United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(H-7508W)

EPA 738-R-93-016
September 1993

EPA Reregistration Eligibility Decision Document

SULFURYL FLUORIDE

United States
Environmental Protection
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Office of Prevention, Pesticides
And Toxic Substances
(H-7508W)

EPA-738-F-93-012
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EPA 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 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.

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 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 $\geq 0.25\%$. 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-contianed 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 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.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CERTIFIED MAIL

SEP 30 1993

OFFICE OF
PREVENTION, PESTICIDES /
TOXIC SUBSTANCES

DowElanco
Quad IV
9002 Purdue Road
Indianapolis, IN 46268-1189

Dear Registrant:

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

To assist you with a proper response, read the enclosed document entitled "Pesticide Reregistration Handbook". This handbook also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific labeling requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Robert Richards at (703) 308-8057.

Sincerely yours,

Peter Caulkins for

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

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REREGISTRATION ELIGIBILITY DECISION

Sulfuryl Fluoride

LIST A

CASE 0176

ENVIRONMENTAL·PROTECTION·AGENCY
OFFICE·OF·PESTICIDE·PROGRAMS
SPECIAL·REVIEW·AND·REREGISTRATION·DIVISION

SULFURYL FLUORIDE REREGISTRATION ELIGIBILITY TEAM

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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_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	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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Appendix D - List of Available Related Documents

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Appendix F - Generic Data Call-In

Attachment A -	Chemical Status Sheet
Attachment B -	Generic DCI Response Forms (Form A) plus Instructions
Attachment C -	Requirements Status and Registrants' Response Forms (Form B) plus Instructions
Attachment D -	List of all Registrant(s) sent this DCI
Attachment E -	Cost Share/Data Compensation Forms

Appendix G - Product Specific Data Call-In

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.[1]

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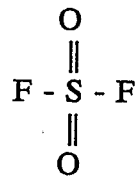
[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Chemical Name:** sulfuryl fluoride
- **Structure:**



- **CAS Registry Number:** 2699-79-8
- **OPP Chemical Code:** 078003
- **Chemical Formula:** F_2O_2S
- **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 $\geq$ 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 (25°C), 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):

TGAI	Sulfuryl fluoride
Color	None
Physical State	Gas at 25°C
Odor	None
Melting Point	-136.7° C at 760 mm Hg
Boiling Point	-55.2° C at 760 mm Hg
Specific Gravity	1.34 at 25°C
Vapor Density	3.52 (air = 1)
Solubility	0.075 g/100 g water at 25°C, 0.78 g/100 cc Wesson oil at 20°C, 1.74 g/100 cc acetone at 22°C, 2.12 g/100 cc chloroform at 22°C
Vapor Pressure	17.7 mm Hg at 25°C
Dissoc. Constant	N/A
Oct./Water Part. Coeff.	N/A
pH	N/A
Stability	Stable to heat. Hydrolyzes slowly in water but rapid in basic solution
Oxidizing or	A mild oxidant

Reducing Action	Reduction potential is -.68V
Flammability	Not flammable
Explodability	Not explodable
Storage Stability	For up to 6 yrs in steel cylinders
Corrosion	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.

a. Acute Toxicity

The acute toxicity data are summarized in the table below:

TEST	RESULTS	TOX CAT
Oral LD_{50}/rats (MRID # 00072289)	100 mg/kg	II
Oral LD_{50}/guinea pigs (MRID # 40839901)	100 mg/kg	II
1 hr Inhalation LC_{50} in rats (MRID # 41099001)	4507 ppm (17.5 mg/L)	III
4 hr Inhalation LC_{50} in mice (MRID # 41769101)	M = 660 ppm (2.56 mg/L) F = 642 ppm (2.49 mg/L)	IV
4 hr Dermal Vapor LC_{50} in rats (MRID # 41712001)	9599 ppm (37.27 mg/L)	IV

M Males
F Females

b. 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).

c. 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 sulfuryl 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 sulfuryl 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).

d. 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).

e. 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).

f. 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).

g. 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).

2. Exposure Assessment

a. 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.

b. 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 ai and 1% impurities which are present as a result of 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 ≥ 0.25%.

