United States
Environmental Protection
Agency

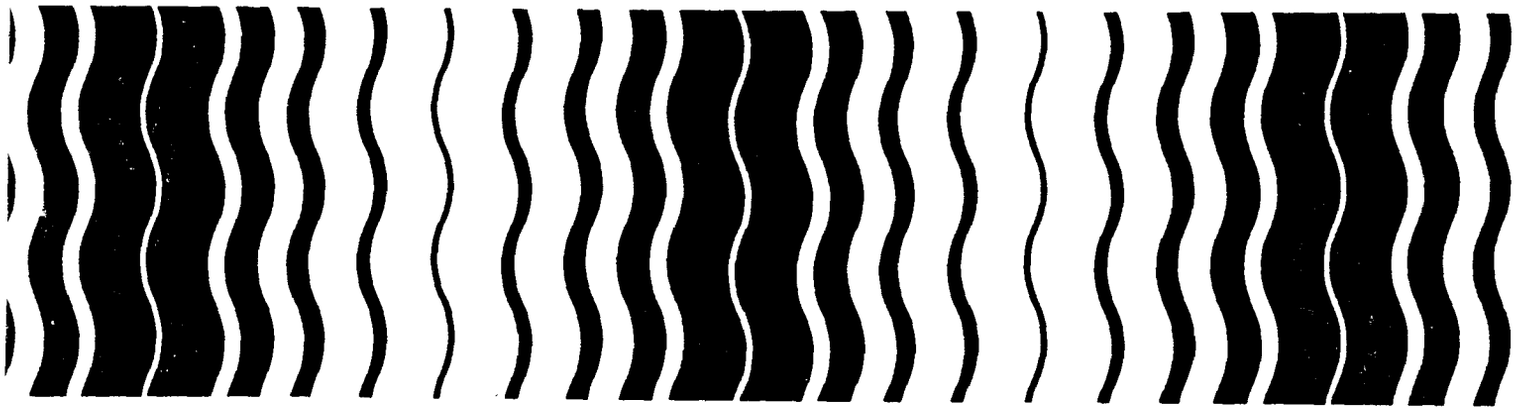
Office of
Pesticides and Toxic Substances
Washington DC 20460

540/RS-88-086

Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing SULFOTEPP as the Active Ingredient



OMB Control No. 2070-005
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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

SULFOTEPP

AS THE ACTIVE INGREDIENT

CASE NUMBER 0338

CAS Registry Number 3689-24-5

EPA Pesticide Chemical Code (Shaughnessy) Number 079501

SEPTEMBER, 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration system 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
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, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program 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" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1]The scientific reviews may be obtained after April 1, 1988 from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (703-487-4650).

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify

the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

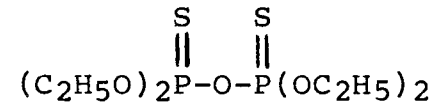
II. CHEMICAL(S) COVERED BY THIS STANDARD

A. Description of chemical(s)

The following chemical(s) are covered by this Registration Standard:

Common name: Sulfotepp
Chemical name: O,O,O',O'- tetraethyl dithiopyrophosphate
CAS Number: 3689-24-5

Sulfotep is the British Standards Institution (BSI) and International Organization for Standardization (ISO) approved common name of an acaricide/insecticide registered in the U. S. by Centerchem, Inc., Fuller Systems, Inc., and Plant Products Corp. The molecular structure is depicted below.



OPP (Shaughnessy) Number: 079501

Empirical Formula: $C_8H_{20}O_5P_2S_2$

Trade names: Bladafume, Dithio, Dithione, and Thiotepp.

Description of physical characteristics of chemical: Pale yellow liquid with a boiling point of 136-139°C at 2 mm Hg; specific gravity of 1.196 d25/4 °C; solubility of 25 mg/l water at room temperature; completely miscible with chloromethane and most organic solvents; a vapor pressure of 22.6 mPa at 20°C.

B. Use Profile

Type of Pesticide: Insecticide/Acaricide

First Registration: 1951

Pests Controlled: aphids, mealybugs, spider mites, thrips, scales, whiteflies

Registered Uses: commercial greenhouses, non-food
Predominant Use(s): azaleas, carnations, chrysanthemums, geraniums, roses, snapdragons

Mode of Activity: organophosphate, non-systemic, contact

Formulation Types Registered: technical material, ready-to-use solution, impregnated materials

Method(s) of Application: liquid fog, smoke generating impregnated materials

III. AGENCY ASSESSMENT

The Agency has reviewed all data in its files as of March 8, 1988 supporting the registration of sulfotepp. Data received by the Agency after this date have not been reviewed for the purposes of this Standard. This section discusses the Agency's scientific findings and conclusions based on these data.

A. SUMMARY

The main area of concern is for human exposure to airborne residues of sulfotepp when used in greenhouses, since this chemical is known to be highly acutely toxic. There are major data gaps in the areas of toxicology, environmental fate, exposure to humans, ecological effects, and product chemistry.

1. TOXICOLOGY

No data are available that meet the Agency's Guideline requirements for the toxicity of sulfotepp. However, data available in the public literature indicate that sulfotepp is highly toxic. In addition, some data on human poisonings are available, but there is no conclusive evidence of a significant poisoning problem due to the pesticide. Studies to fulfill all acute toxicity requirements are required, including an acute delayed neurotoxicity study in the hen. Subchronic 21-day dermal and 90-day inhalation studies are required. A 90-day neurotoxicity study is reserved depending on the results from the acute delayed neurotoxicity study. A teratology study in one species is required and all mutagenicity studies are required.

