

US EPA ARCHIVE DOCUMENT



# RED Sulfuryl Fluoride

September 1993

The information contained in the following document was accurate at the time of publication, but may not reflect EPA's current scientific understanding of this pesticide. For more information about this pesticide, please contact EPA's pesticide Registration Division at 703-305-5447.

**More current information on the regulatory status of this pesticide is available in the following documents:**

Sulfuryl Fluoride, Pesticide Tolerance; Federal Register; January 23, 2004  
<http://www.epa.gov/EPA-PEST/2004/January/Day-23/p1540.htm>

Sulfuryl Fluoride, Pesticide Tolerance, Technical Correction; Federal Register; June 16, 2004  
<http://www.epa.gov/EPA-PEST/2004/June/Day-16/p13288.htm>

Sulfuryl Fluoride, Pesticide Tolerance; Federal Register; July 15, 2005  
<http://www.epa.gov/EPA-PEST/2005/July/Day-15/p13982.htm>



# R.E.D. FACTS

## SULFURYL FLUORIDE

### Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for sulfuryl fluoride.

### Use Profile

Sulfuryl fluoride is an insecticide used to fumigate closed structures and their contents such as domestic dwellings, garages, barns, storage buildings, commercial warehouses, ships in port, and railroad cars. It controls numerous insect pests including termites, powder post beetles, old house borers, bedbugs, carpet beetles, clothes moths and cockroaches, as well as rats and mice. The end-use product is marketed as a liquid gas in pressurized steel containers.

### Regulatory History

Sulfuryl fluoride was first registered in December 1959. In June 1985, EPA issued a registration standard entitled "Guidance for the Reregistration of Pesticide Products Containing Sulfuryl Fluoride as an Active Ingredient" (NTIS PB87-124392), requiring additional product chemistry and occupational and residential exposure studies. Data Call-In Notices issued in July 1990 and November 1992 required additional toxicity data.

Currently, no manufacturing use products and only one end-use product containing the active ingredient sulfuryl fluoride are registered. The single registered

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product, Vikane, contains 99% sulfuryl fluoride and 1% inert impurities. Vikane is classified as a restricted use pesticide due to its inhalation toxicity.

## **Human Health Assessment**

### **Toxicity**

In acute oral toxicity studies using rats and guinea pigs, sulfuryl fluoride has been shown to be moderately toxic; it has been placed in Toxicity Category II for these effects (Category I indicates the highest and Category IV the lowest level of acute toxicity). Sulfuryl fluoride has been placed in Toxicity Categories III and IV for acute inhalation and Category IV for acute dermal vapor toxicity. A two-day neurotoxicity study using rats showed no effects at the highest dose levels.

Four subchronic toxicity studies using rats, rabbits and dogs showed similar results including fluorosis of the teeth, decreased body weights, and effects to the lung, nervous system and brain. In developmental toxicity studies using rats and rabbits, at the highest dose levels or in range-finding studies, some maternal toxicity (reduced body weight gain) and developmental toxicity (reduced fetal body weights) were observed. A reproductive toxicity study using rats showed parental effects to the lungs and brain, and reduced pup weights. Sulfuryl fluoride was negative in three mutagenicity studies.

Several humans poisonings and two deaths have been attributed to sulfuryl fluoride exposure. All resulted from reentering treated homes before they had adequately aerated, inconsistent with label directions.

### **Dietary Exposure**

Sulfuryl fluoride is not registered for any food- or feed-related uses. No tolerances or exemptions from the requirement of a tolerance have been established, and no dietary exposure is anticipated.

### **Occupational and Residential Exposure**

Sulfuryl fluoride is dispensed as a pressurized gas from a steel cylinder through a hose into the interior of an enclosed, sealed structure. People must be evacuated from the structure before it is treated; chlorpicrin, which produces a strong odor and eye irritation, is used as a warning agent and is released within the structure 5 to 10 minutes before sulfuryl fluoride is applied to ensure that the site is vacated. After treatment, the structure remains closed for a period of time (refer to the product label for specific times regarding target pest and environmental conditions) after which the applicator reenters and begins to aerate the area. People not wearing a respirator may not reenter the treated structure until air levels of sulfuryl fluoride have declined to 5 part per million (ppm) or less. Because sulfuryl fluoride is a Restricted Use Pesticide, it may only be applied by or under the direct supervision of a trained, certified applicator.

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Applicators may be exposed to sulfuryl fluoride while applying the pesticide. However, sulfuryl fluoride is introduced as a gas into the target area through a hose, thus, negligible exposure to the applicator is expected until the time of reentry into the treated structure to monitor air levels.

Applicators and residents may be exposed to sulfuryl fluoride through inhalation upon reentry and/or reoccupation of treated structures. Exposure to workers is acute and intermittent, while exposure to residents is acute and lasting. Current product labeling requires applicators to wear protective clothing including respirators when reentering treated structures and prohibits other people from reoccupying treated structures until air levels of sulfuryl fluoride have declined to 5 ppm.

### **Human Risk Assessment**

Sulfuryl fluoride poses no human dietary risks since no food- or feed-related uses are registered and dietary exposure is not anticipated.

EPA is concerned with neurotoxicity associated with inhalation exposure to sulfuryl fluoride. Residents and workers reentering treated structures may be at risk for acute neurotoxic effects from this exposure, which currently is limited to 5 ppm. The Agency has concern that the 5 ppm reentry level may not be appropriate based on the calculated Margins Of Exposure (MOEs) which suggest 2 ppm for adults. In order to provide a further safety measure for children, the current data and the limit of detection of the monitoring devices suggest a reentry level of 1 ppm. However, certain post treatment decline data are not available which might enable the Agency to refine the reentry level. The sulfuryl fluoride registrant has been given the option in the RED document to submit exposure data and any other data that can be used to refine the decline rate of sulfuryl fluoride. These data are due by August 1, 1994. By October 1, 1994, the Agency will make a decision on the reentry level but until these data are evaluated the 5 ppm reentry level will remain in place. If these new data are not useful or not received by August 1, 1994, the reentry level will be established at 1 ppm and revised labeling will be implemented on an accelerated basis.

In addition, a fact sheet must be provided in advance to an adult occupant of each structure to be fumigated, describing why and how buildings are fumigated, the potential risks and safety precautions, as well as who to contact for more information.

Because of uncertainty about neurotoxic effects due to long term exposure to sulfuryl fluoride, workers will be required to wear a NIOSH-approved, self-contained breathing apparatus (SCBA) upon reentry, regardless of air levels of sulfuryl fluoride. EPA is requiring a 90-day inhalation neurotoxicity study in rats to more fully assess human subchronic and chronic effects. Assessment of risks to workers during their working life span, and the need to continue wearing the SCBA

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upon reentry at all air levels of sulfuryl fluoride, will be addressed after this study is received and evaluated.

## **Environmental Assessment**

### **Environmental Fate**

Since sulfuryl fluoride is registered for highly specialized uses, and due to its chemical properties, EPA is not requiring the usual supporting environmental fate data for reregistration. After fumigation and aeration of treated structures, there is little likelihood that nontarget organisms would be exposed to residues of sulfuryl fluoride, or that the pesticide would leach to ground water. Residues of the parent chemical are not expected to remain in the environment for any significant length of time.

### **Ecological Effects Risk Assessment**

Based on its limited use sites and chemical properties, significant environmental exposure is not expected to result from use of sulfuryl fluoride. Therefore, wildlife toxicity data were not required for reregistration, and an ecological risk assessment was not conducted.

## **Additional Data Required**

The generic data base for sulfuryl fluoride is substantially complete. However, EPA is requiring a new 90-day neurotoxicity study in rats, as confirmatory data. Method validation data for indoor air monitoring devices are also required.

EPA is not requiring product-specific data, but is requiring a revised Confidential Statement of Formula and revised labeling for reregistration of the pesticide product containing sulfuryl fluoride.

## **Product Labeling Changes Required**

The end-use product must comply with EPA's current pesticide product labeling requirements. In addition:

! The label must provide specific directions for the use of chlorpicrin as a warning agent to be present in the structure during fumigation at a level \$ 0.25%. Instructions must be provided that the chlorpicrin must be used by persons certified to apply sulfuryl fluoride and that applicators must observe the precautionary statements and safety recommendations appearing on the label of this product.