(1) 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.

(2) Residential/Occupational post application reentry exposure

Because of its physical nature (a gas at 25^{0}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^3. 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:

$$\text{Daily Dose (mg/kg/day)} = \frac{\text{ppm x MW}}{24450} \times \frac{\text{resp. vol. (L/day)}}{\text{Kg body weight}}$$

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 Scenario	Air level ppm	Air level mg/m^3	Daily dose (mg/kg/day) Males	Daily dose (mg/kg/day) 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)].

3. Risk Assessment

a. Dietary

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

b. 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:

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

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^3/24 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/m³	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

1. 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 hydrolizes very slowly in water under neutral conditions. However, it does undergo hydrolysis under alkaline conditions to form fluorosulfuric acid (HSO_3F) and hydrofluoride (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.

2. 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.

1. 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.

2. 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.

1. 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.

2. 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.

3. 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 reeentry at all levels of sulfuryl 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

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of sulfuryl 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.

2. Labeling Requirements for Manufacturing-Use Products

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. 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 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-contianed 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 1/	Maximum Application Rate 1/	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Reentry Level	Geographic Limitations		Use Limitations also see Abbreviations
									Allow	Disallowed	
USES ELIGIBLE FOR REREGISTRATION											
NONFOOD/NONFEED USES											
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 the 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 refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, 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
Product Chemistry			
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
Toxicology			
81-3	Acute Inhalation Toxicity-Rat	CMO	00072289
81-8	Acute Neurotoxicity - Rat	CMO	42772001
82-1	Subchronic - Rat/Rabbit	CMO	40839902, 40890901, 40890902 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
Occupational and Residential Exposure			
133-3	Dermal Exposure	CMO	40333201
133-4	Inhalation Exposure	CMO	40333201, 40839901, 40839902, 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

United States
Environmental Protection
Agency

Office of
Pesticide Programs

October 1991

EPA

Pesticide Reregistration Handbook

How to Respond to the Reregistration Eligibility Document (RED)

PRODUCT REREGISTRATION HANDBOOK

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- C. Sample Label Formats--General Use & Restricted Use
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PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

This Handbook provides instructions to registrants on how to respond to the Reregistration Eligibility Document (hereafter referred to as the "RED") and how to reregister products.

Section I is this introduction.

Section II contains step-by-step instructions which must be followed by registrants responding to the RED.

Section III provides additional instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted.

Detailed instructions are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Under Section 4 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1988, EPA is required to reregister pesticides that were first registered before November 1, 1984. The RED describes in detail the subject chemical, its uses and its regulatory history; describes EPA's decision concerning the eligibility of the uses of the chemical for reregistration; and explains the scientific and regulatory bases for this decision. EPA's reviews of the data by scientific discipline are available upon request.[1] Appendices to the RED contain: (1) a Data Dall-In Notice which requires submission of generic and product specific data and which gives directions for responding, (2) a listing of existing studies that satisfy generic data requirements and (3) a bibliography of the generic studies EPA has reviewed.

C. The Reregistration Process

Reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of EPA's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine whether the data base is substantially complete or there is need for additional generic data, and to determine whether the pesticide is eligible for reregistration. This decision is issued as the RED.

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[1] EPA's science reviews and information on the registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must first respond within 90 days of receipt to the data call-in portion of the RED. Within 8 months of receiving the RED, registrants must submit or cite any data and labels/labeling required for each product. EPA has until 14 months after the RED is issued (i.e., 6 months after the registrants' 8 month deadline) to review the submission for each product and decide whether to reregister it based on the following criteria:

--whether all of the product specific data and labels/labeling are acceptable,

--whether all of the uses on the label/labeling are eligible,

--whether all of the active ingredients in the product are eligible, and

--if no List 1 toxic inert ingredient is contained in the product (a List 1 inert is permitted only if all data for it have been submitted and EPA determines that the inert does not pose any unreasonable adverse effects in that product).

Products which meet all of these criteria will be reregistered. Products which do not meet all of these criteria, but which have acceptable product specific data and labeling, will be processed as amendments in order to implement label changes required by the RED.