2. ENVIRONMENTAL FATE

There are no available environmental fate studies on sulfotepp. Therefore, groundwater contamination potential cannot be assessed at this time. Because of toxicological concerns involving acute hazards (see above), an interim reentry interval in accordance with the proposed § 170.66 of 40 CFR as it pertains to application of smokes, mists, fogs and aerosols in greenhouses is being imposed for the registered uses of sulfotepp. Once adequate data have been submitted and evaluated, the Agency will reconsider this issue. The following list summarizes the environmental fate data requirements for sulfotepp.

Environmental Fate Data Requirements Summary

DEGRADATION STUDIES - LAB
Hydrolysis
Photodegradation - air

METABOLISM STUDIES - LAB
Aerobic metabolism - soil

MOBILITY STUDIES
Adsorption/desorption studies (batch equilibrium study is preferred)
Volatility (lab)
Volatility (field) - [reserved]

REENTRY PROTECTION
Air monitoring of toxicologically significant residues are required for purposes of calculating human exposure (no actual monitoring of human inhalation exposure is to be conducted).

3. ECOLOGICAL EFFECTS

Terrestrial

No data are available for any terrestrial species. An avian single-dose acute oral LD_{50} study and a subacute dietary LC_{50} study using the bobwhite quail are required. No data are required for toxic effects on wild mammals or on honey bees for the existing indoor use patterns.

Aquatic

Freshwater Invertebrates and Fish

The available data indicate that sulfotepp is highly toxic to the rainbow trout and bluegill sunfish. No data are available on effects on freshwater invertebrates. The fish studies only partially fulfill the Agency's data requirements, but may be acceptable if additional data concerning the studies are submitted. An acute LC_{50} study on aquatic invertebrates is required.

Ecological Effects Data Requirement Summary

The following data are required for the present use patterns:

Avian single-dose oral LD_{50} (bobwhite quail)
Avian dietary LC_{50} in one species (bobwhite quail)
Fish acute LC_{50}
Acute LC_{50} on aquatic invertebrates

4. RESIDUE CHEMISTRY

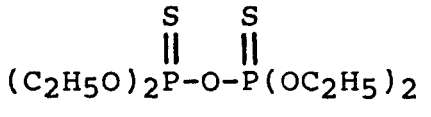
There are no registered uses of sulfotepp on agricultural crops. Residue chemistry data are not required to support the registered uses of sulfotepp on greenhouse non-food crops, except for chemical identity and directions for use. These requirements may be met by submission of the required product chemistry data discussed below.

5. PRODUCT CHEMISTRY

a. PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

Sulfotep is the British Standards Institution (BSI) and International Organization for Standardization (ISO) approved common name of an acaricide/insecticide registered in the U. S. by Centerchem, Inc., Fuller Systems, Inc., and Plant Products Corp. The molecular structure is depicted below.



O,O,O',O'-tetraethyl dithiopyrophosphate is the chemical name (International Union for Pure and Applied Chemistry). Other chemical, common, and trade names include: tetraethyl thiodiphosphate (9th Collective Index), tetraethyl thiopyrophosphate (8th Collective Index), thiodiphosphoric acid tetraethyl ester, ASP-47, Bayer E 393, Bladafume, Dithio, Dithione, sulfotepp (Entomological Society of America approved), and Thiotepp.

Other identifying characteristics and codes are:

Empirical Formula:	$C_8H_{20}O_5P_2S_2$
Molecular Weight:	322.3
CAS Registry No.:	3689-24-5
Shaughnessy No.:	079501
Wiswesser Line-Formula Notation* 2OPS&O2&OPS&O2&O2	
U. S. Department of Agriculture:	ENT 16 273

* A single-line representation of the structural formula for organic chemical molecules.

The above information was obtained from the following sources: Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, 4th Ed., 1979, p. 225; British Crop Protection Council, The Pesticide Manual - A World Compendium, 7th Ed., 1980, p. 498; Farm Chemicals Handbook '88, p. C33; and Analytical Reference Standards and Supplemental Data: The Pesticide and Industrial Chemicals Repository, 1984, p. 98.

The sulfotepp technical products are summarized in Table 1. Confidential Statements of Formula were not available in the registration jackets for EPA Reg. Nos. 8241-5 and 9382-4.

Table 1. Technical sulfotepp products.

Percent Active	EPA Reg. No.	Registrant
95	1327-39	Fuller Systems, Inc.
95	8241-5	Plant Products Corp.
90	9382-4	Centerchem, Inc.

61-2. Description of Beginning Materials and Manufacturing Process

No description has been submitted for this topic by the registrants. The following manufacturing process was obtained from Marshall Sittig's Pesticide Manufacturing and Toxic Materials Control Encyclopedia, pp. 689-690.

> Sulfotep is manufactured by reaction of sulfur with tetraethylpyrophosphate (TEPP) or O,O-diethyl phosphorochloridothioate and aqueous sodium carbonate in the presence of pyridine.

61-3. Discussion of the Formation of Impurities

No discussion was submitted for this topic by the registrants.

b. ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

No data were submitted for this topic by the registrants.

62-2. Certification of Ingredient Limits

Only ingredient limits of the Fuller System, Inc. 95% technical product are known. No data were submitted for this topic by the other registrants.

62-3. Analytical Methods to Verify Certified Limits

No methods were submitted for this topic by the registrants.

c. PHYSICAL AND CHEMICAL CHARACTERISTICS

No data pertaining to the physical and chemical characteristics of any technical product have been submitted. Summarized in Table 2 are physical and chemical properties of the PAI obtained from the British Crop Protection Council, The Pesticide Manual - A World Compendium, 7th Ed., 1980, p. 498. This information is provided for reference purposes only.

Table 2. Physical and chemical properties of pure sulfotepp.