! The label must require that a pesticide fact sheet be provided to an adult occupant of the structure to be fumigated prior to the initiation of the

fumigation contract. This fact sheet, which is labeling, must contain as a minimum of information the following:

- a) Why buildings are fumigated.
- b) How buildings are fumigated.
- c) Potential health risks from overexposure.
- d) Safety precautions and homeowner preparation.
- e) A contact point for additional information.

! Add the following under the Environmental Hazards Statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, consult your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance."

! Due to concern for neurotoxic effects from long term exposure to sulfuryl fluoride upon reentry to treated structures, the Agency requires the following:

Applicators must wear a NIOSH approved self-contained breathing apparatus (SCBA) when reentering a treated structure regardless of air levels of sulfuryl fluoride.

## **Regulatory Conclusion**

Use of the currently registered pesticide product containing sulfuryl fluoride as labeled and specified in the RED document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of this product are eligible for reregistration.

The sulfuryl fluoride product will be reregistered once the confirmatory generic data, revised Confidential Statement of Formula and revised labeling are received and accepted by EPA.

## **For More Information**

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for sulfuryl fluoride during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response

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and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703) 305-5805.

Following the comment period, the sulfuryl fluoride RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone (703) 487-4650.

For more information about sulfuryl fluoride RED document, EPA's pesticide reregistration program, or reregistration of individual products containing sulfuryl fluoride, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.



**REREGISTRATION ELIGIBILITY DECISION**

**Sulfuryl Fluoride**

**LIST A**

**CASE 0176**

## SULFURYL FLUORIDE REREGISTRATION ELIGIBILITY TEAM

### Office of Pesticide Programs:

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Toxicology Branch I  
Tolerance Support Chemistry Branch  
Occupational & Residential Exposure Branch

#### Registration Division

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#### Special Review and Reregistration Division

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#### Other Divisions and Offices

Jean Frane  
Phyllis Flaherty  
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Policy and Special Projects Staff  
Office of Compliance Monitoring  
Office of General Counsel

## GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
LC <sub>50</sub>	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 or feed, e.g., mg/l or ppm.
LD <sub>50</sub>	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). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

## GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.
TWA	Time Weighted Average

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- Attachment B - Generic DCI Response Forms (Form A) plus Instructions
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- Attachment E - Cost Share/Data Compensation Forms

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## EXECUTIVE SUMMARY

This decision document addresses the reregistration eligibility of the pesticide sulfuryl fluoride. Sulfuryl fluoride was first registered in December 1959 as a controlled fumigant of closed (sealed) structures and their contents, such as buildings, dwellings, garages, barns, storage buildings, ships in port, and other structures infested with a variety of pests, i.e. drywood termites, powder post beetles, old house borers, bedbugs and clothes moths. There are no registered uses involving direct application of sulfuryl fluoride to agricultural crops or to food or feed. Sulfuryl fluoride is not registered for the fumigation of stored grains or cereals.

In June 1985, the Environmental Protection Agency (referred to as "the Agency") issued a registration standard entitled "Guidance for the Reregistration of Pesticide Products Containing Sulfuryl Fluoride as the Active Ingredient" (NTIS PB87-124392). The registration standard summarized the available data supporting the registration of sulfuryl fluoride and required additional data to assure that proper use of the pesticide poses no unreasonable adverse effects to human health or the environment. Also, Data Call-In Notices issued in July 1990 and November 1992 required additional toxicity data.

The current reentry level following sulfuryl fluoride treatment is 5 ppm. The Agency believes that this level may not be appropriate. Calculated MOEs suggest a reentry level of 2 ppm for adults in order to reach MOEs of 100, generally considered an acceptable MOE. In order to provide a further safety measure for children, the current data and the limit of detection of available monitoring devices suggest a reentry level of 1 ppm. However, certain post treatment decline data are not available which might enable the Agency to refine the reentry level. The Agency is providing the registrant until August 1, 1994 to submit these exposure data and any other data that can be used to refine the decline rate of sulfuryl fluoride. These data may also be useful in establishing a reentry level for non-residential structures. Until these data are evaluated the current 5 ppm level will remain in place. By October 1, 1994, the Agency will make a decision on the reentry level. If these new data are not useful in making this determination or are not received by August 1, 1994, the reentry level will be established at 1 ppm for dwellings, and 2 ppm for non-residential structures and vehicles where young children are not expected to be exposed. Revised labeling reflecting the lower levels will then be implemented on an accelerated schedule.

The Agency is requiring a 90-day inhalation neurotoxicity study in rats (guideline 82-5) because subchronic/chronic exposure to workers cannot be ruled out. Method validation data for the Miran and Interscan gas analyzers (also listed under guideline 133-4) and/or any other method used are also required to confirm the level of detection.

Before reregistering the product containing sulfuryl fluoride, the Agency is requiring that a revised Confidential Statement of Formula (CSF) be submitted within eight months of the issuance of this document. Additionally, in order to remain in compliance with FIFRA, revised labeling must also be submitted at the same time. After reviewing the revised CSF and labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister the product.

## I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base 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" criterion of FIFRA.

This decision document presents the Agency's decision regarding the reregistration eligibility of the registered uses of sulfuryl fluoride. The document consists of six sections. Section I is the introduction. Section II describes sulfuryl fluoride, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for sulfuryl fluoride. Section V discusses the reregistration requirements for sulfuryl fluoride. Finally, Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.<sup>1</sup>

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<sup>1</sup>EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.



## II. CASE OVERVIEW

### A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

! **Chemical Name:** sulfuryl fluoride

O

5

! **Structure:** F - S - F

5

O

! **CAS Registry Number:** 2699-79-8

! **OPP Chemical Code:** 078003

! **Chemical Formula:** F<sub>2</sub>O<sub>2</sub>S

! **Molecular Weight:** 102.07

! **Trade and Other Names:** Vikane

! **Basic Manufacturer:** DowElanco

### B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of the uses of sulfuryl fluoride is in Appendix A.

For Sulfuryl Fluoride:

**Type of Pesticide:** Insecticide (fumigant)

**Use Sites:** Terrestrial Non-Food (wood protection treatment to forest products-seasoned), Terrestrial Non-Food and Outdoor Residential (wood protection treatment to buildings/products outdoor), Indoor Non-Food (commercial transportation facilities; commercial/ institutional/industrial premises/equipment-indoor), building Indoor Residential (domestic dwellings, domestic/household dwellings contents; wood protection

treatment to buildings/products indoor).

**Target Pests:** Drywood termite, Formosan subterranean termite, powder post beetle, old house borer, death watch beetle, bedbugs, clothes moths, carpet beetle (except egg stage), cockroaches (Oriental, American, German and Brown Banded), rodents (rats, mice).

**Formulation Types Registered:** Pressurized Gas - 99% sulfuryl fluoride

**Method and Rates of Application:**

Equipment - by cylinder and dispensing device

Method and Rate - one pound of product per 1,000 cubic feet of space for a 24-hour exposure period with temperatures of 70° or above; 2 pounds per 1,000 cubic feet of space for 24 hours if temperature is 55 to 65° F. Exposure varies with the environmental conditions and the target pest. For tarpaulin fumigation, use a highly resistant material of at least 4 mil thickness.

Warning Agent - Chloropicrin must be present in the structure during fumigation at a level \$ 0.25%.

**C. Data Requirements**

Data required in the June 1985 Registration Standard for sulfuryl fluoride included studies on product chemistry, and occupational and residential exposure. These data were required to support the uses listed in the Registration Standard. Data Call-In Notices were also issued in July 1990 and November 1992 which required toxicology data. Appendix B includes all data requirements identified by the Agency needed to support reregistration for currently registered uses.

A 90-day inhalation neurotoxicity study in the rat is being required to examine subchronic/chronic exposure to workers. Method validation data for the Miran and Interscan gas analyzers and/or any other method used are also required to confirm the level of detection of the monitoring devices.

**D. Regulatory History**

Sulfuryl fluoride is a well known compound whose chemical and toxicological properties are extensively documented in published literature and studies submitted to the Agency. In June 1985, a Registration Standard was issued for sulfuryl fluoride which

summarized the available data supporting registration. The standard concluded that additional scientific data would be necessary to support the registration or reregistration of products which contain sulfuryl fluoride.

At the time the Registration Standard was issued in 1985 there were only three registered end-use products and no manufacturing use products containing sulfuryl fluoride as the sole active ingredient. Presently, there is only one active registered product sold under the trade name Vikane.

