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

APR 16 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient sulfur. The RED is the Environmental Protection Agency's evaluation of the sulfur data base and presents the Agency's conclusions on which uses are eligible for reregistration and under what conditions and requirements. Also enclosed is the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

The RED identifies outstanding product specific data requirements for end-use products and manufacturing-use products. These requirements are listed on the Requirements Status and Registrant's Response Form, which, along with the Data Call-In Response Form listing all of your company's products subject to the RED, is included as an Attachment. Instructions for completing both forms are contained in the RED package. All product specific data must be submitted and found acceptable by EPA before a product can be reregistered.

The RED identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on a review of the generic data for the active ingredient. In addition, in order to be reregistered, all product labeling must be in compliance with format and content labeling as described in 40 CFR 156.10 and all labeling changes imposed by Pesticide Regulatory (PR) Notices.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and must be followed carefully. There are several key points to remember in preparing your response to the RED:

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- If generic or product-specific data are required, registrants must submit an initial response within 90 days of receipt of the RED. Forms for generic data must be completed separately from forms for product specific data and must be marked with different internal distribution codes (see page 6 of the Reregistration Handbook). Preprinted forms for each product have been included in the RED package.

- If expedited labeling changes are required, registrants must submit them within the time frame specified in the RED. Normally, however, labeling changes and applications for reregistration must be submitted within 8 months from the issuance of the RED. Refer to pages 3-5 of the Reregistration Handbook for instructions.

- Cite-all is no longer a valid response for fulfilling product-specific data requirements. You must commit to generate the data, cite specific data, or select other allowable options. If you cite data, you must provide Master Record Identification Numbers (MRID) for each data requirement for each product. For previously submitted data each registrant must determine that the study meets the Agency's acceptance criteria for data, which are enclosed. If the data do not meet these criteria then the registrant must commit to generate data or choose an appropriate response option on the Requirements Status and Registrant's Response Form.

- Grouping of products for Acute Toxicological Testing: In order to reduce the costs of testing, the Agency has "grouped" identical or similar products together for purposes of acute toxicity testing. This is discussed on page 9 of the Handbook and in an attachment to the RED.

- The data requirements in the RED are issued under the authority of Section (3)(c)(2)(B) of FIFRA. Failure to adequately respond to the data requirements specified in the RED within the timeframe provided may result in the issuance of a Notice of Intent to Suspend affecting products containing sulfur.

Questions on product-specific data requirements and labeling (both End-Use Products and Manufacturing-Use Products) should be directed to the Registration Division Product Manager Team for sulfur, Carl Grable at 703-557-1900. Questions on the generic database should be directed to Eric Feris, the Review Manager in the Special Review and Reregistration Division (call through the Federal Information Relay Service at 1-800-877-8339; when the

operator answers, have him call Mr. Feris at 703-308-8048).

The Agency is prepared to meet with any registrants who have questions about responding to the sulfur RED. If you want to meet with the Agency, you must contact Mr. Feris within two weeks of your receipt of the RED. The Agency intends to have one combined meeting with interested registrants. If there are any requests for such a meeting, the Agency will notify all registrants who requested a meeting of the location and date. Requests for a meeting will not extend the 90 day or 8 month response deadlines.

Sincerely,

Allan S. Abramson

Allan S. Abramson, PhD
Acting Director
Special Review and
Reregistration Division

Enclosures

REREGISTRATION ELIGIBILITY DOCUMENT

SULFUR

LIST A

CASE 0031

March, 1991

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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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 in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
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.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product

GLOSSARY OF TERMS AND ABBREVIATIONS (CONT'D)

MPT	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

The Agency's records show that the use of sulfur as a pesticide goes back as early as the 1920s. The Agency's pesticide data base shows that there are 237 Section 3 and 44 Section 24(c) sulfur registrations. In dust and flowable formulations, it is used both as a fungicide and an insecticide on a variety of field crops, fruits, vegetables, and ornamental plants. The major high usage sites include grapes, peaches, sugarbeets, and citrus. Sulfur is also used as a fertilizer or as a soil amendment for reclaiming alkaline soils.