Guidelines Reference No., 40 CFR 158, Subpt C Name of Property	Description
63-2. Color	pale yellow
63-3. Physical state	liquid
63-6. Boiling point	136-139°C/2mm Hg
63-7. Specific gravity	1.196 d25/4°C
63-8. Solubility	25 mg/l water at room temperature; completely miscible with chloromethane and most organic solvents
63-9. Vapor pressure	22.6 mPa at 20°C

Product Chemistry Data Requirements Summary

Product Identity and Composition

Product Identity and Disclosure of Ingredients
Description of Beginning Materials
and Manufacturing Process

Discussion of Formation of Impurities

Analysis and Certification of Product Ingredients

Preliminary Analysis of Product Samples
Certification of Ingredient Limits
Analytical Methods to Certify Limits

Physical and Chemical Characteristics

Color
Physical State
Odor
Melting Point
Boiling Point
Density, Bulk Density or Specific Gravity
Solubility
Vapor Pressure
Dissociation Constant
Octanol/Water Partitioning Coefficient
pH
Stability
Oxidizing or Reducing Action
Flammability
Explodability
Storage Stability
Viscosity
Miscibility
Corrosion Characteristics

B. PRELIMINARY RISK ASSESSMENT

As previously discussed briefly above, there are no data available on technical sulfotepp satisfying the basic toxicology requirements of the Guidelines. Therefore, no preliminary risk assessment is possible at this time. In the absence of such an assessment, the toxicology summary is presented below.

1. Toxicology Summary

Sulfotepp is a restricted use pesticide. It is used on greenhouse nonfood crops (ornamental plants and forest trees), for control of aphids, mealybugs, spider mites, scales, thrips and whiteflies. In the past, sulfotepp has been known to be an impurity in the pesticide, Diazinon. From the toxicity data on Diazinon, the Agency is aware that sulfotepp is highly acutely toxic. However, no data are available on the Technical Product. No tolerances exist for sulfotepp. No studies are available for registered uses. Data required are listed in Tables A and B in Appendices I, the Data Appendices.

2. ADI Reassessment

An ADI reassessment is not necessary because there are no approved tolerances for sulfotepp.

C. OTHER SCIENCE FINDINGS

1. Exposure Assessment:

The Agency does not have any exposure data on sulfotepp. Data are required to do an assessment of exposure under 40 CFR 158.390 and these data are listed in Table A.

The only health statistics available for sulfotepp come from California. The ratio of poisonings to applications reported in 1981-1984 was somewhat higher than the average reported for 54 selected pesticides, but not unusually high. This ratio is based on a single poisoning only (to a chamber fumigator). There was only one other poisoning in California since 1975, which was listed as a worker exposed to drift or residue in 1977. Given these data, there is no conclusive evidence of a significant poisoning problem due to sulfotepp.

2. Ecological Effects

a. Ecological Effects Profile

Freshwater fish acute toxicity data indicate that sulfotepp is highly toxic to the rainbow trout [LC_{50} = 1.0 (0.8 - 1.3) ppm] and bluegill sunfish [LC_{50} = 0.36 (0.27 - 0.46 ppm)].

b. Ecological Hazard Assessment

Sulfotepp is registered only for indoor greenhouse use on ornamental plants. Ecological hazard assessments are not performed for indoor uses.

D. TOLERANCE REASSESSMENT

A tolerance reassessment is not necessary since there are no registered uses for sulfotepp that require tolerances under FFDCA.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of the limited data available and other relevant information on sulfotepp the Agency has made the following determinations:

1. Sulfotepp is not a candidate for Special Review at this time.

Rationale: Since available data are quite limited, the Agency is not yet able to make a determination as to whether any of the criteria specified in 40 CFR 154.7 have been met or exceeded.

2. Restricted use

The current position stated in 40 CFR 162.31 that all products containing the active ingredient sulfotepp must bear labeling for RESTRICTED USE is to be continued, based on an acute inhalation hazard to humans.

Rationale: There is sufficient information of a collateral nature based on sulfotepp as an impurity in Diazinon for the Agency to conclude that sulfotepp is highly acutely toxic to mammals, and by inference to humans. Data to characterize the risk are required.

3. Groundwater concerns

The Agency is requiring submission of the minimal studies needed for determination of the groundwater contamination potential of sulfotepp. These include laboratory degradation studies on hydrolysis (161-1) and photodegradation in air (161-4); a laboratory metabolism study for aerobic soil organisms (162-1); and mobility studies on adsorption/desorption (163-1), and volatility in the laboratory (163-2). The mobility study on volatility in the field (163-3) is being reserved at the present time, but may be required depending on the results of laboratory studies.

Rationale: Since it is not possible to determine the groundwater contamination potential without data on the environmental fate of a pesticide and since the aforementioned studies are required by the Guidelines for any pesticide used on greenhouse non-food crops, these studies are necessary in order to fill the data gaps for the environmental fate of sulfotepp. The laboratory study on photodegradation in air is being required due to the high vapor pressure of sulfotepp [1.7×10^{-4} mm Hg or 22.6 mPa at 20°C.] and the possibility that fumes may be sensitive to photodegradation.

4. Reentry requirements

The Agency has determined that the present reentry requirements of from 1.5 hours to overnight, and ventilation of the greenhouse structure for one or two hours, are inadequate to fully protect humans exposed to airborne residues of sulfotepp. An interim reentry interval in accordance with proposed Subpart F, § 170.66 of 40 CFR, as it pertains to application of smokes, mists, fogs or aerosols in greenhouses is being imposed for the uses of sulfotepp until adequate data have been submitted and evaluated.

Rationale: Reentry data are required for sulfotepp under 40 CFR § 158.390. Those data are required by § 158.390 if the pesticide and its use patterns meet both of certain toxicity and exposure criteria. Sulfotepp meets these criteria.