EPA Reg No. 62719-4  
 Registrant: Dow Elanco

Sulfuryl fluoride is a gas at room temperature (25EC), but the registered end use product is marketed as a liquified gas in pressurized steel cylinders containing 99% sulfuryl fluoride and 1% inert impurities which are a result of the manufacturing process. The marketable registered gas is of the same purity as the Technical Grade of the Active Ingredient (TGAI).

### III. SCIENCE ASSESSMENT

Sulfuryl fluoride is a structural fumigant registered for uses in closed, sealed buildings for control of numerous pests. It is currently classified as a Restricted Use Pesticide, based on acute inhalation toxicity to humans. OSHA has established an 8-hr Time Weighted Average (TWA) limit of 5 ppm for sulfuryl fluoride, based on adverse health effects (FR vol. 57; # 114; 06/12/92). Sulfuryl fluoride has no food/feed uses.

#### A. Product Chemistry Assessment

The physical and chemical characteristics of sulfuryl fluoride are described below (MRID #s 40361001, 42703701, 42703702, and 47012303):

<b>TGAI</b>	Sulfuryl fluoride
<b>Color</b>	None
<b>Physical State</b>	Gas at 25EC
<b>Odor</b>	None
<b>Melting Point</b>	-136.7E C at 760 mm Hg
<b>Boiling Point</b>	-55.2E C at 760 mm Hg
<b>Specific Gravity</b>	1.34 at 25EC
<b>Vapor Density</b>	3.52 (air = 1)
<b>Solubility</b>	0.075 g/100 g water at 25EC,

	0.78 g/100 cc Wesson oil at 20EC, 1.74 g/100 cc acetone at 22EC, 2.12 g/100 cc chloroform at 22EC 17.7 mm Hg at 25EC
<b>Vapor Pressure</b>	
<b>Dissoc. Constant</b>	N/A
<b>Oct./Water Part. Coeff.</b>	N/A
<b>pH</b>	N/A
<b>Stability</b>	Stable to heat. Hydrolyzes slowly in water but rapid in basic solution
<b>Oxidizing or Reducing Action</b>	A mild oxidant Reduction potential is -.68V
<b>Flammability</b>	Not flammable
<b>Explodability</b>	Not explodable
<b>Storage Stability</b>	For up to 6 yrs in steel cylinders
<b>Corrosion</b>	Non-corrosive in the absence of moisture in steel cylinders

The product is sold as a pressurized liquified gas. On contact with water, it hydrolyzes initially to chlorosulfonic acid and hydrogen fluoride and ultimately to sulfuric acid and hydrogen fluoride. Accordingly, it must be contained and used with caution.

**B. Human Health Assessment**

**1. Toxicology Assessment**

Adequate animal toxicological data on sulfuryl fluoride are available and will support reregistration eligibility of sulfuryl fluoride as a non-food/non-feed use pesticide. Some confirmatory data, however, are required (see under V.A.1). The available data are reported below.

**(1) Acute Toxicity**

The acute toxicity data are summarized in the table below:

TEST	RESULTS	TOX CAT
Oral LD <sub>50</sub> /rats (MRID # 00072289)	100 mg/kg	II

Oral LD <sub>50</sub> /guinea pigs (MRID # 40839901)	100 mg/kg	II
1 hr Inhalation LC <sub>50</sub> in rats (MRID # 41099001)	4507 ppm (17.5 mg/L)	III
4 hr Inhalation LC <sub>50</sub> in mice (MRID # 41769101)	M = 660 ppm (2.56 mg/L) F = 642 ppm (2.49 mg/L)	IV
4 hr Dermal Vapor LC <sub>50</sub> in rats (MRID # 41712001)	9599 ppm (37.27 mg/L)	IV

M Males  
F Females

**(2) 2-Day Inhalation Neurotoxicity Study**

An acute neurotoxicity study in rats (GL # 81-8) was required in a November 1992 Data Call-In because acute neurotoxicity data are necessary for a determination of short-term exposure risk following reentry into homes fumigated with sulfuryl fluoride.

In a 2-day inhalation neurotoxicity study, rats were administered sulfuryl fluoride (6 hrs/day, for 2 consecutive days) at levels of 0, 100, or 300 ppm (M - 0, 97 or 290 mg/kg/day; F - 0, 109 or 326 mg/kg/day). A NOEL was established at greater than or equal to the high dose (300 ppm). Parameters examined included electrophysiological, functional and motor activity. Other neurotoxicity parameters usually examined in this type of study were not required since they were not detected at these dose levels in 90-day or chronic rat studies. The Agency considers that the requirement for an acute neurotoxicity study in rats is satisfied by this study (MRID # 427720-01).

**(3) Subchronic Toxicity**

In a general subchronic toxicity study, administration of sulfuryl fluoride to rats by inhalation for 6 hours/day for 90 days at doses of 30, 100, or 300 ppm (M - 29, 97, or 290 mg/kg/day; F - 33, 109, or 326 mg/kg/day), resulted in a NOEL of 30 ppm and an LEL of 100 ppm based on fluorosis of the teeth. Signs of

toxicity at 300 ppm included decreased body weight, lesions of the nasal passage (inflammation), lung (alveolar histiocytosis), and brain (microscopic vacuolation of the caudate-putamen nucleus and white fiber tracts of the internal capsule) (M,F); and very slight hyperplasia of the collecting ducts of the kidney (F) (MRID # 408909-02).

An inhalation neurotoxicity 90-day study in rats at the same dose levels also resulted in a NOEL of 30 ppm. The LEL of 100 ppm also had evidence of toxicity including fluorosis of the teeth, pale foci in the pleura, and aggregates of macrophages in the lung. There were also electrophysiologic signs of neurotoxicity at this dose including slowing of the visual evoked response and somato-sensory response (F), and auditory brain stem response (M). At 300 ppm there was vacuolation of the caudate putamen which is consistent with the general 90-day rat study (MRID #s 408399-02, 408909-03).

Administration of sulfuranyl fluoride by inhalation for 6 hours/day for 90 days to rabbits at doses of 30, 100, or 300 ppm (11, 38, or 114 mg/kg/day) resulted in similar signs of toxicity although brain lesions occurred at lower levels. The NOEL was 30 ppm. The LEL was 100 ppm based on decreased body weights, decreased liver weight and mottling of the teeth (M,F), and microscopic vacuolation of the white matter of the brain (F). In addition, at 300 ppm (M,F) there was alveolar histiocytosis, histologic changes in the nasal epithelium, and microscopic malacia to vacuolation of the internal and external capsules, putamen, and globus pallidus of the brain (MRID # 408909-01).

Administration of sulfuranyl fluoride in a 90-day inhalation dog study (6 hours/day) at doses of 0, 30, 100 or 200 ppm resulted in a NOEL of 100 ppm (2.5 mg/kg/day) and an LEL of 200 ppm (5.0 mg/kg/day) based on decreased mean body weight and body weight gain. There were also slight histologic lesions in the caudate nucleus of the basal ganglia midbrain (M,F) at

200 ppm. In addition, one male with the above lesion also had transient clinical neurologic signs including lateral recumbency, tremors, incoordination, salivation, and tetany followed by inactivity (MRID 422566-01).

#### **(4) Developmental Toxicity**

There was no developmental or overt maternal toxicity associated with administration of sulfuryl fluoride by inhalation to pregnant rats for six hours/day on gestation days 6-15 at doses of 0, 25, 75, or 225 ppm (27, 81, or 244 mg/kg/day) (MRID # 00090015). Maternal toxicity of decreased body weight gain was observed at 300 ppm in the range-finding study.

When administered by inhalation to pregnant rabbits at doses of 0, 25, 75 or 225 ppm (0, 10, 28, or 85 mg/kg/day) for six hours/day on gestation days 6-18, the NOEL for both maternal and developmental toxicity was 75 ppm. The LEL was 225 ppm for both maternal toxicity (reduced body weight gain) and developmental toxicity (reduced fetal body weights and crown rump length) (MRID # 00090015).

#### **(5) Reproductive Toxicity**

A two-generation reproduction toxicity study in rats administered sulfuryl fluoride by inhalation at doses of 0, 5, 20, or 150 ppm (M - 0, 4, 17, or 130 mg/kg/day; F - 0, 5, 20, or 152 mg/kg/day) for 6 hours/day, 5 days/week, resulted in a parental NOEL of 5 ppm and LEL of 20 ppm based on an increased incidence of aggregates of alveolar macrophages in the lungs. At 150 ppm, there was an increased incidence of vacuolation of the myelinated caudate-putamen fiber tracts in the brain. The reproductive NOEL of 20 ppm and the LEL of 150 ppm were based on reduced pup weights in both the F1 and F2 generations (MRID # 421798-01).