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

This section provides directions for submitting timely and adequate responses necessary to reregister products containing the active ingredient covered by the RED. Registrants must follow these steps exactly to avoid suspension of their products. All products containing the active ingredient in the RED [i.e., manufacturing use products, end use products and special local need (SLN or Section 24c) registrations] are subject to the requirements of the RED. Figure 1 summarizes how and when to respond to the RED. A step-by-step explanation follows.

Step 1. Are Expedited Label Changes Required? In some instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED. If expedited label changes are not required, go to Step 2.

a. Application for Registration (EPA Form 8570-1). Complete

and sign the form. In Section II, insert the phrase "Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)." Applications for expedited label changes will be processed as applications for amended registration. Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for label/labeling changes and follow the instructions in Section III.C. and the Appendix of this Handbook for revising the label and labeling for each product.

Step 2. Are data required? If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension. No time extensions will be given for responding within 90 days.

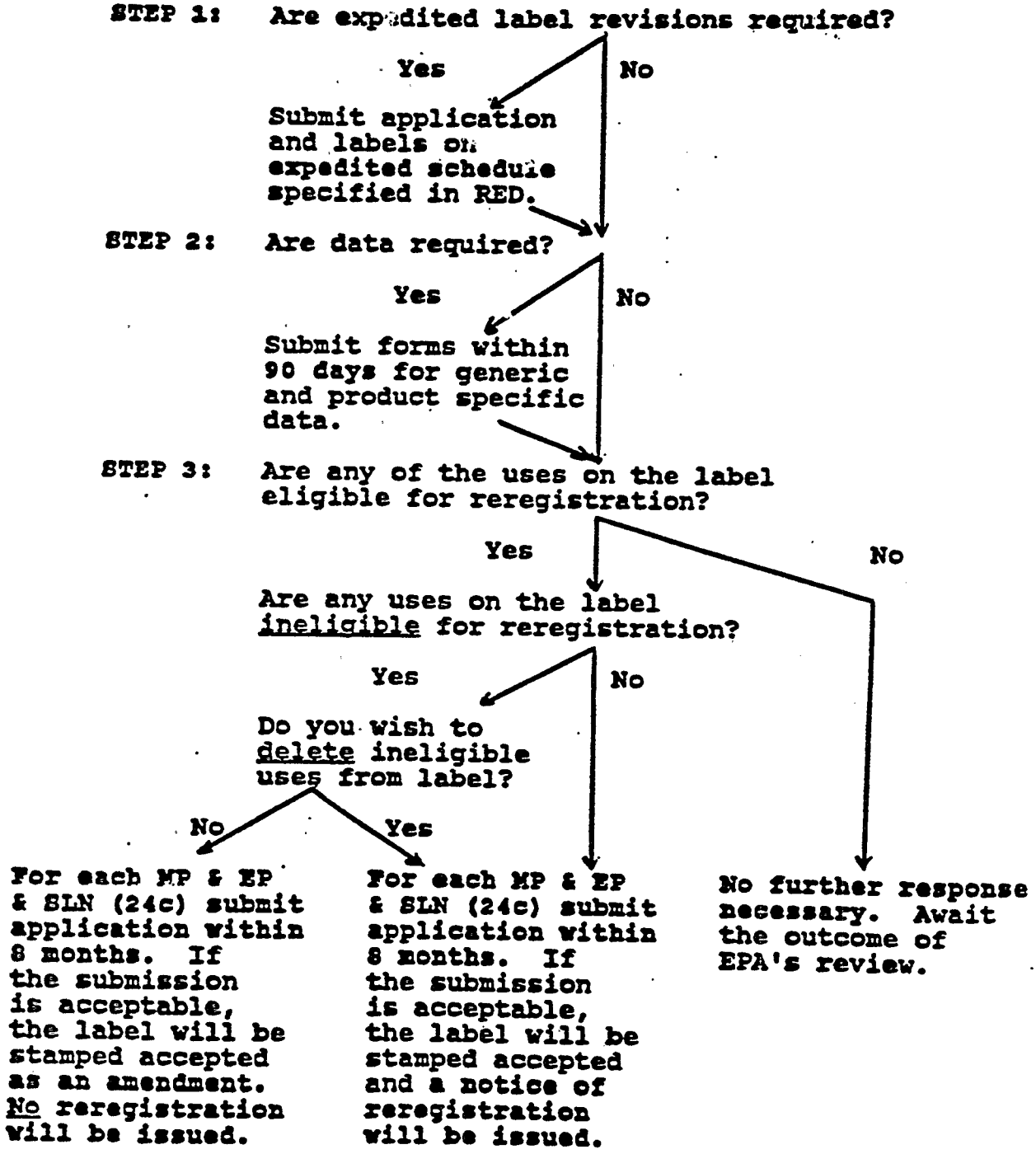
Step 3. Are Uses of a Pesticide Eligible for Reregistration? If any uses of the active ingredient(s) covered by the RED are eligible for reregistration, follow these instructions. If no uses are eligible, no further response may be needed (see page 5).