In the case of sulfotepp, human exposure monitoring data must not be submitted. In other cases, human exposure monitoring data have been accepted when the Registrants chose to submit those, but the hazard at high levels of airborne sulfotepp residues could be so great that those data must not be gathered. Therefore, the Agency is requiring monitoring of toxicologically significant residues in air over a given time period.

According to the provisions of proposed § 170.66(a), no worker shall be allowed or directed to enter or remain in a reentry-restricted area before the reentry interval specified in paragraph (b) has expired, unless: (1) The worker will have no contact with pesticide residues on treated surfaces or in soil, water, or air; or (2) The following requirements for early reentry workers are met: (i) Personal protective equipment specified on the pesticide labeling for early reentry activities is worn; (ii) Duties related to personal protective equipment specified in § 170.16 are met; (iii) Decontamination provisions specified in § 170.18 are available; (iv) Training specified in § 170.12(b) is given; (v) Any other requirement regarding early reentry specified on the pesticide labeling is met.

§ 170.66(b) as proposed, states in (2) that for any pesticide applied in the form of a smoke, mist, fog or aerosol [in the greenhouse], the reentry-restricted area shall be the entire nonporous enclosed area within which the pesticide is applied until the reentry interval specified on the pesticide labeling has expired. Since sulfotepp has a vapor pressure such that it behaves like a fumigant, the Agency is imposing a reentry interval in accordance with § 170.66(b)(1), which states:

> For any pesticide identified on the pesticide labeling as a fumigant, the reentry-restricted area shall be the entire nonporous enclosed area within which the pesticide is applied. The reentry interval shall extend until all vapors have dispersed, as defined by one of the following criteria:

(i) Two hours of ventilation using fans or other mechanical ventilation systems.

(ii) Four hours of ventilation using vents, windows or other passive ventilation systems.

(iii) Eleven hours with no ventilation, followed by one hour of mechanical ventilation.

(iv) Eleven hours with no ventilation, followed by two hours of passive ventilation.

(v) Twenty-four hours with no ventilation.

(vi) The air concentration of the fumigant is measured to be less than or equal to the permissible exposure level specified on the product labeling.

Since (vi) is not applicable until the registrants have submitted air monitoring data in accordance with § 158.390 to establish a permissible exposure level for sulfotepp, and (v) would not allow the present common practice of overnight treatments of greenhouses to continue during the data-gathering phase, the Agency proposes to limit the reentry interval options to (i) through (iv), as described in Sec. IV.D. below.

5. Protective clothing requirements are being imposed as labeling amendments for all registered products containing sulfotepp for end-use application in commercial greenhouses, as described in Sec. IV.D. below.

Rationale: Sulfotepp is highly acutely toxic (approx. 5 mg/kg acute oral LD_{50} to rat according to Pesticide Index - Fourth Edition, 1969, p. 356, D. E. H. Frear, editor). Although we do not have a complete toxicological data base or enough information to allow a preliminary risk assessment to be made, the early history of use recognized the acute hazard involved and called for the use of protective clothing. To come into compliance with FIFRA, uniform wording will be required in order to standardize the text on current labels.

6. Labeling requirements

The requirements specified in Section IV.D.3. below and in the Labeling Appendices must be satisfied, as appropriate, for all products containing sulfotepp, whether the products are used in the formulation or manufacture of end-use products containing sulfotepp or as end-use products for treating greenhouse flower crops (non-food) of azaleas, carnations, chrysanthemums, geraniums, roses and snapdragons, applied as liquid fog or smoke-generating impregnated materials.

7. Studies that will receive immediate review.

The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain of the data being required by the Agency are essential to resolve risk concerns, or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive immediate review.

40 CFR §158.290 Environmental Fate

161-1	Hydrolysis
161-4	Photodegradation in Air
162-1	Aerobic Soil Metabolism
163-1	Adsorption/Desorption
163-3	Volatility (Lab)

§158.340 Toxicology

81-1	Acute Oral - Rat
81-2	Acute Dermal
81-3	Acute Inhalation - Rat
81-4	Eye Irritation - Rabbit
81-5	Dermal Irritation - Rabbit
81-6	Dermal Sensitization - Guinea Pig
81-7	Acute Delayed Neurotoxicity - Hen

§158.490 Ecological Effects

71-1	Avian Single-Dose Oral LD_{50}
71-2	Avian Dietary LC_{50}
72-1	Fish Acute LC_{50}
72-2	Acute LC_{50} Aquatic Invertebrates

8. Continuation of registration.

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing sulfotepp may be sold, distributed, formulated and used. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain sulfotepp, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain sulfotepp. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

In order to remain in compliance with FIFRA, the Agency will require that product labeling of technical grade and manufacturing-use products containing sulfotepp bear appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To remain in compliance with FIFRA, manufacturing-use products may be labeled for formulation into end-use products

only for the commodities listed below. The EPA Compendium of Acceptable Uses[1] lists all registered uses, as well as approved maximum application rates and frequencies.

-Greenhouse non-food use on:

Azaleas
Carnations
Chrysanthemums
Geraniums
Roses
Snapdragons

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1 The Compendium may be obtained from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (703-487-4650).

D. REQUIRED LABELING

In order to remain in compliance with FIFRA, manufacturing use products (and end-use products, if covered by Standard) must bear appropriate labeling as specified in 40 CFR 156.10. Appendix II contains information on label requirements.