#### **(6) Mutagenicity**

Sulfuryl fluoride was negative for bacterial gene mutations when tested at up to

cytotoxic levels with and without metabolic activation (MRID # 41603001).

Sulfuryl fluoride did not cause chromosomal aberrations when tested in the mouse micronucleus assay, at doses up to 520 ppm (80% of the acute LC50) (MRID # 41448601).

Sulfuryl fluoride was negative in the UDS assay in rat primary hepatocytes when tested at levels of 204 to 1020 ppm (MRID # 42179802).

#### **(7) Other toxicology information**

Human poisonings and fatalities have been reported after sulfuryl fluoride exposure. Some residents entering sulfuryl fluoride fumigated houses 2 to 5 hours after aeration experienced chest pains, dyspnea, nausea, and vomiting. There have been two reports of deaths of persons entering sulfuryl fluoride treated houses. One entered the house illegally and was found dead in the morning, and a homeowner died of cardiac arrest after sleeping in the house overnight following fumigation. A plasma fluoride level of 0.5 mg/L (10 times normal) was found in this individual following exposure. (ACGIH, 1971; NIOSH, 1978; Nuckolls, 1987; PIMS, 1980; Taxay, 1966).

##### **a. Exposure Assessment**

###### **(1) Dietary Exposure**

No dietary exposure is expected from the use of sulfuryl fluoride as a non-food/non-feed use fumigant. Therefore, there are currently no tolerances or exemptions from the requirements of a tolerance established for this chemical.

###### **(2) Occupational and Residential**

Sulfuryl fluoride is a structural fumigant registered for use in closed, sealed buildings (dwellings, garages, barns, storage buildings, etc.) for control of numerous pests, including drywood termites, powder post beetles, old house



borers, bedbugs, and clothes moths. Sulfuryl fluoride is not registered for the fumigation of stored grains or cereals. It is a gas at 25 C. The registered end-use product is supplied as a liquified gas in pressurized steel cylinders which contain 99% sulfuryl fluoride and 1% impurities which are present as a result of the manufacturing process. Sulfuryl fluoride is classified as a restricted use pesticide based on inhalation toxicity to humans and may only be used by or under the supervision of certified applicators wearing appropriate protective clothing.

Application of this product must be used in conjunction with chloropicrin. Chloropicrin must be present in the structure at a level of 0.25%.

**(a) Mixer/loader/applicator exposure**

Based on the method of application, use pattern, and current label requirements for the use of respiratory protection, worker dermal and inhalation exposure to sulfuryl fluoride, if it occurs, will be intermittent and very low.

**(b) Residential/Occupational post application reentry exposure**

Because of its physical nature (a gas at 25°C), oral and dermal exposure to residues of sulfuryl fluoride or its degradates which may remain on/in household contents or indoor air after the required aeration period are expected to be very low.

There is, however, a potential for inhalation exposure upon reoccupation/reentry of treated homes. The exposure may be either acute (residents and workers) or intermittent (workers during their working life span). In response to the Registration Standard, the registrant has submitted air monitoring data (GL # 133-4) for sulfuryl fluoride in 10 houses fumigated at 16 g/m<sup>3</sup>. After aeration to a level equal to or lower than 5 ppm, the houses were closed again, and the air concentration of sulfuryl fluoride

measured. The results indicated that average concentrations of sulfuryl fluoride remained at or below 5 ppm (mean concentration = 4.5 ppm) during the monitoring period after aeration and closure; however, individual maximum concentrations ranged from 5 ppm immediately following aeration to approximately 16 ppm 60 minutes after aeration and closure. Data were not provided for airborne residues of sulfuryl fluoride remaining in homes at levels much below 5 ppm or beyond 120 minutes (MRID # 418177-01).

In two other data submissions, a total of 22 houses were fumigated in the usual manner and at customary application rates, then aerated to a level equal to or lower than 5 ppm. Indoor air was monitored for 24 hours after closure although only a limited number of samples were collected between 6 and 24 hours. In the first project (four houses), of the 25 air samples collected at or near 24 hours after closure, three were at the 1-ppm level and all others at levels below the operational sensitivity of the detection devices (1 ppm). In the second project (18 houses) virtually all air samples measured at or near 24 hours after closure were at non-detectable levels (<1 ppm) (MRIDs 42447101 and 42447102).

Acute inhalation exposures of residents and workers reentering fumigated houses after aeration may be estimated using the following equation and assumptions:

$$\text{Daily Dose (mg/kg/day)} = \frac{\text{ppm} \times \text{MW}}{\text{weight (L/day)}} \times \frac{\text{resp. vol.}}{\text{Kg body weight}}$$

- Assumptions:
- Molecular Weight = 102.07,
  - adult body weights of 70 kg/male and 60 kg/female
  - respiratory volume (resp. vol. based on 16 hours rest + 8 hours light work; ventilation rates (L/min) are respectively 7.4 (M) and 4.5 (F) at rest and 29 (M)

and 16 (F) with light work,  
 - 100% pulmonary absorption, and  
 - various air levels [5 ppm as per current label, 4.5 ppm (mean value from DowElanco study MRID # 418177-01), or theoretically reduced values of 2, 1 and 0.5 ppm.

Potential exposures are shown in the table below:

**Estimated Daily Doses at Various Levels of Sulfuryl Fluoride**

Exposure (mg/kg/day) Scenario	Air level		Daily dose	
	ppm	mg/m <sup>3</sup>	Males	Females
Current label	5	20.87	6.27	4.17
DowElanco measurement	4.5	18.77	5.64	3.75
Exposure reduced to	2	8.34	2.51	1.67
Exposure reduced to	1	4.17	1.25	0.83
Exposure reduced to	0.5	2.08	0.62	0.42

Assessment of intermittent exposure of workers during their working life span will be addressed after the required 90-day inhalation neurotoxicity study is submitted and evaluated.

Post fumigation desorption data (GL # 133-4), also submitted in response to the Registration Standard, indicated that sulfuryl fluoride is desorbed at low levels (probably in the ppb range) from various household materials for up to 40 days following fumigation and aeration and that there are no degradates desorbed from these materials (MRID # 403332-01).

Based on the overall indoor air

monitoring and post fumigation desorption data, sulfuryl fluoride residues appear to dissipate to very low levels within 24 hours and the dissipation would be expected to continue. Therefore, the Agency believes that air levels of sulfuryl fluoride in homes fumigated at recommended label rates should be negligible within a short period of time after fumigation and aeration. However, quantitation is limited by the sensitivity of the analytical instruments [Miran infrared analyzer (LOD = 1 ppm) or Interscan gas analyzer (LOD = 1 ppm)].

**b. Risk Assessment**

**(1) Dietary**

Dietary risk is not expected since there are no food or feed uses for sulfuryl fluoride.

**(2) Occupational and Residential**

The Agency has a concern for neurotoxicity associated with inhalation exposure to sulfuryl fluoride. Histopathology of one or more brain anatomical structures has been a consistent observation in 90-day inhalation studies in several experimental animal species including the rat, rabbit, and dog (MRID #s 4080909-02, 4080909-01, and 422566-01). Neurologic signs such as tremor, incoordination, and tetany also were observed in the dog (MRID # 422566-01) as well as slowing of several electrophysiologically evoked responses in the rat (MRIDs 408399/02-03). In humans, poisonings and fatalities have been reported after sulfuryl fluoride exposure. Some residents entering sulfuryl fluoride fumigated houses 2 to 5 hours after aeration experienced chest pains, dyspnea, nausea, and vomiting. These symptoms occurred as a result of early reentry, not in accordance with label aeration procedures. There have been two reports of deaths of persons entering sulfuryl fluoride treated houses. One entered the house illegally and was found dead in the morning, and a homeowner died of cardiac arrest

after sleeping in the house overnight following fumigation.

Residents and workers reentering treated houses may be at risk for acute neurotoxic effects from exposure to sulfuryl fluoride. Workers, but not residents, may also be exposed intermittently over the course of their working life span. Using the potential exposures estimated above [B.2.b-(2)] for residents and workers, the margin of exposures (MOEs) for acute exposure may be estimated by the following equation:

$$\text{MOE} = \frac{\text{NOEL (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

Assumptions: - the NOEL is 300 ppm based on the 2-day inhalation neurotoxicity study, which the Agency considers to be the most appropriate NOEL for determining acute/subacute exposure, and  
 - conversion of rat ppm into mg/kg/day based on respiratory volumes (m<sup>3</sup>/24 hours) of 0.37 (M) and 0.26 (F) and body weight (kg) of 0.4 (M) and 0.25(F).