EPA's decision on the eligibility of each of the uses of the active ingredient(s) is presented in the RED. If any uses of a chemical are eligible for reregistration, registrants for manufacturing-use products (MPs), end-use products (EPs) and special local needs registrations (SLNs), must submit the items below for each product within 8 months of the date of issuance of the RED:

a. Application for Reregistration (use EPA Form 8570-1). Complete and sign the form. In Section II of that form, check the box "Other" and insert the phrase "Application for Reregistration." Use only an original application form with a red identifier number in the upper right-hand corner.

b. Five (5) copies of revised draft label and labeling. Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are ineligible uses on the label or labeling, you may delete such uses and avoid all requirements and consequences which may be associated with ineligible uses (e.g, generic data requirements, cancellation, suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

FIGURE 1. HOW AND WHEN TO RESPOND TO THE REREGISTRATION ELIGIBILITY DOCUMENT (RED) FOR MANUFACTURING USE PRODUCTS (MPs), END-USE PRODUCTS (EPs) and SPECIAL LOCAL NEEDS REGISTRATIONS (SLNs).



c. Product Specific Data. You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within 90 days of receipt of the RED and submission or citation of data is due within 8 months of the issuance of the RED.

d. Two (2) copies of the current Confidential Statement of Formula (EPA Form 8570-4, revised February 85). Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation. If CSFs are not provided for the alternate formulas, they will not be reregistered and will no longer be acceptable. The Appendix of this Handbook has specific instructions for completing the CSF form.

e. Certification With Respect to Citation of Data (EPA Form 8570-31). This form must be completed, signed and submitted for each product to assure that the data compensation provisions of FIFRA are met.

B. When No Response is Needed

If no uses of a pesticide are eligible for reregistration, it is unlikely that you will be required to submit product specific data or labeling. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

--Available data indicate that one or more of the criteria for an in-depth special review have been met;

--Additional generic data are required.

In the first instance, if the active ingredient is placed into special review, reregistration activities associated with those uses of the chemical are stopped until EPA makes a final determination. At that time, EPA will indicate which uses may be eligible for reregistration and which uses are to be cancelled. If some or all of the previously ineligible uses become eligible for reregistration, EPA will start the reregistration process for products containing only eligible uses.

In the second instance, based upon the review of studies for an active ingredient during reregistration, additional generic data (e.g., second- or third-tier studies) may be needed (see the RED). In such cases, the chemical's uses will not be eligible for reregistration until the additional generic data have been submitted to and reviewed and found acceptable by EPA. If the data are reviewed and found to be acceptable, EPA will indicate which uses will be eligible for reregistration and will initiate reregistration of products containing previously ineligible uses. If the data are not submitted, products containing the active ingredient may be suspended.

C. Where to Respond

By U.S. Mail:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

By express mail or by hand delivery:

Document Processing Desk (insert distribution code)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

These mailing addresses and the following distribution codes must be used to assure the timely receipt and processing of your submissions. Not using them may significantly delay the handling of your submissions:

RED-SRRD-xxx (where xxx is the case code given on the front of the RED)--use this distribution code for all responses pertaining to or containing generic data. Such responses include the 90-day response forms for generic data or hard copies of generic data.