In December of 1982, The Agency issued the document "Registration Standard for Pesticide Products Containing Sulfur as the Active Ingredient." The Registration Standard required no new scientific studies. After completing its review for reregistration, the Agency now concludes that the data base on sulfur is complete and no new generic data are required. There are no toxicological endpoints of concern and sulfur is generally recognized as safe as stated in 40 CFR §180.2(a). However, because there is concern about dermal and eye irritation to field workers reentering fields treated with sulfur dust, the Agency is imposing a 24-hour reentry requirement on all sulfur-containing pesticide products. This stems from the a requirement of the 1982 Registration Standard that a proposed reentry interval be submitted. Since no reentry interval has been submitted in response to the Registration Standard, the Agency is, in accordance with the Standard, requiring the submission of labels adopting the most restrictive reentry interval established by a state (24 hours).

Based on the results of its reregistration review, EPA has concluded that all registered uses of sulfur are eligible for reregistration. Before reregistering each product, the Agency is requiring that product specific data and revised labeling be submitted within 8 months of the issuance of this document. In an effort to reduce the time, resources, and number of animals needed to fulfill the acute toxicology data requirements for sulfur containing end use products, the Agency has "batched" products considered to be similar with respect to acute toxicity testing requirements. After reviewing these data and the revised labels, the Agency will determine whether to reregister a product based on whether or not that product meets the requirements in Section 3(c)(5) of FIFRA. End use products containing sulfur in combination with other active ingredients will not be reregistered until the Reregistration Eligibility Documents for all active ingredients contained in that product are issued. However, product specific data for these products are being called in at this time.

I. INTRODUCTION

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

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration of sulfur. The document consists of five sections. Section I is this introduction. Section II describes sulfur, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration decision for sulfur. Section V deals with product reregistration.

Additional details concerning the Agency's review of available data are available on request. The Agency's reviews of specific reports and information on the set of registered uses considered for the Agency's analyses may be obtained from the OPP Public Docket, Field Operations Division, (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460.

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION DECISION

A. Identification of Active Ingredient

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

Chemical Name: Sulfur

Common Name: Sulfur

CAS Number: 7704-34-9

Office of Pesticide Programs
Chemical Code Number: 077501

Empirical Formula: S

B. Use Profile

Type of Pesticide: insecticide, fungicide, and rodenticide

Pests Controlled: mites, insects, fungi, and vertebrates

Registered Use Patterns and Sites:

Terrestrial Food Crops: caneberries, grapes, citrus, almonds, macadamia nuts, pistachio nuts, apples, pears, quinces, stone fruits, bananas, dates, figs, mangos, pineapple, hops, cucurbits, eggplant, peppers, tomatoes, beets, broccoli, brussel sprouts, cabbage, cauliflower, collards, chinese cabbage, kale, kohlrabi, dandelion, endive, artichokes, lettuce, mustard (greens), parsley, spinach, chard, swiss chard, turnips, beets, carrots, garlic, onions, parsnips, potatoes, radishes, rutabagas, salsify, sweet potatoes, beans (colored, dry, lima, bush, green, pole, string, succulent, and snap), peas (field, blackeyed, and succulent), cowpeas, okra, asparagus, alfalfa, peanuts, soybeans, barley, oats, rice, rye, sorghum, wheat, small grains, sugarcane, avocados, cotton, horseradish, mint, peppermint, spearmint, mustard, olives, peanuts, sunflowers and agricultural uncultivated areas.

Terrestrial Feed Crops: grapes, citrus, almonds, apples, pineapple, hops, tomatoes, beets, turnips, parsnips, potatoes, beans (colored, dry, lima, bush, green, pole, string, succulent, and snap), peas (field, blackeyed, and succulent), grasses (forage), cowpeas, alfalfa, clover, peanuts, vetch, soybeans, barley, oats, rice, rye, sorghum, wheat, small grains, sugarcane, cotton, flax, mint, peppermint, spearmint, mustard, peanuts, sunflowers, rangeland and agricultural uncultivated areas.

