above, short- and intermediate-term MOEs are under 20 for both high and low exposure activities up to 38 hours following fumigation. Current labeling allows reentry between 2 and 24 hours. The Agency and registrants have agreed on label amendments that will partially address these concerns. Reentry intervals which fully address these estimated risks are not practical for growers.

At least two incidents of sulfotepp exposure have been reported in the California Pesticide Illness Surveillance Program, 1982-1995, that resulted from sulfotepp leaking from a treated greenhouse. In one of those cases, eight people in a residential area 200-300 feet away from the treated greenhouse were exposed. Label amendments include a requirement of a buffer zone around treated greenhouses.

D. Risk Management Decision

Risks to applicators have been addressed by mitigation measures outlined below. These measures are reflected in label amendments that have been agreed to by the registrants. Risks to postapplicators cannot be adequately mitigated, and remain a concern to the Agency. The

registrants have signed an agreement for voluntary cancellation with a five-year phase-out. The rationale for this decision is discussed in detail below.

1. Applicator Risk

For applicators, dermal exposure can occur while opening a canister and inserting the sparkler, in the event of an accidential spill, and in case of possible contact with residue on the outside of a spent canister. To mitigate this risk, the registrants have voluntarily agreed to amend labels to require chemical-resistant gloves.

Applicators are at risk for inhalation exposure to sulfotepp during lighting of canisters, and upon reentry to activate ventilation. To manage these risks, the registrants have voluntarily agreed to amend labels as follows:

- In addition to baseline attire of long-sleeved shirt, long pants, shoes, socks, and PPE consisting of chemical-resistant gloves, a full-face respirator will be required for applicators opening five or fewer canisters, OR if exposure will be ten minutes or less from the time the first canister is ignited.

- In addition to baseline attire of long-sleeved shirt, long pants, shoes, socks, and PPE consisting of chemical-resistant gloves, SCBA will be required for applicators opening six or more canisters, OR if exposure will be greater than ten minutes from the time the first canister is ignited.

- Application directions will be amended to minimize potential exposure time by specifying the sequence of steps required to apply the product. Specifically, labels will state explicitly that all canisters shall be in place before the first is ignited. See Table 3 for more detail.

- If circulating fans are used during treatment, the fans may not be turned on until after the applicator(s) has exited the greenhouse.

- An additional person outside of the greenhouse must maintain constant visual or voice contact with any handler who is applying or otherwise handling sulfotepp in a greenhouse. This includes handlers who enter a greenhouse during fumigation to operate ventilation equipment. The person monitoring the sulfotepp handler must have immediate access to the PPE that the fumigant labeling requires for applicators.

2. Postapplicator Risks

Postapplication workers are at risk for dermal exposure during activities such as watering, harvesting, packing and shipping plants. Risks were found to be very high even after 38 hours following fumigation. These estimated risks cannot be adequately mitigated.

Inhalation exposure is a concern for postapplication workers. MOEs range from 2 to16 for all air concentrations measured within 48 hours of fumigation and after initial ventilation. This suggests the possibility of risk to retail customers in a treated commercial greenhouse. The registrants have voluntarily agreed to amend labels to strengthen ventilation criteria and increase reentry intervals, with the following provisions:

- No person, other than a certified applicator wearing PPE as specified above, shall enter a treated structure from the start of application until the following ventilation has occurred: 11 hours with no ventilation followed by (1) five air exchanges; or (2) one hour of mechanical ventilation (fans); or (3) two hours of passive (vents) ventilation.

- Following the initial ventilation period described above, workers may enter a treated structure to perform hand labor tasks for limited provided (1) they work in the sulfotepp-treated area no more than 4 hours in the first 24 hours following application; (2) they work in the sulfotepp-treated area no more than 4 hours in the period 24 hours to 48 hours following aplication; AND (3) for the first 48 hours following application when any worker is present in the treated greenhouse, the greenhouse is ventilated -- continuously or intermittently -- so that within each hour one of the following ventilation criteria has been met: 2 air exchanges or 5 minutes of mechanical (fans) ventilation, or 10 minutes of passive (vents, windows) ventilation.

- Prohibit entry by retail customers for 48 hours after application or until ventilation criteria have been met.

3. Residential and Bystander Risks

Incidents due to leakage from greenhouses treated with sulfotepp indicate that there is some degree of risk to bystanders in proximity to treated structures. In addition, current labels do not prohibit use in residential greenhouses if applied by a certified pesticide applicator. The registrants have voluntarily agreed to label amendments to address these risks as follows:

- Prohibit use in greenhouses with attached structures, unless the greenhouse is entirely sealed off from the attached structure.

- Restrict use to commercial greenhouses only. Use in residential greenhouses or other indoor plant sites is prohibited.

- Prohibit use in any greenhouse that is located within 100 feet in any direction of a residential area (e.g., homes, apartments, schools, playgrounds, recreation areas).