RED-RD-PMxx (where xx is the Product Manager team number)--use this distribution code for all responses pertaining to or containing product specific data or labeling. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

III. SUBMISSION OF DATA AND LABELS/LABELING

This section provides additional instructions concerning responses required for generic data, product specific data and labels/labeling.

A. Generic Data

During EPA's evaluation of an active ingredient for reregistration, additional generic data requirements may be identified that registrants must fulfill. In some instances these data requirements would have to be satisfied before an active ingredient or some of its uses could be declared eligible for reregistration. In other cases, these new data requirements would not affect the eligibility of the active ingredient, but would be necessary to confirm EPA's assessment of that chemical.

Any new data requirements and how they affect reregistration eligibility of a chemical are discussed in the RED. If new generic data requirements are imposed in a Data Dall-In Notice in the RED, registrants must respond as described in that Notice. The RED also contains instructions for completing these forms, a citation of EPA's legal authority for requiring the new data, a listing of options available to registrants for satisfying the data requirements and the name of the contact person for inquiries.

B. Product Specific Data

Product specific data may be required for the reregistration of each pesticide product in three areas--product chemistry, acute toxicity and efficacy.

1. Product Chemistry

Following are instructions for submitting product-specific data and a discussion of EPA's policy on inert ingredients.

a. Data

All data requirements for MPs, EPs and SLNs (24c's) are specified in the Data Call-In Notice in the RED. In addition:

--If you cite data from another identical, registered product, you must identify the EPA registration number of that product.

--If the product-specific data submitted or cited do not pertain to an identical formulation to the product submitted for reregistration, then new product-specific data are required to be submitted by the deadline specified in the Data Call-In Notice. The only exception is for products which EPA "groups" together a being similar enough to depend on the same data. Such groupings are discussed in the appendix to the RED (for acute toxicity purposes, for example), if it was feasible to do so.

b. Inert Ingredients

EPA has implemented a strategy for regulating inert ingredients which affects the reregistration of pesticide products. This strategy, issued on April 22, 1987 (52 FR 13305-13309) and updated on November 22, 1989 (54 FR 48314-48316), adopted certain policies designed to reduce the potential for adverse effects from pesticide products containing intentionally added inert ingredients. EPA divided the known inert ingredients into four categories:

--Inerts of toxicological concern (List 1) for which available data demonstrate toxic effects of concern (includes about 50 chemicals).

--Potentially toxic inerts (List 2) for which only limited data are available, but such data or the chemical structure suggest the potential for toxicity (includes about 60 chemicals).

--Inerts of unknown toxicity (List 3) for which no data or bases for suspecting toxic effects are available (includes up to 2,000 chemicals).

--Inerts of minimal concern (List 4) which are generally regarded as innocuous (includes about 290 chemicals).

When a RED is issued and any uses of an active ingredient are declared eligible for reregistration, all products containing that active ingredient will be subject to reregistration. EPA will, as part of the reregistration review, examine the inert ingredients of each product prior to reregistration to ensure that they do not present unreasonable risks. In reviewing the product chemistry data, EPA will identify List 1 inerts. EPA will continue to encourage registrants to eliminate any List 1 inerts present. Reregistration of products containing only List 2, 3 or 4 inerts will be unaffected by the inerts strategy.

Consistent with the strategy on inerts, a product containing a List 1 inert ingredient will <u>not</u> be reregistered until a full risk assessment of the product has been conducted, based on the data called in for that inert ingredient. However, the existing registration of a product containing a List 1 inert will remain valid as long as the product bears the required label warning and is in compliance with any outstanding DCI, or other activity under the inerts strategy.

Any product containing a List 2, 3 or 4 inert <u>may</u> be reregistered <u>if</u> it meets all other requirements for reregistration. As the inerts strategy is implemented and data for the List 2 and 3 inerts are reviewed, EPA may move these inerts to the other Lists. If an inert were moved to List 1, products containing that inert would become ineligible for reregistration. Inert ingredients must also meet normal registration and tolerance requirements, as applicable.

2. <u>Acute Toxicity</u>

The data call-in notice in the RED specifies the acute toxicity data required for reregistration of each MP or EP. It indicates whether any of the standard tests have been waived and, if so, why.