The MOEs for acute exposure are presented in the following table:

MARGINS OF EXPOSURE FOR ADULT RESIDENTS REENTERING HOMES TREATED WITH SULFURYL FLUORIDE

Exposure Scenario	ppm	mg/m <sup>3</sup>	Daily Dose (mg/kg/d) (16 hrs rest + 8 hrs light work/d)		NOEL ppm	NOEL mg/kg/d (M/F)	MOE	
			Males	Females			Males	Females
Current label	5	20.87	6.27	4.17	300	290/326	46	78
DowElanco measurement	4.5	18.77	5.64	3.75	300	290/326	51	87

If exposure were reduced to:	2	8.34	2.51	1.67	300	290/326	116	196
	1	4.17	1.25	0.83	300	290/326	232	393
	0.5	2.08	0.62	0.42	300	290/326	464	786

Based on the above calculations, the Agency believes that a reentry level of less than 5 ppm may be appropriate. There are several factors that create an element of uncertainty in establishing a suitable level. First, the calculated MOEs could be an over estimate of the risk to occupants for the following reasons: (1) the NOEL was derived from a study with a constant level of exposure, whereas, dissipation of sulfuryl fluoride is expected to continue over time following fumigation, and (2) a pulmonary absorption of 100% is assumed. Another factor contributing to the uncertainty regarding the appropriateness of the 5 ppm level is that the available exposure data are limited for the period between 6 hours and 24 hours following beginning of aeration procedures. At 24 hours sulfuryl fluoride residues in all test houses were non-detectable or at very low levels. Without these data the Agency cannot calculate a precise rate of decline applicable to all treated structures. Additional data may enable the Agency to estimate more accurately the rate of decline in sulfuryl fluoride levels and determine an appropriate reentry level. The existing data suggest a reentry level of 2 ppm to provide adequate MOEs for adults.

However, the Agency is also concerned with the possible heightened sensitivity of children to pesticides and believes an additional safety factor is warranted. Very young children may be more susceptible than adults to sulfuryl fluoride neurotoxicity because the developing brain may be more vulnerable to chemical injury. According to a recent report by the National Academy of Sciences, the central nervous system (CNS) continues to develop during the postnatal life (NAS Report, 1993). The NAS Report also noted that "quantitative differences in toxicity between children and adults are usually less than a factor of 10-fold." Although the NAS Report focused on dietary risk to children, the Agency still

believes it appropriate to apply a safety factor in this case because of the reasons noted above. The Agency has not yet developed guidance on what factor between 1 and 10 would be appropriate and under what circumstances. The Agency believes that lowering the reentry level to 1 ppm, the operational sensitivity of the monitoring devices, would provide an adequate safety margin. Lowering the acceptable reentry concentration to 1 ppm (the operational sensitivity of the Miran detector in the field) would provide a margin of exposure of approximately 500 for adult residents entering the homes (464 for males and 786 for females) and approximately 100 for children. These estimates were based on an assumed air level of 0.5 ppm (according to Agency practice, a value of half the limit of detection is used in exposure calculations). Because of the conservative assumptions on which the MOEs are based, and the lack of more definitive guidance on what factor to use for additional protection of children, the Agency believes the 1 ppm level is adequate and will require a reentry level of 1 ppm if the additional data mentioned above cannot be used to determine a more suitable reentry level between 1 and 5 ppm. The Agency believes that use of a greater MOE would result in reentry levels below the limit of detection of current monitoring devices.

The Agency is providing the registrant with the opportunity to submit these exposure data and any other data that can be used in refining the decline rate of sulfuryl fluoride. These data may also be useful in establishing a reentry level for non-residential structures. If the registrant elects to submit these data, they must be submitted by August 1, 1994. During the period between issuance of this RED and October 1, 1994, the reentry level will remain at 5 ppm. The Agency will make a decision on the reentry level by October 1, 1994. If the new data are not received by August 1, 1994 or are not useful in making this determination, the reentry level will be established at 1 ppm for dwellings, and 2 ppm for non-residential structures and vehicles where young children are not expected to be exposed. Revised labeling reflecting the lower reentry levels will be required.

The MOEs for longer term exposure to sulfuryl fluoride will be addressed when the required 90-day inhalation toxicity study is submitted and evaluated.

Although several 90-day inhalation studies are available, the Agency does not consider them appropriate for long term risk assessment for the following reasons:

- the toxicological end-point of concern is neurotoxicity,
- the 90-day inhalation studies in rats, rabbits, and dogs were deficient (too few animals on test, inadequate histopathology, lacking in functional observational battery/motor activity testing, or no positive control data),
- the NOEL in the 2-generation reproduction study in rats was based on respiratory effects, not neurotoxic effects.

### **C. Environmental Assessment**

#### **a. Environmental Fate**

Under normal circumstances the terrestrial non-food and outdoor residential use patterns would trigger environmental fate data requirements. However, in this case the product containing this active ingredient is registered for highly specialized uses which involve fumigation of barns, household or domestic dwellings, ships, buses, railway cars, commercial storages or warehouses, seasoned forest products and residential building materials to control existing infestation of various insects and pests. The Agency has decided, based on the pesticide's chemical properties, and specialized use patterns, that the terrestrial non-food and outdoor residential use pattern classifications do not require supporting data as described in 40 CFR Part 158. In particular, the pesticide acts not as a wood protection treatment, but simply as a fumigant to control existing infestations. After the treatment and aeration of the fumigated areas there is little likelihood of residues of sulfuryl fluoride which would result in exposure to non-target organisms or impact the environment by leaching into ground water.

Further, sulfuryl fluoride hydrolyzes very slowly in water under neutral conditions. However, it does undergo hydrolysis under alkaline conditions to form fluorosulfuric acid ( $\text{HSO}_3\text{F}$ ) and hydrofluoride ( $\text{HF}$ ). These degradation products are easily removed from water by further reacting with oxides and salts of oxo acids. Sulfuryl fluoride also reacts readily with nucleophilic



substances. Because sea water is normally around pH 8 and soil contains many nucleophilic substances, it is not expected that residues of the intact parent would remain in the environment for any significant time from the uses listed above.

#### **b. Ecological Effects**

Based on the chemical properties of sulfuryl fluoride, no ecological effects data were required in the 1985 Registration Standard. Generally, basic wildlife toxicology tests are required to support terrestrial/outdoor uses of a pesticide. However, based upon the Agency's conclusions noted above and the limited use sites, significant environmental exposure is not expected to result from use of sulfuryl fluoride. Therefore, wildlife toxicity data have not been required and an ecological effects risk assessment was not conducted.

### **IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

#### **A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients 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 sulfuryl fluoride active ingredients. 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 sulfuryl fluoride. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sulfuryl fluoride, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of sulfuryl fluoride and to determine that sulfuryl fluoride as currently registered can be used according to label directions without resulting in unreasonable adverse effects to man and the environment. The Agency therefore

finds that all currently registered products containing sulfuryl fluoride as the active ingredient are eligible for reregistration, so long as they are in compliance with the requirements specified herein. The reregistration of particular products is addressed in Section V of this document.

The Agency makes its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency finds that all uses of sulfuryl fluoride are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing sulfuryl fluoride, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

**a. Eligibility Decision**

Based on the reviews of the generic data for the active ingredient sulfuryl fluoride, a determination that unreasonable adverse effects to human health or the environment are unlikely from the current registered uses of sulfuryl fluoride if labeled and used as specified in this document, the Agency concludes that products containing sulfuryl fluoride are eligible for reregistration.

The Agency has determined that sulfuryl fluoride products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks or adverse effects to humans or the environment.

**b. Eligible and Ineligible Uses**

The Agency has determined that all uses of sulfuryl fluoride are eligible for reregistration.

**B. Regulatory Position**

The following is a summary of the regulatory positions and rationales for sulfuryl fluoride. Where

labeling revisions are needed, specific language is set forth in Section V of this document.

**a. Tolerance Reassessment**

There are no food uses of sulfuryl fluoride and therefore no tolerances or exemptions from the requirement of a tolerance established for this chemical.

**b. Restricted Use Classification**

The Agency is maintaining the classification of sulfuryl fluoride as a restricted use pesticide based on inhalation toxicity. This pesticide may only be used by or under the supervision of certified applicators wearing appropriate protective clothing.