No pesticide product containing sulfotepp may be released for shipment by the registrant after September 30, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing sulfotepp may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after September 30, 1990, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for MPs must list the active ingredient as:

O,O,O',O'-tetraethyl dithiopyrophosphate

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

a. Statements applicable to all products

GENERAL WARNINGS AND LIMITATIONS: Sulfotepp is classified as a RESTRICTED USE PESTICIDE by Title 40, Code of Federal Regulations, Part 162, Section 31, on the basis of its acute inhalation hazard to humans.

b. Statements for Manufacturing-Use Products

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans, wetlands, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

c. Statements for End-Use Products

RESTRICTED USE:

RESTRICTED USE PESTICIDE
Due to very high acute inhalation toxicity to humans.
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.

General Warnings and Limitations:

Close all greenhouse vents prior to use. Block or barricade entries and post warning signs. Do not place generators on wood or other flammable materials as fire hazard may result.

Reentry Statement: Reentry after applying is restricted until one of the following intervals has elapsed:

(1) Two hours of ventilation using fans or other mechanical ventilation systems.

(2) Four hours of ventilation using vents, windows or other passive ventilation systems.

(3) Eleven hours with no ventilation, followed by one hour of mechanical ventilation.

(4) Eleven hours with no ventilation, followed by two hours of passive ventilation.

If necessary to reenter the greenhouse for any reason during the specified intervals after application, protective clothing described in the Worker Protection Statement must be worn. All greenhouses must be posted during the exposure period and until safe to reenter.

Worker Protection Statement:

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING LOADING, APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, EARLY REENTRY TO TREATED AREAS, AND DISPOSAL OF THE PESTICIDE.

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical-resistant gloves and chemical-resistant shoes, shoe coverings, or boots. Wear goggles and a pesticide respirator approved by the National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA) at all times during application and early reentry to treated areas.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, drinking, eating, or use of the toilet.

AFTER WORK, that is, immediately after completing work with this pesticide, take off all clothing and shoes. Shower using soap and water. Do not reclothe with contaminated clothing and shoes. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to the instructions included with the respirators. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated, so that routine maintenance with soap and water cannot remove spilled or undiluted sulfotepp from any drenched non-chemical-resistant protective suit, must be destroyed according to State and local regulations. HEAVILY CONTAMINATED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

4. Directions for Use

a. Statements for Manufacturing Use Products

The following identifying phrase must appear directly below the product name:

"An insecticide for formulating use only."

The following statement must appear in the Directions for Use section of the label:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

In the Directions for Use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for greenhouse ornamental flowers: azaleas, carnations, chrysanthemums, geraniums, roses, and snapdragons."

b. Statements for End-Use Products

The following statement must appear in the Directions for Use section of the label for all end-use products:

"Calculate volume in cubic feet of greenhouse space to be treated in order to determine amount of product required for application. Use only this amount."

The following paragraph or similar wording should appear in the Directions for Use section for all end-use products:

"General Application and Use Directions:

Apply in greenhouses with ornamental plants only. Do not use on edible plants. Turn off all misting systems. Keep generators a minimum of 2 feet away from plants. Temperatures in the greenhouse should be between 70°F to 90°F (21.1°C to 32.2°C). Foliage and blooms should be free of moisture and relative humidity should be low. Soil should be moist but do not water on the day of application. Do not apply on rainy or windy days. Pick open blooms before application."

The following optional wording is recommended for smoke generator products:

"Where the greenhouse being fumigated is large enough to require that generators be placed in more than one walk, it is recommended that one person be assigned to light the generators in each walk starting at the end farthest from the exit, so that the fumigation in each walk may start simultaneously and all persons exit from the house simultaneously."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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 registrants 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 requirements notice, the Agency will consider

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other

registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be 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 submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. <u>You request that EPA amend your registration by deleting the uses for which the data are needed</u>. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, 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 (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with 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 Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of 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 or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Sulfotepp Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

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

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products.

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to 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 numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable 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 Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT Sulfotepp. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?[1]	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§158, Subpart C, Product Chemistry					
Product Identity and Composition:					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[2]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[3]	6 Months
Analysis and Certification of Product Ingredients:					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes[4]	12 Months

(Continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR ...

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?[1]	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§ 158, Subpart C, Product Chemistry (continued).					
Physical and Chemical Characteristics:					
63-2 - Color	TGAI	No	N/A	Yes[5]	6 Months
63-3 - Physical State	TGAI	No	N/A	Yes[5]	6 Months
63-4 - Odor	TGAI	No	N/A	Yes[5]	6 Months
63-5 - Melting Point	TGAI	No	N/A	Yes[5,6]	6 Months
63-6 - Boiling Point	TGAI	No	N/A	Yes[5,7]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	N/A	Yes[5]	6 Months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[5]	6 Months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[5]	6 Months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[5]	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	No	N/A	Yes[5,8]	6 Months
63-12 - pH	TGAI	No	N/A	Yes[5,9]	6 Months
63-13 - Stability	TGAI	No	N/A	Yes[5]	6 Months

(Continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT Sulfotepp (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?1/	Bibliographic Citation1/	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§ 158, Subpart C, Product Chemistry (continued).					
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

FOOTNOTES:

1. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2. Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

3. A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

(Continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT Sulfotepp (Continued).

§ 158, Subpart C, Product Chemistry (continued).

FOOTNOTES (Continued):

4. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

5. Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

6. Data needed if the technical chemical is a solid at room temperature.

7. Data required if the technical product is a liquid at room temperature.

8. Data required if the technical product is organic and nonpolar.

9. Data required if the test substance is dispersible in water.

TABLE A. GENERIC DATA REQUIREMENTS FOR SULFOTEPP.