If feasible, EPA will "batch" products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each baatch of products. This approach will impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The

main benefits of this approach are to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants may contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants may choose to conduct their own studies.

3. Product Performance

Consult the Data Call-In section of the RED to determine whether Product Performance data are required for your product.

Product performance (efficacy) data are generated in studies designed to document how candidate pesticide formulations perform as pest control agents. These data include tests run to determine whether a formulation is lethal to certain pest species, to document the effectiveness of the formulation in controlling pest species in actual use situations, and to determine whether certain claims beyond mere control of a pest (e.g., "six-month residual effect," "kills Warfarin resistant house mice," etc.) are justified.

EPA has standard protocols for certain efficacy tests. In general, standard methods have been developed for tests needed to substantiate claims that have been made frequently for pesticide products. As the scope of potential pesticidal claims is extremely broad, the Agency does not have standard methods for tests needed to substantiate many pesticide claims, especially those that are uncommon. The Product Performance Guidelines, Subdivision G, offer general guidance for developing protocols for efficacy testing. Proposed protocols should be submitted to EPA for review before tests are initiated.

a. Efficacy Data Submission Waiver Policy

FIFRA gives the Administrator of EPA authority "to waive data requirements pertaining to efficacy" but does not require that efficacy data requirements be waived for any class of pesticide product registered under Section 3 of the Act. As a matter of policy, EPA does not require submission of efficacy data to support many types of pesticidal claims but does require submission of such data for certain types of claims. As noted in 40 CFR 158.640, this waiver applies to the submission of efficacy data rather than to the generation of efficacy data. EPA expects each registrant to "ensure through testing that his products are efficacious when used in accordance with commonly accepted pest control practices."

This general policy notwithstanding, EPA may, at any time, require a registrant to submit efficacy data to support any claim made for a product. EPA also may require that certain claims of effectiveness be established before a Section 3 registration is granted.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation
☐ Alternate Formulation

B. Page

See Instructions on Back

1. Name and Address of Applicant/Registrant *(include ZIP Code)*

2. Name and Address of Producer *(include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(include Area Code)*

21. Date

b. Claims and Products for Which Efficacy Data Generally Are Required

Submission of efficacy data at reregistration typically is required for the following types of products:

1. products claimed to control microorganisms that pose potential threats to public health;

2. products claimed to control vertebrate pests that may directly or indirectly transmit diseases to humans;

3. potentially very hazardous products for which EPA determines that it is necessary to conduct a "risk-benefits" analysis;

4. products of types for which EPA has reasons (e.g., consumer complaints, unlikely claims, unusual use patterns, etc.) to question claims; and

C. Labels and Labeling

To remain in compliance with FIFRA, the label and labeling of each product must be revised to meet the requirements for reregistration as described below. "Labeling" includes the container label and any written, printed or graphic matter that accompanies the pesticide in U.S. commerce at any time (such as technical bulletins, collateral labeling, etc.). Applications for new uses or labeling changes that do not pertain to reregistration must be filed separately from the application for reregistration described in Step 3 earlier. Changes to labeling which must be made for reregistration include, but are not limited to:

1. Labeling changes specified in the RED. Such changes may include statements on RESTRICTED USE, groundwater hazards, protective clothing/equipment, endangered species, environmental hazards, etc.

2. The format and content of labeling as described in 40 CFR 156.10. When further acute testing is needed, the currently accepted precautionary statements will usually be retained until testing is completed and the data are reviewed.

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations, regulatory decisions and policies issued by EPA which are relevant to the pesticide. Your product's labeling must reflect any applicable requirements which are in effect at the time the RED is issued. Some existing notices are referred to in Section B. of the Appendix.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

C. Sample Label Formats--General Use & Restricted Use

D. Label Regulations (40 CFR 156.10)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product-specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 and Pesticide Regulatory (P.R.) Notices require that specific labeling statements appear at certain locations on the label. The sample label formats in Appendix C show where these statements are to be placed.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR 156.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the producer, registrant or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text. [40 CFR 156.10(c)]

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is normally required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural

formulations, the pounds per gallon of active ingredient must be indicated on the label. [40 CFR 156.10(h)(iv)]

Item 6C. NAMES TO BE USED IN INGREDIENT STATEMENT - The acceptable common name, if there is one, shall be used, followed by the chemical name. If no common name has been established, the chemical name alone shall be used. Chemicals related to the active ingredient are allowed to be listed only if efficacy data supporting such claims are submitted or referenced. If such data are provided, the related chemicals must be listed separately and not as a portion of the active ingredient.