**c. Labeling Rationale**

! The registrant has proposed an additional label amendment to remove the following portion of the protective clothing statement from sulfuryl fluoride labels:

"Sulfuryl fluoride is heavier than air and may be trapped inside (clothing) and cause skin injury. Wear full body clothing and shoes or disposable protective clothing. Immediately after application, remove clothing, shoes, and socks."

Based on the method of application (i.e., introduction of sulfuryl fluoride into the target area via a hose), negligible exposure to the applicator would be expected until time of reentry into the fumigated structure to monitor air levels. Therefore, the Agency agrees that the above statement may be removed from sulfuryl fluoride labels.

! Because of uncertainty about neurotoxic effects from long term exposure to sulfuryl fluoride, workers will be required to wear a NIOSH approved, self-contained breathing apparatus (SCBA) upon reentry, regardless of air levels of sulfuryl fluoride. The

Agency is requiring a 90-day inhalation neurotoxicity study in rats to more fully assess human subchronic and chronic effects. Assessment of risks to workers during their working life span, and the need to continue wearing the SCBA upon reentry at all levels of sulfuric fluoride, will be addressed after this study is received and evaluated.

## **V. ACTIONS REQUIRED BY REGISTRANTS**

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use (MP) and end-use products (EUP).

### **A. Manufacturing-Use Products**

#### **a. Additional Generic Data Requirements**

The generic data base supporting the reregistration of sulfuric fluoride for the above eligible uses has been reviewed and determined to be substantially complete for issuance of a Reregistration Eligibility Decision document. However, the Agency considers the following new data requirements confirmatory. (Refer to Appendix F for further information regarding these requirements.)

A neurotoxicity study was not required by the Registration Standard for reregistration of this chemical. However, a 90-day neurotoxicity study in the rat submitted voluntarily by the registrant demonstrated slowing of the visual evoked response (VER) and somatosensory response (SER) wave forms in females and the auditory brain stem response (ABR) in males at 100 ppm, as well as lesions of the caudate-putamen nuclei at the high dose level. However, functional observation batteries and motor activities were not monitored adequately. Ninety-day inhalation toxicity studies in rats, rabbits and dogs at the same exposure concentration levels demonstrated similar neurohistologic lesions at similar (higher in dogs) doses. In addition, the dogs displayed signs consistent with neurologic toxicity. Because of concern that the chemical may produce other neurotoxic responses, and because subchronic/chronic exposure of workers cannot be presently ruled out, a new 90-day neurotoxicity study in rats (GL # 82-5B) is required

using the Subdivision F Neurotoxicity Guidelines.

Method validation data for the Miran and Interscan gas analyzers (also listed under GL # 133-4) and/or any other method used are also required.

**b. Labeling Requirements for Manufacturing-Use Products**

There are currently no manufacturing-use products registered for sulfuryl fluoride.

**B. End-Use Products**

**a. Additional Product-Specific Data Requirements**

No additional product-specific data are required for the one registered sulfuryl fluoride end-use product.

**b. Labeling Requirements for End-Use Products**

It is the Agency's position that, in order to remain in compliance with FIFRA, all products must comply with the following label specifications:

! The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10, with PR Notice 84-5 "Label Improvement Program for Fumigants" and with Supplement # 4 of PR Notice 93-7 "Worker Protection Standard Guidance for Fumigants". Registrants should follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

! The label must provide specific directions for the use of chloropicrin as a warning agent to be present in the structure during fumigation at a level \$ 0.25%.

Instructions must be provided that the chloropicrin must be used by persons certified to apply sulfuryl fluoride and that applicators must observe the precautionary statements and safety recommendations

appearing on the label of this product.

! The label must require that a pesticide fact sheet be provided to an adult occupant of the structure to be fumigated prior to the initiation of the fumigation contract. This fact sheet, which is labeling, must contain as a minimum of information the following:

- a) Why buildings are fumigated.
- b) How buildings are fumigated.
- c) Potential health risks from overexposure.
- d) Safety precautions and homeowner preparation.
- e) A contact point for additional information.

! Add the following under the Environmental Hazards Statement:

Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, consult your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance.

! Due to concern for neurotoxic effects from long term exposure to sulfuryl fluoride upon reentry to treated structures, the Agency requires the following:

Applicators must wear a NIOSH approved self-contained breathing apparatus (SCBA) when reentering a treated structure regardless of air levels of sulfuryl fluoride.

### **C. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision Document (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, 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. Refer to "Existing Stocks of Pesticide Products; State of Policy";

Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell sulfuryl fluoride products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. If the Agency decides to establish a 1 ppm reentry level on October 1, 1994, then the policy will be reconsidered to establish an accelerated label change schedule.

**APPENDIX A**

Table of Use Patterns  
Subject to Reregistration



**APPENDIX A - Use Patterns Subject to Reregistration for Case 0176, [Sulfuryl fluoride]**

SITE	Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate <sup>1/</sup>	Maximum Application Rate <sup>1/</sup>	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Reentry Level	Geographic Limitations		Use Limitations also see Abbreviations
									Allow	Disallowed	
<b>USES ELIGIBLE FOR REREGISTRATION</b>											
<b>NONFOOD/NONFEED USES</b>											
Commercial/Institutional/Industrial/Premises/Equipment Indoor Use Groups: Indoor Non-Food											
Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	
Commercial Transportation Facilities-Nonfeed/Nonfood Use Groups: Indoor Non-Food											
Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: C, E, F, G, H.	
Household/Domestic Dwellings Use Groups: Indoor Residential											
Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	
Household/Domestic Dwellings Content Use Groups: Indoor Residential											
Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	
Wood Protection Treatment to Buildings/Products Indoor Use Groups: Indoor Residential											
Non-Soil Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	
Wood Protection Treatment to Buildings/Products Outdoors Use Groups: Terrestrial Non-Food and Outdoor Residential											
Non-Soil Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	
Wood Protection Treatment to Forest Product (seasoned) Use Groups: Terrestrial Non-Food											
Non-Soil Fumigation, When Needed, Cylinder	PrGs	1 lb./1,000 cuft.	2 lbs./1,000 cuft.	Not spec.	Not spec.	NA	5 ppm (20 mg/cubic meter)	NA	NA	Limitations: A, B, D, E, F.	

Abbreviations used

- Header: Max.=maximum; min.=minimum; apps=applications; not spec=not specified; na=not applicable
- Form: PrGs= Pressurized Gas
- Rate: 1/ = exposure time at these rates varies with the temperature.
- Limitations:
- A). Do not use any canister (breathing apparatus) longer than 2 hours, even when used at lower concentrations or in fresh air.
  - B). In cold weather, the air temperature within the building should be warmed to 55°F before introducing the fumigant.
  - C). When fumigating for insect pests, do not apply when the temperature at the site of activity is below 40°F.
  - D). When fumigating a single unit within or connected to a larger structure (townhouses, apartments, etc.) all units must be vacated.
  - E). Remove all edible items including drugs and medicines before fumigation.
  - F). Extinguish all flames, including pilot lights, hot water heaters, gas refrigerators, ranges, ovens, broilers, etc.
  - G). Turn off or unplug all electrical heating elements.
  - H). Shut off automatic switch controls for appliances and lighting systems.

**APPENDIX B**

**Table of the Generic Data Requirements  
and Studies Used to Make the  
Reregistration Decision**

## GUIDE TO APPENDIX B

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

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR, Part 158. The reference number accompanying each test refers to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (703) 487-4650.
2. Use Pattern (Column 2). This column indicates the use pattern for which the data requirements apply. The following letter designations are used for the given use patterns:
  - A Terrestrial food
  - B Terrestrial feed
  - C Terrestrial non-food
  - D Aquatic food
  - E Aquatic non-food outdoor
  - F Aquatic non-food industrial
  - G Aquatic non-food residential
  - H Greenhouse food
  - I Greenhouse non-food
  - J Forestry
  - K Residential outdoor
  - L Indoor food
  - M Indoor non-food
  - N Indoor medical
  - O Indoor residential
3. Bibliographic citation (Column 3). If the Agency has accepted data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) Number, but may be a "GS" number if no MRID number has been assigned. Refer to the bibliography appendix for a complete citation of the study.

## APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SULFURYL FLUORIDE  
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
<u>Product Chemistry</u>			
61-1	Product Identity and Disclosure of Ingredients	CMO	47012303
61-2	Description of Beginning Material and Manufacturing Process	CMO	47012303, 42703701
61-3	Discussion of Formation/Impurities	CMO	47012303
62-1	Preliminary Analysis	CMO	42703702
62-2	Certification of Limit	CMO	42703701
62-3	Analytical Method to Verify Certification of Limits	CMO	42703701
63-2	Color	CMO	47012303
63-3	Physical State	CMO	47012303

63-4

Odor

CMO

47012303

## APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SULFURYL FLUORIDE  
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
63-7	Density, Bulk Density, or Specific Gravity	CMO	40361001
63-14	Oxidizing or Reducing Action	CMO	40361001
63-15	Flammability	CMO	40361001
63-16	Explodability	CMO	40361001
63-17	Storage Stability	CMO	40361001
63-20	Corrosion Characteristics	CMO	40361001

## APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SULFURYL FLUORIDE  
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
<u>Toxicology</u>			
81-3	Acute Inhalation Toxicity-Rat	CMO	00072289
81-8	Acute Neurotoxicity - Rat	CMO	42772001
82-1 40890902	Subchronic - Rat/Rabbit	CMO	40839902, 40890901, 40890903
83-3	Teratogenicity-Rat/Rabbit	CMO	00090015
83-4	2-Generation Repro - Rat	CMO	42179801
84-2	Gene Mutation (Ames Test)	CMO	41603001, 42179802
84-2b	Structural Chromosomal Aberr	CMO	41448601



APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SULFURYL FLUORIDE  
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
<u>Occupational and Residential Exposure</u>			
133-3	Dermal Exposure	CMO	40333201
133-4 40839902,	Inhalation Exposure	CMO	40333201, 40839901, 41817701

**APPENDIX C**

**Bibliography**

**Citations Considered to be Part of the Data Base  
Supporting Reregistration**

## APPENDIX C

### SULFURYL FLUORIDE BIBLIOGRAPHY

Citations Considered to be Part of the  
Data Base Supporting Reregistration

#### CHEMICAL NAME; SULFURYL FLUORIDE

- 00072289 Dow Chemical Company (1959) The Acute Vapor Toxicity of Vikane As Determined on Male and Female Rats: Single Exposures of Groups of Rats to High Concentrations of Vikane in Air. (Unpublished study received on unknown date under 464-236; CDL:022799-F).
- 00090015 John, J.A.; Hanlye, T.R., Jr.; Ovellette, J.H.; et al. (1981) Vikane (TM): Inhalation Teratology Study in Rats and Rabbits: Lab. No. 917. Final report. (Unpublished study received December 16, 1981 under 464-236; submitted by Dow Chemical U.S.A., Midland, MI.; CDL: 246489-A).
- 40333201 Scheffrahn, R; Spenkel, R. (1987) Post-fumigation Fate of Sulfuryl Fluoride: Desorption from Structural Commodities and Transient and Permanent Residues in Projected and Exposed Foodstuffs: Project Identification GH-C 1939. Unpublished study prepared by Dow Chemical U.S.A. 77 p.
- 40361001 Wichman, K. (1987) Sulfuryl Fluoride...: Physical and Chemical Characteristics. Unpublished study prepared by Agricultural Chemistry R&D Laboratories. 4 p.
- 40839901 Miller, R.; Calhoun, L.; Keyes, D.; et. al. (1980) Sulfuryl Fluoride (Vikane Fumigant): An LC50 Determination: Project ID K-016399-013. Unpublished study prepared by the Dow Chemical Co. 244 p.
- 40839902 Miller, J.; Albee, R.; Eisenbrandt, D.; et. al. (1986) Neurological Examination of Fischer 344 Rats Exposed to Sulfuryl Fluoride (Vikane Gas Fumigant) for 13 Weeks: Project ID: K-016399-026. Unpublished study prepared by the Dow Chemical Co. 110 p.

- 40890901 Nitschke, K.; Zimmer, M.; Eisenbrandt, D. (1987) Sulfuryl Fluoride (Vikane Gas Fumigant); 13-Week Inhalation Toxicity Study with Rabbits; Study ID K-016399-025B. Unpublished study prepared by the Dow Chemical Co. 135 p.
- 40890902 Nitschke, K.; Dittenber, D.; Eisenbrandt, D. (1987) Sulfuryl Fluoride (Vikane Gas Fumigant); 13-Week Inhalation Toxicity Study with Rats: Study ID K-016399-025R. Unpublished study prepared by the Dow Chemical Co. 158 p.
- 40890903 Miller, J.; Albee, R.; Eisenbrandt, D.; et. al. (1987) Subchronic Neurotoxicity in Rats of the Structural Fumigant, Sulfuryl Fluoride. Neurotoxicology and Teratology 10(2):127-133.
- 41448601 Gollapudi, B.; McClintock, M.; Nitschke, K. (1990) Evaluation of Sulfuryl Fluoride in the Mouse Bone Marrow Micronucleus Test: Lab Project No.: TXT:K-016399-033. Unpublished study prepared by the Dow Chemical Co. 37 p.
- 41603001 Gollapudi, B.; Samson, Y.; Zempel, J. (1990) Evaluation of Sulfuryl Fluoride in the Ames Salmonella/Mammalian-Microsome Bacterial Mutagenicity Assay: Lab Project No.: TXT:K-016399-037. Unpublished study prepared by the Dow Chemical Co. 41 p.
- 41769101 Nitschke, K. (1990) Sulfuryl Fluoride: Acute LC50 Study with CD-1 Mice: Lab Project No.: K-016399-031: K-016399-031B. Unpublished study prepared by the Toxicology Research Laboratory/Dow Chemical Co. 56 p.
- 41817701 Indoor Airborne Residues of Methyl Bromide and Sulfuryl Fluoride in Fumigated Houses After Aeration.
- 42179801 Breslin; Liberacki; Kirk; Bradley; and Crissman (1992) Two Generation Inhalation Reproduction Study in Sprague Dawley Rats; Study ID# K-016399-042.
- 42179802 Gollapudi, B.; McClintock, M.; Zempel, J. (1991) Evaluation of Sulfuryl Fluoride in the Rat Hepatocyte

Unscheduled DNA Synthesis (UDS) Assay; Study ID# K-016399-043.

42703701 Reregistration of Sulfuryl Fluoride Product and Residue Chemistry Review; Study ID# KJB51292, 4 p. and Study ID# KJB5129CA, 5 p.

42703702 Series 62: Analysis and Certification of Product Ingredients of Vikane Gas Fumigant; Study ID# GH-C 2977 83 p.

42772001 Albee, R.; Spencer, P.; Bradley, G. (1993) Sulfuryl Fluoride: Electrodiagnostic, FOB and Motor Activity Evaluation of Nervous System Effects From Short Term Exposure; Study ID# K-016399-045. 164 p.

**APPENDIX D**

**List of Available Related Documents**

## APPENDIX D

The following is a list of available documents related to sulfuryl fluoride. Its purpose is to provide a path to more detailed information if it is required. These accompanying documents are part of the Administrative Record for Sulfuryl Fluoride and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. Sulfuryl Fluoride RED Fact Sheet (included in this RED)
4. PR Notice 91-2 (Included in this RED) Pertains to the Label Ingredient Statement

The following Federal publications on sulfuryl fluoride are available and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

1. Guidance for the Reregistration of Pesticide Products Containing Sulfuryl Fluoride as the Active Ingredient (The 1985 Registration Standard): NTIS Stock No. PB86-173937
2. Pesticide Fact Sheet (No. 26) for sulfuryl fluoride: NTIS Stock No. PB87-124392

**APPENDIX E**

**Pesticide Reregistration Handbook**



**APPENDIX F**

**Generic Data Call-In**

## DATA CALL-IN NOTICE

### CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments A through E; or
2. why you believe you are exempt from the requirements listed in this Notice and in Attachment C, Requirements Status and Registrant's Response Form, (see section III-B); or
3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment D).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).



This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You Are Receiving This Notice
- Section II - Data Required By This Notice
- Section III - Compliance With Requirements Of This Notice
- Section IV - Consequences Of Failure To Comply With This Notice
- Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

- Attachment A - Data Call-In Chemical Status Sheet
- Attachment B - Data Call-In Response Form
- Attachment C - Requirements Status And Registrant's Response Form
- Attachment D - List Of All Registrants Sent This Data Call-In Notice
- Attachment E - Cost Share And Data Compensation Forms

## **SECTION I. WHY YOU ARE RECEIVING THIS NOTICE**

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient. You have been sent this Notice because you have product(s) containing the subject active ingredient.