Terrestrial Non-Food Crop: tobacco, Epcot display crops (not for consumption), ornamental herbaceous flowering/foliage/vine plants, ornamental lawns and turf, golf course turf, recreation area lawns, ornamental woody shrubs and vines, ornamental and/or shade trees, wood protection treatment to forest products (seasoned), nonagricultural uncultivated areas and nonagricultural outdoor buildings/structures.

Aquatic Food Crop: rice and irrigation systems.

Greenhouse Food Crop: brambles, blackberries, blueberries, grapes, citrus, apples, pears, cherries, nectarines, peaches, plums, cucumber, squash, tomatoes, lettuce, potatoes, beans and peas.

Greenhouse Non-Food Crop: ornamental herbaceous flowering/foliage/vine plants and ornamental woody shrubs and vines.

Indoor Food: sheep (meat), goats (meat), beef/range/feeder cattle (meat), hogs/pig/swine (meat), poultry and birds.

Indoor Non-Food: horses.

Indoor Residential: cats (adult/kittens), dogs/canines (adult/puppies), household/domestic dwellings indoor premises, pet/sleeping quarters, household/ domestic dwellings contents, human body clothing/clothing while being worn (insect control) and human clothing (insect control).

Residential Outdoor: ornamental herbaceous flowering/foliage/vine plants, ornamental lawns and turf, ornamental woody shrubs and vines, ornamental and/or shade trees, household/domestic dwellings outdoor premises and refuse/solid waste containers (outdoor)(garbage cans).

Registered Formulations:

Types: technical grade, manufacturing use, and end use

Forms: dust, granular, wettable powder, wettable powder/dust, impregnated material, emulsifiable concentrate, flowable concentrate, soluble concentrate/liquid and liquid-ready to use

Methods of Application:

Types of treatments: animal, premise (enclosed, open, and exterior), outdoor, spray, dust, pour on, fumigation, water application, seed, soil, human, clothing, litter and bedding

Timing: foliar, bloom, delayed dormant, dormant, prebloom, nonbearing, seed crop, nursery stock, postharvest, postharvest to nonstored commodity, popcorn, seed bed, plant bed, root stock, seedling stage, seed

Equipment: hand held duster, dust box, irrigation, aircraft, and ground

C. Regulatory History

Agency records indicate that the use of sulfur as a pesticide dates back as early as the 1920s. The Agency developed a Registration Standard (NTIS # PB86-102043) in 1982 which listed data gaps in the Agency's data base on Sulfur . The only data requirement imposed by the 1982 Registration Standard was a proposal for reentry intervals for foliar application on each crop on which sulfur application was registered. No additional data have been required since the issuance of the 1982 Registration Standard.

III. AGENCY ASSESSMENT OF SULFUR

The Agency has conducted a thorough review of the scientific data base for sulfur. Based on evaluation of these data, the Agency has no reason to change the major findings made in the 1982 document "Registration Standard for Pesticide Products Containing Sulfur as the Active Ingredient." These findings are summarized below:

A. Identification of Active Ingredient

Sulfur is a non-metallic element with an atomic weight of 32.06. Technical sulfur is a yellow, odorless solid that exists in two allotropic forms - monoclinic (melting point of 119°C) and rhombic crystals (melting point of 112.8°C). Sulfur is practically insoluble in water and slightly soluble in ethanol and ether; the crystalline forms are soluble in carbon bisulfide (CS_2). At room temperature, sulfur is not chemically active. However, when heated,

sulfur combines with oxygen to form sulfur dioxide and sulfur trioxide. Sulfur will spontaneously ignite between 248°C and 266°C at atmospheric pressure in the presence of air and oxygen. Sulfur combines directly with all metals, except gold and platinum.