Item 6D. INERT INGREDIENTS RECLASSIFIED AS ACTIVE INGREDIENTS - If EPA has reclassified chemicals from inert ingredient status to active ingredient status, registrants of affected products must change the ingredient statement accordingly (See 52 FR 13307-8, April 22, 1987). If such pesticides have food uses, tolerances must either be established for such uses, or an exemption from the requirement for tolerances must be obtained.

Item 6E. NOMINAL CONCENTRATION - The amount of active ingredient declared in the ingredient statement must be the nominal concentration of the product as defined in 40 CFR 158.153(i) and described in P.R. Notice 91-2.

Item 7. WARNINGS AND PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation). If your product has been classified for restricted use, then these requirements apply:

1. **All uses restricted.** The following statements must be placed in a black box at the top of the front panel of the label and labeling:

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word [see table in 40 CFR 156.10(h)(1)(iv)]. No statements of any kind may appear above this RUP statement.

   b. The reason for the the restricted use classification must appear below the RUP statement. The RED will prescribe this statement.

   c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification." The RED will specify what statement must be used.

2. **Some but not all uses restricted.** If the RED states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in

accordance with PR Notice 83-2, March 29, 1983.

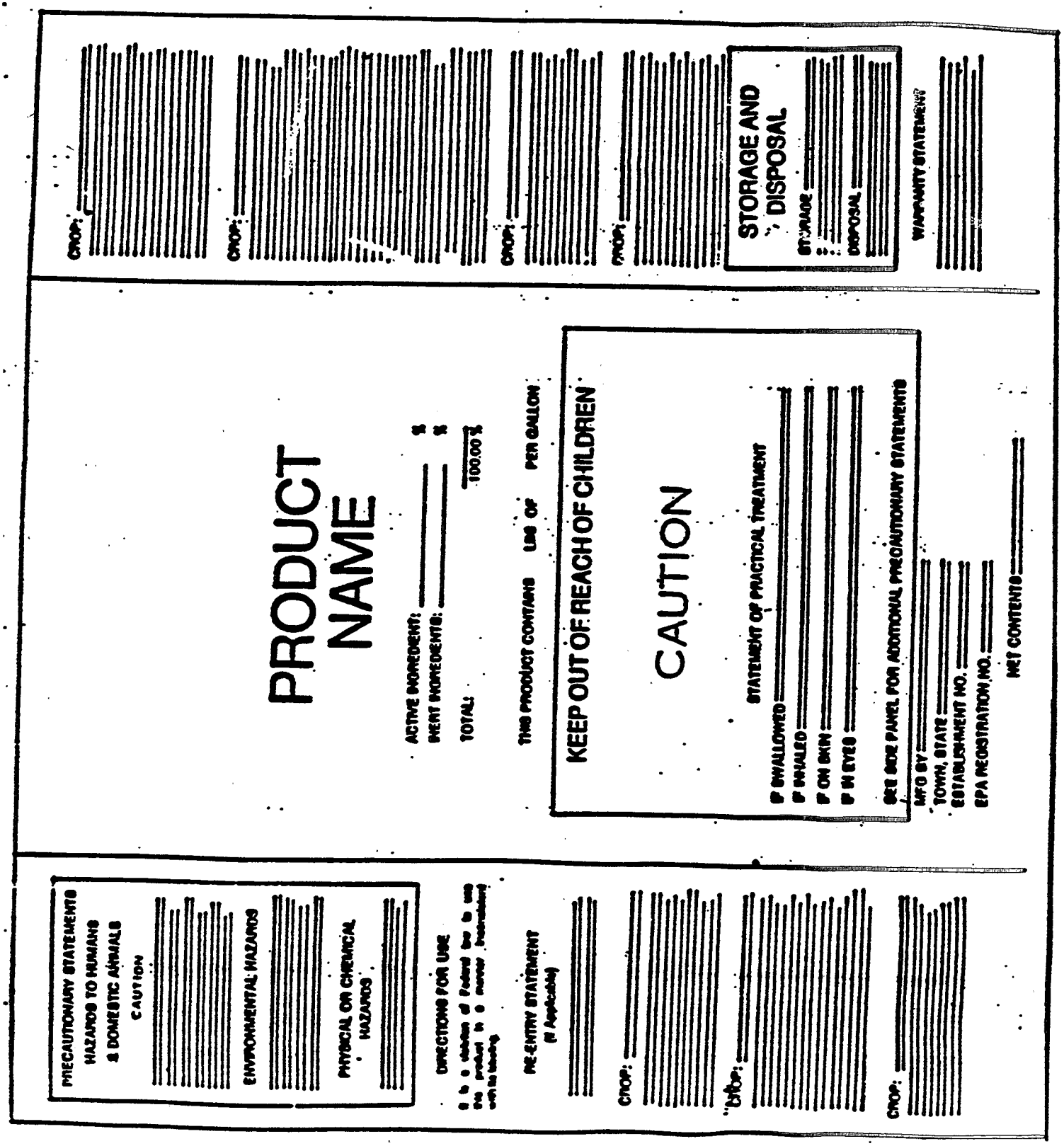
Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to P.R. Notices 83-3 and 84-1 to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10(i)(2)]