Data Requirement		Test substance	Does EPA have data?	Bibliographic Citation	Must additional data be submitted?	Time frame for submission
§158, Subpart D						
§158.240 Residue Chemistry						
171-2	Chemical Identity[1]					
171-3	Directions for use		(See Index)			
171-4	Nature of the residue (Metabolism) - Plants		No	N/A	No[2]	
171-4	Nature of the residue (Metabolism) - Livestock		No	N/A	No[2]	
171-4	Residue analytical methods		No	N/A	No[2]	
171-4	Storage stability		No	N/A	No[2]	
171-4	Magnitude of the residue in plants		No	N/A	No[2]	
171-4	Magnitude of residue in Meat/Milk/Poultry/Eggs		No	N/A	No[2]	

1. The same chemical identity data are required as under §158, Subpart C, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

2. Not required for the registered use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Pattern	Does EPA have data to satisfy this requirement? (Yes, No, Partially)	Bibliographic citation[1/]	Must additional data be submitted under FIFRA § 3(c)(2)(B)?	Time frame for submission
§158, Subpart D (Continued)						
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	F	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA					
161-3 - On Soil	TGAI or PAIRA					
161-4 - In Air	TGAI or PAIRA	F	No		Yes[2/]	9 Months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	F	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA					27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA					27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA					27 Months
						(12 Months - Progress Report)

(Continued).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Pattern	Does EPA have data to satisfy this requirement? (Yes, No, Partially)	Bibliographic citation[1]/	Must additional data be submitted under FIFRA § 3(c)(2)(B)?	Time frame for submission
§158, Subpart D (Continued)						
§158.290 Environmental Fate (continued)						
MOBILITY STUDIES:						
163-1 - Adsorption/Desorption and Leaching	TGAI or PAIRA	F	No		Yes[3]/	12 Months
163-2 - Volatility (Lab)	TEP	F	No		Yes[4]/	12 Months
163-3 - Volatility (Field)	TEP	F	No		Reserved[5]/	To be Determined

FOOTNOTES:

1. EPA Accession Number.

2. Sulfotepp has a high vapor pressure; sulfotepp fumes may be sensitive to photodegradation.

3. The adsorption/desorption (batch equilibrium) study is preferred. This study should also be conducted with major metabolites found in the aerobic soil metabolism study.

4. The reported vapor pressure of sulfotepp is 1.7×10^{-4} mm Hg or 22.6 mPa (20°C); sulfotepp is considered highly toxic.

5. The field studies may be required depending on the results of the laboratory studies.

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158, Subpart D (Continued)						
§158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	F	No	-	Yes	9 months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	F	No	-	Yes	9 months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	F	No	-	Yes	9 months
81-4 - Eye Irritation - Rabbit	TGAI	F	No	-	Yes	9 months
81-5 - Dermal Irritation - Rabbit	TGAI	F	No	-	Yes	9 months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	F	No	-	Yes	9 months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	F	No	-	Yes	12 months

(Continued).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158, Subpart D (Continued)						
§158.340 Toxicology (continued)						
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent	TGAI	F	No	-	No[1]/	
Non-rodent	TGAI	F	No	-	No[1]/	
82-2 - 21-Day Dermal - Rabbit	TGAI	F	No	-	Yes	12 months
82-3 - 90-Day Dermal - Rat	TGAI	F	No	-	No[2]/	
82-4 - 90-Day Inhalation - Rat	TGAI	F	No	-	Yes	15 months
82-5 - 90-Day Neurotoxicity	TGAI	F	No	-	[Reserved][3]/	

(Continued).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158, Subpart D (Continued)						
§158.340 Toxicology (continued)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent	TGAI	F	No	-	No[2/]	
Non-Rodent	TGAI	F	No	-	No[2/]	
83-2 - Oncogenicity Study -						
Rat	TGAI	F	No	-	No[2/]	
Mouse	TGAI	F	No	-	No[2/]	
83-3 - Teratogenicity - Rat	TGAI	F	No	-	Yes[4/]	15 months
83-3 - Teratogenicity - Rabbit	TGAI	F	No	-	Yes[4/]	15 months
83-4 - Reproduction - Rat	TGAI	F	No	-	No[2/]	

(Continued, footnotes follow).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158, Subpart D (Continued)						
§158.340 Toxicology (continued)						
MUTAGENICITY TESTING:						
84-2 - Gene Mutation (Ames Test)	TGAI	F	No	-	Yes	9 months
84-2 - Chromosomal Aberration	TGAI	F	No	-	Yes	12 months
84-4 - Other Mechanisms of Mutagenicity	TGAI	F	No	-	Yes	12 months
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA	F	No	-	No2/	
86-1 - Domestic Animal Safety	Choice	F	No	-	No2/	

(Continued, footnotes follow).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

§158, Subpart D (Continued)

§158.340 Toxicology (continued)

FOOTNOTES:

1. This study is not required because there is no oral exposure and because of requirements for subchronic dermal and inhalation studies.

2. This study is not required under the existing use patterns.

3. This study is reserved until the results of the acute delayed neurotoxicity study become available. If the results of the acute study are positive in the hen, then this study is required.

4. A teratology study in one species is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158, Subpart D (Continued)						
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP					
132-1 - Soil Dissipation	TEP					
133-3 - Dermal Exposure	TEP					
133-4 - Inhalation Exposure	TEP	F	No	-	Yes[1]/	27 months
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	F	No	-	Reserved[2]/	
202-1 - Drift Field Evaluation	TEP	F	No	-	Reserved[2]/	

1. The registrant is required to propose an acceptable reentry label statement based upon airborne residue levels measured after observing the proposed label conditions, on estimated human exposure to those residues, and on toxicity (No Observed Effect Level) of Sulfotepp. Human exposure should be estimated from the levels of the airborne residues assuming a respiration rate of 60 liters/minute. Data from monitoring of actual human inhalation exposure must not be gathered.