B. Human Health Assessment

1. Toxicology Data Base

All toxicology data requirements are satisfied. No further data were required in the 1982 Registration Standard and no additional data have been submitted. The results of the review of the toxicology data base are presented below:

a. Acute and Subchronic Toxicity

The LD_{50} for 98% sulfur from an acute oral rat study is >5 g/kg (category IV toxicity). The LD_{50} for 98% sulfur from an acute dermal rabbit study is >2 g/kg (category III toxicity). The LC_{50} for a rat inhalation study with 98% sulfur is >2.56 mg/l (category III toxicity). The primary dermal irritation studiy indicates Category IV toxicity. A guinea pig dermal sensitization study shows sulfur is not a skin sensitizer. A primary eye irritation study in rabbits using 98% sulfur shows sulfur to be an eye irritant with Category III toxicity. Optical application of sulfur to rabbits produced conjunctival redness and discharge. The table below summarizes the toxicity values and categories (note that for dermal and eye irritation and skin sensitization, specific values do not apply):

Toxicity Route	Value	Category
Acute oral	>5g/kg	IV
Acute dermal	>2g/kg	III
Acute inhalation	>2.56mg/l	III
Eye irritation	n/a	III
Dermal irritation	n/a	IV
Skin sensitizer	n/a	NO

Subchronic inhalation exposure to sulfur in rats shows body weight depression, decreased blood sulfhydryl contents,

decreased serum peroxidase levels, and increased serum albumin.

b. Human Chronic Toxicity

Epidemiological studies with mine workers who were exposed to sulfur dust and sulfur dioxide (SO_2) during their lifetimes revealed ocular disturbances as one of the principal toxicity signs. Chronic bronchitis was generally found in those individuals as well as chronic sinusal effects and respiratory disturbances.

c. Other Chronic Toxicological Effects

As stated in the 1982 Registration Standard, there are no known risks of oncogenic, teratogenic, or reproductive hazards associated with sulfur. Sulfur, in its elemental, reduced, or oxidized forms, represents approximately 1.9 percent of the total weight of the earth. The sulfates and sulfides are common in their various mineral forms. Most aquatic and terrestrial environments are high in sulfur, sulfur-deficient environments being quite rare in nature. Since elemental sulfur at low levels is generally recognized as safe (40 CFR §180.2) and since it does not give rise to metabolites other than such as are well known to be intermediary or end products of mammalian metabolic reactions, the intent of chronic testing requirements do not apply to elemental sulfur and its possible metabolites. Chronic exposure to sulfur is the natural state. No toxicology data gaps exist. Sulfur has also been shown to be non-mutagenic in microorganisms.

2. Dietary Exposure

All residue data requirements are satisfied. No further data were required in the 1982 Registration Standard and no additional data have been submitted. Since there are no toxicological endpoints of concern, no risk assessment was performed for dietary exposure. Sulfur is a pesticide chemical that is generally recognized as safe as noted in 40 CFR §180.2(a).

Further, there are no minor use considerations for sulfur, no Codex Maximum Residue Levels, nor has a Reference Dose been established.

3. Occupational Exposure

Based on incidents of pesticide-related illness, primarily skin and eye irritation, which were reported among fieldworkers in California, the Agency has determined that a reentry hazard exists for fieldworkers reentering sites following foliar application of sulfur dust. The 1982 Registration Standard required registrants to propose a reentry interval for foliar application of sulfur based on one of the following: a) the longest or most restrictive existing reentry interval for sulfur imposed by any state, which, as described in the Standard, is a 24-hour reentry interval established by the State of California: b) data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the toxicity of sulfur; or c) a determination of the time beyond which there are no detectable dislodgeable residues remaining in the worker environment. Since the issuance of the Registration Standard, no reentry data have been submitted to support a reentry interval of less than 24 hours. Therefore, a 24-hour reentry interval labeling requirement is being imposed (along with other labeling requirements outlined elsewhere in this document) on sulfur-containing pesticide products.