COLLATERAL LABELING .

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. Collateral labeling must be made part of the response to the RED and submitted for review.

LABEL FORMAT FOR UNCLASSIFIED PRODUCTS



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
Due to (insert reason*)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

(*for example, "Due to high acute toxicity.")

PRODUCT
NAME

ACTIVE INGREDIENT: _____ %
INERT INGREDIENTS: _____ %
TOTAL: 100.00%

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER—POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

LABEL FORMAT FOR PRODUCTS CLASSIFIED FOR RESTRICTED USE

submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

AUTHORITY: 7 U.S.C. 136-136y.

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regu-

lations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average con-

tent of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such

that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment in some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(l) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978. Redesignated and amended at 53 FR 15991, 15999, May 4, 1988]

APPENDIX F

Generic Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

SEP 30 1993

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, <u>all of the following three criteria must be clearly met</u>:

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.

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 i 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 initialled 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 you response.

Item 11. Enter the phone number of your company contact.

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 062719
DOWELANCO
9330 ZIONSVILLE RD
INDIANAPOLIS IN 46268

2. Case # and Name
0176 Sulfuryl Fluoride
Chemical # and Name 078003
Sulfuryl fluoride

3. Date and Type of DCI
GENERIC
SEP 30 1993

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
62719-4					

8. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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:

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

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.

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 062719
DOWELANCO
9330 ZIONSVILLE RD
INDIANAPOLIS IN 46268

2. Case # and Name
0176 Sulfuryl Fluoride
Chemical # and Name 078003
Sulfuryl fluoride

3. Date and Type of DCI
GENERIC
SEP 30 1993

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
82-5(b) *	90-day neurotox-mammal		Y			CMO	TEP	24 mos.	
133-4 *	Inhal. passive dosimetry expo		Y			CMO	TEP	24 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0176 Sulfuryl Fluoride
Chemical # and Name
078003 Sulfuryl fluoride

GUIDELINE	COMMENT
82-5(b)	A 90-day neurotoxicity study in the rat 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 moniotred adequately. 90-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 types of neurotoxicity, and because subchronic/chronic exposure of workers cannot be presently ruled out, a new 90-day neurotoxicity study in rats is required using the Subdivision F Neurotoxicity Guidelines.
133-4	Method validation data for the Miran infrared and Interscan gas analyzers and/or any other method used are required.

LIST OF REGISTRANTS

RECEIVING THIS DATA CALL-IN

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0176 Sulfuryl Fluoride
Chemical # and Name
078003 Sulfuryl fluoride

Company Number	Company Name	Additional Name	Address	City & State	Zip
062719	DOWELANCO		9330 ZIONSVILLE RD	INDIANAPOLIS IN	46268

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

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 St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

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 St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	