2. Reserved until all the toxicity data requirements are fulfilled.

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158, Subpart D (Continued)						
§158.490 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING:						
71-1 - Acute Avian Oral Toxicity	TGAI	F	No	-	Yes[3/]	9 months
71-2 - Avian Subacute Dietary						
- Upland Game Bird	TGAI	F	No	-	Yes[3/]	9 months
71-3 - Wild Mammal Toxicity	TGAI	F	No	-	No[2/]	
71-4 - Avian Reproduction	TGAI	F	No	-	No[2/]	
71-5 - Simulated and Actual Field Testing for Mammals & Birds	TEP	F	No	-	No[2/]	

(Continued, footnotes follow).

TABLE A

GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158, Subpart D (Continued)						
§158.490 Wildlife and Aquatic Organisms (Continued)						
AQUATIC ORGANISM TESTING:						
72-1 - Freshwater Fish Toxicity						
- Coldwater Species	TGAI	F	Partially[5/]	00104043	Yes[4/]	9 months
72-2 Acute Toxicity to Freshwater Invertebrates	TGAI	F	No	-	Yes	9 months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	F	No	-	No[2/]	
72-4 - Fish Early Life Stage	TGAI	F	No	-	No[2/]	
72-4 - Aquatic Invertebrate Life Cycle	TGAI	F	No	-	No[2/]	
72-5 - Fish Full Life-Cycle	TGAI	F	No	-	No[2/]	
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	F	No	-	No[2/]	
72-7 - Simulated or Actual Field Testing for Aquatic Organisms	TEP	F	No	-	No[2/]	

(Continued, footnotes follow).

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

§158, Subpart D (Continued)

§158.490 Wildlife and Aquatic Organisms (continued)

FOOTNOTES:

1. Data must be submitted no later than [9 months from receipt of Guidance Package], unless otherwise indicated.

2. As per 40 CFR 158.490, data are not required for this indoor, greenhouse use pattern.

3. Only testing with one species (bobwhite quail) is required for this use pattern.

4. Only testing with one species (rainbow trout) is required for this use pattern.

5. Certain information, such as the amount of solvent used; whether control contained solvent and, if so, how much; photoperiod; time and location of water quality measurements; fish behavior, including signs of toxicity other than mortality; were not reported. If this information was recorded and can be reported to the Agency, it is possible that these studies may be upgraded.

TABLE A
GENERIC DATA REQUIREMENTS FOR Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?1/	Timeframe for Submission
§158, Subpart D (Continued)						
§158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	F	No	-	No	
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	F	No	-	No	
141-4 - Honey Bee Subacute Feeding Study						
141-5 - Field Testing for Pollinators	TEP	F	No	-	No	

1. Ecological Effects Branch, Hazard Evaluation Division, has determined that no data are required on sulfotepp and honey bees, as sulfotepp is registered only for indoor use.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp.

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?[1]	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§ 158, Subpart C, Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[2]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[3]	6 months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[4]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes[5]	12 months
62-2 - Certification of Ingredient Limits	MP	No	N/A	Yes[6]	12 months
62-3 - Analytical Method to Verify Certified Limits	MP	No	N/A	Yes[7]	12 months

(Continued).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp.

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?[1]	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§ 158, Subpart C, Product Chemistry (Continued)					
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[8]	6 months
63-3 - Physical State	MP	No	N/A	Yes[8]	6 months
63-4 - Odor	MP	No	N/A	Yes[8]	6 months
63-7 - Density, Bulk Density or Specific Gravity	MP	No	N/A	Yes[8]	6 months
63-12 - pH	MP	No	N/A	Yes[8,9]	6 months
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[8,10]	6 months
63-15 - Flammability	MP	No	N/A	Yes[8,11]	6 months
63-16 - Explodability	MP	No	N/A	Yes[8,12]	6 months
63-17 - Storage Stability	MP	No	N/A	Yes[8,13]	15 months

(Continued).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp (continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?[1]	Bibliographic Citation[1]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
§158, Subpart C, Product Chemistry (Continued)					
Physical and Chemical Characteristics (continued)					
63-18 - Viscosity	MP	No	N/A	Yes[8,14]	6 months
63-19 - Miscibility	MP	No	N/A	Yes[8,15]	6 months
63-20 - Corrosion Characteristics	MP	No	N/A	Yes[8]	15 months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

FOOTNOTES:

1. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2. The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3. Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

(Continued).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp (continued).

§158, Subpart C, Product Chemistry (Continued)

FOOTNOTES, continued:

4. A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6. Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570 Rev. 2-85.

7. Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8. Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

9. Data required if the test substance is dispersible in water.

10. Data required if the product contains any oxidizing or reducing agents.

(Continued).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp (continued).

§158, Subpart C, Product Chemistry (Continued)

FOOTNOTES, continued:

11. Data required if the product contains combustible liquids.

12. Data required if the product is potentially explosive.

13. This test for long term storage stability must be under warehouse conditions.

14. Data required if the product is a liquid.

15. Data required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Sulfotepp

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§ 158, Section D						
§ 158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP	F	No	-	Yes	9 months
81-2 - Acute Dermal Toxicity - Rabbit	MP	F	No	-	Yes	9 months
81-3 - Acute Inhalation Toxicity - Rat	MP	F	No	-	Yes	9 months
81-4 - Primary Eye Irritation - Rabbit	MP	F	No	-	Yes	9 months
81-5 - Primary Dermal Irritation - Rabbit	MP	F	No	-	Yes	9 months
81-6 - Dermal Sensitization - Guinea Pig	MP	F	No	-	Yes	9 months

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

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.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

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 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)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL 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)].

SUMMARY-3

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).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 156.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

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)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). 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."