4. Human Risk Assessment

The human risks, if any, from both dietary and occupational exposures are considered to be very low because of the general knowledge of the chemical Sulfur, its ubiquitious occurrence, and its low toxicity, as well as its long history of use by humans, including some pharmaceutical applications.

C. Environmental Assessment

All environmental fate and ecological effects data requirements have been satisfied. No further environmental fate data were required in the 1982 Registration Standard, nor were any ecological effects data required.

1. Environmental Fate Assessment

In the 1982 Registration Standard, all environmental fate data requirements were waived based on the fact that sulfur is a natural component of the environment.

The only environmental concern with elemental sulfur is that upon oxidation it forms sulfuric acid, which can acidify soil or water ecosystems. In soil management systems, elemental sulfur is a common soil amendment used to acidify calcareous soil and increase the fertility. As a soil amendment or pesticide, the recommended application rate for sulfur can range from 10 to 50 lbs/A. Therefore, elemental sulfur used as a pesticide or soil amendment would be expected to have a similar acidification effect on the environment; however, this is not necessarily a deleterious effect. In soil and water management systems, the application of lime, i.e., Calcium carbonate, is recommended to neutralize the acidity generated through sulfur oxidation.

The use of elemental sulfur, applied either as pesticide or soil amendment is not an environmental concern because it will become incorporated into the natural sulfur cycle. The fate of sulfur is dependent on environmental redox conditions. Under aerobic soil conditions, elemental sulfur is oxidized to sulfate via microbial metabolism. The dissipation of sulfate is dependent on leaching and soil organic matter immobilization. Under anaerobic conditions, elemental sulfur is reduced to sulfide (S^{2-}) via microbial metabolism. The subsequent fate of sulfide is dependent on metal sulfide precipitation or volatilization of hydrogen sulfide. Hence, elemental sulfur should not pose an environmental problem because it rapidly dissipates into the natural sulfur cycle.

2. Ecological Effects Assessment

In the 1982 Registration Standard, no additional ecological effects data were required. No new ecological effects data has been submitted since the issuance of the Registration Standard. The Agency has reviewed the available information for sulfur and has determined that all data requirements are satisfied.

a. Ecological Effects Data

There are six acceptable studies on the ecological effects of sulfur. The 8-day dietary LC_{50} for bobwhite quail (Colinus virginianus) is reported to be >5620 ppm in a study using a 95% sulfur wettable powder formulation. The 96-hour LC_{50} values for two fish species, bluegill sunfish (Lepomis macrochirus) and rainbow trout (Salmo gairdneri), are >180 ppm in a study using a 99.5% sulfur dust formulation. The 48-

hour LC_{50} for daphnia (Daphnia magna) and the 96-hour LC_{50} for mysid shrimp (Mysidopsis bahia) is reported to be >5000 and 736 ppm respectively in a study using 90% sulfur. Two beneficial insect studies demonstrated that sulfur (98% dust and 92% wettable powder) is low in toxicity to the honey bee (Apis mellifera) through contact and ingestion.

These studies are sufficient to characterize sulfur as practically non-toxic to the species tested.

b. Ecological Effects Risk Assessment

Due to the large annual sulfur usage and the relatively high rates of application, there is a potential for non-target organisms to be exposed to sulfur. Some precautionary labeling is being required. The risks associated with sulfur use, however, would appear to be low. Sulfur is ubiquitous and is a required nutrient for some organisms. More important, the available data indicate low order toxicity to the species tested. Little hazard to non-target organisms is expected from the use of sulfur.