4. Benefit Considerations

The Agency recognizes that sulfotepp fills a specific niche as an end-of-season treatment for whitefly in ornamentals. As a dry smoke, it effectively penetrates the foliage and leaves no discoloration as a wet application would. Sulfotepp also plays a role in integrated pest management. In light of the benefits of sulfotepp to the industry as well as its low volume of use, the Agency agreed to a five-year phase-out of sulfotepp production, distribution, and use. The five-year timeframe is intended to allow growers time to transition to alternatives to sulfotepp before it becomes unavailable.

V. Actions Required of Registrants

Both registrants have been unable to support the data requirements for reregistration and have signed an agreement for voluntary cancellation of the registration of technical grade sulfotepp as well as their end-use products containing sulfotepp. Production of end-use product will cease by September 30, 2002. From October 1, 2002, until September 30, 2004, remaining stocks of sulfotepp products may be sold. After September 30, 2004, it will be unlawful for any sulfotepp product to be sold or used. The registrants have committed to submit by October 8, 1999, a request to revise labels in accordance with Table 3. All sulfotepp products manufactured, sold or distributed will bear the revised labeling within 45 days after the registrants receive the EPA-approved labels.

A. Manufacturing-Use Products

The generic database for sulfotepp is inadequate for regulatory purposes. As a result of the voluntary cancellation, the registrants will not be required to submit the data.

Until the cancellation takes effect, to remain in compliance with FIFRA, manufacturing-use product (MP) labeling must be revised to comply with all current EPA regulations, Pesticide Reregistration (PR) Notices, and applicable policies. The MP labeling must bear the labeling contained in the table at the end of this section.

B. End-Use Products

Label changes are necessary to implement measures outlined in Section IV above. These changes include personal protective equipment requirements, user safety requirements, reentry intervals, and other restrictions. Specific language to implement these changes is specified in Table 3, which follows.

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
Required on all MUPs	"Only for formulation into insecticide products for the following use(s):" [*fill blank only with those uses that are being supported by MP registrant*].	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for 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

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish, birds, and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Directions for Use

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE Due to very high dermal toxicity to humans. For retail sale to and use only by certified applicators and only for those uses covered by the applicator's certification. Use by non-certified applicators, even those under the direct supervision of a certified applicator, is prohibited."	Top of Front Panel and Beginning of Directions for Use

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
PPE Requirements Established by the RED	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant insert correct material). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." Applicators and other handlers must wear: -- Long-sleeved shirt & long pants -- Shoes plus socks -- Chemical-resistant gloves -- NIOSH-approved air-supplying respirator that is one of the following types: - a supplied-air respirator (MSHA/NIOSH approval number prefix TC-19C) or - a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F)." EXCEPTION: Handlers are permited to wear a NIOSH-approved organic-vapor-removing respirator (see types below) instead of an air-supplying respirator ***provided*** they meet one of the following criteria: (1) the handler will ignite five or fewer canisters ***and*** will be in the greenhouse for less than 10 consecutive minutes starting when the first canister is ignited OR (2) the handler will enter the treated greenhouse to operate ventilation equipment after application is complete (smoke is no longer being generated) but before full ventilation has taken place ***and*** will remain in the treated greenhouse for less than 10 consecutive minutes. The NIOSH-approved organic-vapor-removing respirator must be equipped with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH-approved organic vapor cartridge or a canister equipped with any N^2, R, P, or HE prefilter." "The organic-vapor cartridge must be replaced with a new organic-vapor cartridge and new HEPA prefilter just prior to each use in sulfotepp-treated areas."	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
User Safety Requirements	"In addition, any handler who handles this product in a greenhouse, including a handler who enters the greenhouse before the ventilation criteria have been met to initiate ventilation, must maintain continuous visual or voice contact with another handler. That other handler must have immediate access to the PPE required on this labeling for handlers in the event entry into the fumigated greenhouse becomes necessary for rescue." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
Restricted-Entry Interval	"Entry (including early entry that would otherwise be permitted under the WPS) by any person -- other than a correctly trained and equipped certified applicator who is performing a handling task permitted by the WPS -- is PROHIBITED in the entire greenhouse (entire enclosed structure/building) from the start of application until the greenhouse is ventilated as follows: 11 hours with no ventilation followed by (1) 5 air exchanges; (2) 1 hour of mechanical ventilation (fans); or (3) 2 hours of passive (vents) ventilation." "After the initial ventilation criteria have been met, workers are permitted to enter the treated greenhouse to perform tasks, including hand labor tasks, *provided* (1) they work in the sulfotepp-treated area no more than 4 hours in the first 24 hours following application; (2) they work in the sulfotepp-treated area no more than 4 hours in the period 24 hours to 48 hours following application; AND (3) for the first 48-hours following application when any worker is present in the treated greenhouse, the greenhouse is ventilated -- continuously or intermittently -- so that within each hour one of the following ventilation criteria has been met: 2 air exchanges or 5 minutes of mechanical (fans) ventilation, or 10 minutes of passive (vents, windows) ventilation."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	Not needed for this product. Early entry by workers is prohibited.	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
Double Notification Statement	"Notify workers of the application by warning them orally and by posting fumigant warning signs at all entrances to the greenhouse. The signs must bear the skull and crossbones symbol and state: (1) "Danger/Peligro". (2) "Greenhouse under fumigation, DO NOT ENTER/NO ENTRE", (3) the date and time of fumigation. (4) (insert name of product) in use, and (5) name, address and phone number of the applicator. Post the fumigant warning sign instead of the WPS sign for this application, but follow all WPS requirements pertaining to location, legibility, size, and timing of the posting and removal."	Directions for Use, Agricultural Use Requirements Box