2. Some but not all uses restricted. If the Regulatory Position and Rationale 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.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval 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 Appendix II, STOR, PEST/DIS, and CONT/DIS 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]

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. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

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

(reason for classifying)

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

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:

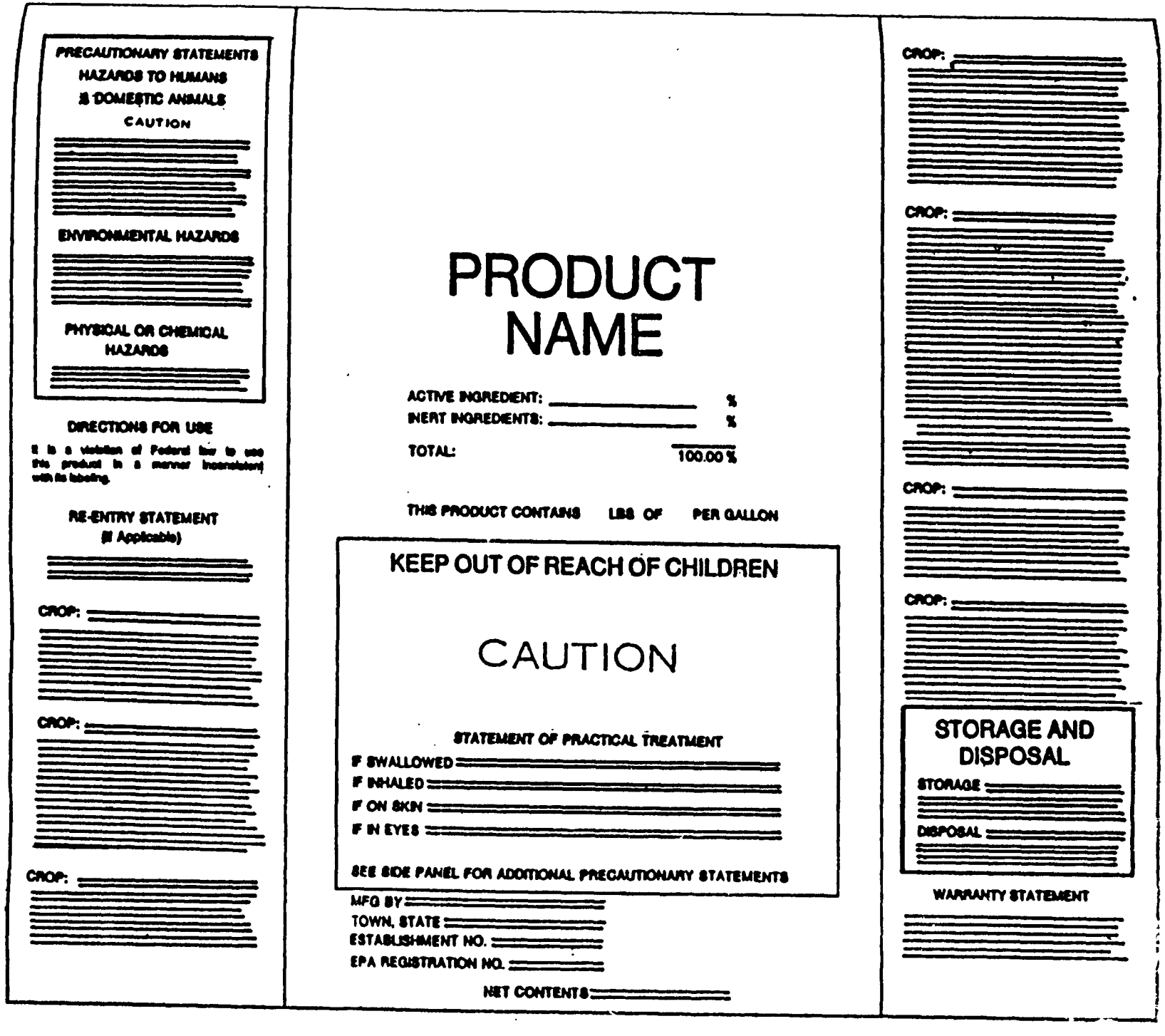
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION
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)
CROP:
CROP:
CROP:
PRODUCT NAME
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
CAUTION
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:
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
WARRANTY STATEMENT

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 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 regulations 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;

NOTE: § 162.10 was redesignated as § 156.10 in Volume 53, page 15991 of the Federal Register, dated May 4, 1988, and is referred to by its new designation throughout this document.

(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 [illegible] 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 § 162.15, 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 [illegible] ment;

(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 § 162.6(b)(4).

(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 semisolid, 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 content 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 par-

allel 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.

(i) *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 practi

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	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	8	8
Above 5 to 10	10	8
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

(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

(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

(i) *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 162.10(j) 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 § 162.10(j)(2).

(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 § 162.10(h)(1)(iv)), 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.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36871, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing.* (1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or 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.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. 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.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disp

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardo Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal stateme

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

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

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

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

   "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several lay of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #
[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

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

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

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

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

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Sulfotepp Standard

MRID	CITATION
00104043	Allen, R. (1975) Toxicity of Dieldrin to Bluegill Sunfish and Rainbow Trout. (Unpublished study received July 16, 1975 under 9386-10; submitted by Vinings Chemical Company, Atlanta, Georgia; CDL: 223094-B)

IV. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of generic data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____ .

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: _____
(Signature)

Dated: _____ _____
(Typed)

EPA	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above (Check below)	I am complying with Data Requirements by - Citing MR ID No.	Submitting Data (Attached) (Check below)	(For EPA Use Only) Accession numbers assigned
Sec. 158. Subpart C Product Chemistry					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158. 340 Toxicology	of Subpart D				
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto 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.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

GUIDANCE DOCUMENT DATE	
ACTIVE INGREDIENT	

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) 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	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

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