## **SECTION II. DATA REQUIRED BY THIS NOTICE**

### **II-A. DATA REQUIRED**

The data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### **II-B. SCHEDULE FOR SUBMISSION OF DATA**

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

## **II-C. TESTING PROTOCOL**

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

## **II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY**

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

## **SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE**

### **III-A. SCHEDULE FOR RESPONDING TO THE AGENCY**

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.



### **III-B. OPTIONS FOR RESPONDING TO THE AGENCY**

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, Attachment B and the Requirements Status and Registrant's Response Form, Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment A.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 557-2126.



If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. **Generic Data Exemption** - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

- a. The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;
- b. Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- c. You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment B and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. **Satisfying the Data Requirements of this Notice** There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you

must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified timeframe (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a

protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study.

In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer,

or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

**Option 3, Offer to Share in the Cost of Data Development** -- If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment E. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer.

The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

**Option 4, Submitting an Existing Study** -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required

date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j):

" '[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

**Option 5, Upgrading a Study** -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment A. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

**Option 6, Citing Existing Studies** -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally

will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

### III-D REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

- a(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.
- (ii). Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

- b. **Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.**
- c. **Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.**
- d(i). **A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.**
- (ii). **A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.**
- e. **For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.**
- f. **A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.**

**Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.**



2. **Request for Waiver of Data -- Option 9 on the Requirements Status and Registrant's Response Form.** This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). **If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice.** Within 30 days of your receipt of the Agency's written decision, you must submit a revised **Requirements Status and Registrant's Response Form** indicating the option chosen.

#### **IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE**

##### **IV-A NOTICE OF INTENT TO SUSPEND**

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

#### **IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE**

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data,

including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### **IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS**

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and

good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

**SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS**

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

**SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment B) and a completed Requirements Status and Registrant's Response Form (Attachment C) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment A. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Daniel M. Barolo, Director  
Special Review and  
Reregistration Division

**Attachments**

A - Data Call-In Chemical Status Sheet

- B - Data Call-In Response Form
- C - Requirements Status and Registrants Response Form
- D - List of Registrants Receiving This Notice
- E - Cost Share and Data Compensation Forms

## ATTACHMENT A

## SULFURYL FLUORIDE: DATA CALL-IN STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing sulfuryl fluoride.

This attachment, the Data Call-In Chemical Status Sheet, contains the reregistration regulatory history of sulfuryl fluoride, an overview of data required by this notice, and point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, (3) Attachment C, the Requirement Status and Registrant's Response Form, (4) Attachment D, List of All Registrants Receiving This Notice, and (5) Attachment E, the Cost Share and Data Compensation Forms in replying to this sulfuryl fluoride Data Call-In. Instructions and guidance accompany each form.

REREGISTRATION HISTORY

In June 1985, EPA issued a Registration Standard on Sulfuryl Fluoride. In the Registration Standard, EPA identified data required to support existing uses of the pesticide and determined whether existing data were acceptable and sufficient to satisfy the requirement. Under the 1985 Registration Standard, registrants were required to generate data to fill in data gaps and replace unacceptable studies. Data Call-In Notices were also issued in July 1990 and November 1992 which required additional toxicology data.

The Agency has reviewed the data submitted in response to the 1985 Registration Standard and the July 1990 and November 1992 Data Call-In Notices and has reevaluated its position on data needed to support the continued registration of sulfuryl fluoride. A Reregistration Eligibility Document is being issued for Sulfuryl Fluoride with this Data Call-In Notice which states the Agency has determined the available data shows that use of sulfuryl fluoride will not pose an unreasonable adverse risk to human health or the environment. However, the RED also identifies confirmatory data the Agency needs to complete the database for sulfuryl fluoride.

DATA REQUIRED BY THIS NOTICE

The Agency's findings regarding the adequacy of the database for sulfuryl fluoride are contained in the Requirements Status and Registrant's Response, Attachment C.

The Agency has concluded that additional data on sulfuryl fluoride are needed in the following areas: toxicology and occupational and residential exposure. The required additional data are listed in Attachment C. These data are confirmatory.

Depending on the results of the studies required in this Notice and in the Registration Standard and subsequent DCI's, additional testing may be required.

#### **INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the requirements and procedures established by this Notice, please contact Robert Richards, Chemical Review Manager, at (703) 308-8057.

All Response to this Notice should be submitted to:

**Robert Richards, Chemical Review Manager  
Reregistration Branch  
Special Review and Reregistration Division (H7508W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460**

**RE: Sulfuryl Fluoride**

## SPECIFIC INSTRUCTIONS FOR THE DATA CALL-IN RESPONSE FORM

This form is designed to be used to respond to data call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1 through 4 will have to be preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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### INSTRUCTIONS

- Item 1. This item identifies your company name, number and address.
- Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. This item identifies the date and type of data call-in.
- Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
- Item 5. Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.



- Item 6a.** Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice. If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-in Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

- Item 6b.** Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.
- Item 7a.** Check this Item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.
- Item 7b.** Check this Item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.
- Item 8.** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.
- Item 9.** Enter the date of signature.
- Item 10.** Enter the name of the person EPA should contact with questions regarding your response.
- Item 11.** Enter the phone number of your company contact.

**SPECIFIC INSTRUCTIONS FOR COMPLETING  
THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM**

**Generic Data**

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. **DO NOT** use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

## INSTRUCTIONS

- Item 1. This item identifies your company name, number and address.
- Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. This item identifies the date and type of data call-in.
- Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.
- Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

- Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:
- A Terrestrial food
  - B Terrestrial feed
  - C Terrestrial non-food
  - D Aquatic food
  - E Aquatic non-food outdoor
  - F Aquatic non-food industrial
  - G Aquatic non-food residential
  - H Greenhouse food
  - I Greenhouse non-food crop
  - J Forestry
  - K Residential
  - L Indoor food
  - M Indoor non-food
  - N Indoor medical
  - O Indoor residential

**Item 7.** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

<b>EP</b>	<b>End-Use Product</b>
<b>MP</b>	<b>Manufacturing-Use Product</b>
<b>PAI</b>	<b>Pure Active Ingredient</b>
<b>PAI/M</b>	<b>Pure Active Ingredient and Metabolites</b>
<b>PAIRA</b>	<b>Pure Active Ingredient Radiolabelled</b>
<b>PAIRA/M</b>	<b>Pure Active Ingredient Radiolabelled and Metabolites</b>
<b>PAIRA/PM</b>	<b>Pure Active Ingredient Radiolabelled and Plant Metabolites</b>
<b>TEP</b>	<b>Typical End-Use Product</b>
<b>TEP __%</b>	<b>Typical End-Use Product, Percent Active Ingredient Specified</b>
<b>TEP/MET</b>	<b>Typical End-Use Product and Metabolites</b>
<b>TEP/PAI/M</b>	<b>Typical End-Use Product or Pure Active Ingredient and Metabolites</b>
<b>TGAI</b>	<b>Technical Grade Active Ingredient</b>
<b>TGAI/PAI</b>	<b>Technical Grade Active Ingredient or Pure Active Ingredient</b>
<b>TGAI/PAIRA</b>	<b>Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled</b>
<b>MET</b>	<b>Metabolites</b>
<b>IMP</b>	<b>Impurities</b>
<b>DEGR</b>	<b>Degradates</b>
<b>*</b>	<b>See: guideline comment</b>

**Item 8.** This item identifies the time frame allowed for submission of the study or protocol identified in item 5. The time frame runs from the date of your receipt of the Data Call-In Notice.

**Item 9.** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

- 1. (Developing Data)** I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.
- 2. (Agreement to Cost Share)** I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

3. **(Offer to Cost Share)** I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.
4. **(Submitting Existing Data)** I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.
5. **(Upgrading a Study)** I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
6. **(Citing a Study)** I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.
7. **(Deleting Uses)** I am attaching an application for amendment to my registration deleting the uses for which the data are required.
8. **(Low Volume/Minor Use Waiver Request)** I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
9. **(Request for Waiver of Data)** I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

- Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.**
- Item 11. Enter the date of signature.**
- Item 12. Enter the name of the person EPA should contact with questions regarding your response.**
- Item 13. Enter the phone number of your company contact.**

## APPENDIX G

### Product Specific Data Call-In

**There are no product specific data being called in for sulfuryl fluoride. Refer to "labeling requirements for end-use products" for information regarding submission of updated product labels.**