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "For use in commercial greenhouses only. Use in residential greenhouses or other indoor plant sites is prohibited." "Do not apply this product to a greenhouse that is attached to another structure, including another greenhouse, unless the greenhouse to be treated is entirely sealed off from the other structures." "Do not apply this product in any greenhouse that is located within 100 feet in any direction of a residential area (e.g., homes, apartments, schools, playgrounds, recreation areas)." "Entry to a treated structure by retail customers is prohibited for 48 hours after treatment, or until ventilation criteria have been met." Use of this product after September 30, 2004 is prohibited.	Direction for Use directly above the Agricultural Use Box.

Table 3: Summary of RED Labeling Requirements for Sulfotepp		
Description	**Required Labeling**	**Placement on Label**
Site Specific Application Restrictions	Application Instruction must include the following steps. The importance of performing the steps in the sequence presented must be made explicit. (1) All entries to the structure must be blocked/barricaded and posted with the required fumigant warning signs; (2) All greenhouse vents must be closed and all circulating fans must be turned off. (3) All misting systems must be turned off. (4) A certified applicator wearing the baseline attire plus chemical-resistant gloves must perform the remaining tasks. (5) Remove or puncture (whichever is appropriate) the tops or sides (whichever is appropriate) of the canisters. (Choice of words should be appropriate to the container.) (6) An ignitor (sparkler) must be inserted into each canister so that the coated portion is facing downward with the bare wire portion plus a small part of the coated portion remaining exposed. (7) Each canister must be placed in position in the greenhouse. (8) After all canisters are set out, the canister furthest from the exit to the greenhouse must be ignited first. (9) Applicator(s) must wear the appropriate respirator and must be monitored continuously from the start of ignition until the applicator has exited the greenhouse. (10) If the canisters are placed in parallel walks, rather than one central aisle, one applicator must be assigned to light the canisters in each walk, at least one of which shall be a certified pesticide applicator, so that fumigation starts simultaneously and all applicators exit the greenhouse simultaneously. (11) Each applicator lights the ignitor in each canister using a hand-held propane torch or butane lighter (not matches or wicked cigarette lighter) that should remain lit for the entire application. (12) Each applicator continues quickly to the next can until all cans are ignited, then exits the greenhouse immediately. (13) Entry into the greenhouse to relight ignitors that failed to activate the smoke generator is prohibited (if any smoke generator is activated in the greenhouse) unless the task is performed by a certified applicator wearing the specified personal protective equipment, including an air-supplied respirator or SCBA. The use of an organic-vapor removing respirator is prohibited for this task, regardless of the length of time spent in the treated area. (14) If circulating fans are used, the fans may not be turned on until after the applicator(s) have exited the greenhouse.	Direction for Use under General Precautions and Restrictions and or Application Instructions

References

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Appendix: Related Documents and How to Access Them

This Reregistration Eligibility Decision is supported by documents that are presently maintained in the OPP docket. The following sections indicate the means to view or obtain copies of paper or electronic versions of these documents and lists titles of documents that are now in the docket files.

Availability at OPP Docket Room

The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 p.m.

The docket initially contained the preliminary risk assessment and related documents as of September 9, 1998. Sixty days later the first public comment period closed. The EPA then considered comments and updated the risk assessment. The response to comments, risk assessment, summary and overview of the risk assessment were added to the docket on June 30, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room. Some documents may be downloaded or viewed via the Internet (http://www.epa.gov/oppsrrd1/op/)

Documents Added to Docket After June 30, 1999

The following documents were added to the docket after June 30, 1999:

Dumas, Richard. Notes of Meeting on Sulfotepp, April 15, 1999.
Farrell, Robbi. Notes of Meeting on Sulfotepp, August 11, 1999.
Farrell, Robbi. Notes of Conference Call on Sulfotepp, August 30, 1999.
Farrell, Robbi. Potential Occupational Labeling Changes for Sulfotepp.
No author. Sign-in Sheet, Meeting on Sulfotepp, August 11, 1999.
Farrell, Robbi. Notes of Meeting on Sulfotepp, September 22, 1999.
No author. Sign-in Sheet, Meeting on Sulfotepp, September 22, 1999.