IV. REREGISTRATION DECISION FOR SULFUR

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of all the generic (i.e., active-ingredient specific) data required to support reregistration of products containing sulfur as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing sulfur. Appendix A identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of sulfur, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix A were sufficient to allow the Agency to assess registered uses of sulfur and to determine for all such uses that sulfur can be used without resulting in unreasonable adverse effects on the environment. The Agency therefore finds that all products containing sulfur as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

B. Additional Generic Data Requirements

The generic data base supporting the reregistration of products containing sulfur has been reviewed and determined to be complete. No further generic data are required to support reregistration. However, registrants are reminded that any changes since the Registration Standard was issued in 1982 in the manufacturing process for technical sulfur, and any detection of new impurities since that time, must be reported to the Agency under 40 CFR 152.46. Failure to inform the Agency of either changes in the manufacturing process or of detection of new impurities could constitute violations of FIFRA.

C. Labeling Requirements for Manufacturing-Use Products

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

2. Based on the reviews of the generic data, the following additional label statements are required:

   a. In the directions for use, the following statement must appear: "Formulators using this product are responsible for obtaining EPA registration of their formulated products."

   b. In the directions for use, the following statement regarding acceptable use patterns must appear: "For formulation into end-use products intended only for (list acceptable sites).

   c. In the Environmental Hazards section the following statement must appear: "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an

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 EPA.

V. PRODUCT REREGISTRATION

A. Determination of Eligibility

Based on the reviews of the generic data for the active ingredient sulfur, the products containing sulfur are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data and determine whether to reregister individual products. The Agency will not, however reregister any product until all generic data on each active ingredient contained in the product has been evaluated for reregistration and the Reregistration Eligibility Document has been issued.

B. Product Specific Data Requirements

The product specific data requirements are stated in Appendix D (Data Call-In Notice).

C. Labeling Requirements for End-Use Products

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

2. All outdoor end-use product labels are to bear the following statements:

   a. "Do not apply directly to water or swamps, bogs, marshes, and potholes. Do not contaminate water when disposing of rinsate or equipment washwater."

   b. "Do not enter into treated area until at least 24 hours after the completion of application to the area unless wearing the protective clothing listed below. During early reentry into treated areas (less than 24 hours after the completion of application) to perform hand labor tasks, wear long pants (or coveralls), long sleeved shirt, shoes, socks, chemical/water resistant gloves, goggles or face shield."

c. "Pesticide Handlers: During mixing, loading and application of this product, wear long pants (or coveralls), long sleeved shirt, shoes, socks, chemical/water resistant gloves, and goggles or face shield."

APPENDIX A

Generic Data Citations Supporting the Reregistration of Sulfur

GUIDE TO APPENDIX A

Appendix A contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix 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.

The data table is 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. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

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

3. Bibliographic citation (Column 3). 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.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement		Use Pattern	Citation
61-1	Identity	All	[1]
63-2	Color	All	05012688
63-3	Physical State	All	05015875
63-4	Odor	All	05013038
63-5	Melting Point	All	05015875
63-6	Boiling Point		waived
63-7	Density	All	05011811
63-8	Solubility	All	05015159
63-9	Vapor Pressure	All	05011817
63-11	Octanol/Water Partition Coeff.		waived
63-12	pH		waived

[1] Data taken from internal files and chemical handbooks.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement		Use Pattern	Citation
63-13	Stability	All	05015159
81-1	Acute Oral Toxicity	All	00009932
81-2	Acute Dermal Toxicity	All	00009951
81-7	Acute Neurotoxicity		n/a
82-1	Subchronic Oral Toxicity	A,B,D,H,L	05012348
82-2	Subchronic 21-Day Dermal		n/a
82-3	Subchronic 90-Day Dermal		n/a
82-4	Subchronic Inhalation		n/a
83-1	Chronic Feeding		n/a
83-2	Oncogenicity	A,B,D,H,L	05011353
83-3	Teratogenicity		n/a
83-4	Reproduction		n/a

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement		Use Pattern	Citation
84-4	Mutagenicity	All	05011624
85-1	Metabolism		n/a
71-1	Avian Oral LD_{50}		waived [2]
71-2	Avian Dietary LC_{50}	A,B,C,D,K	GS0031-0003
71-3	Wild Mammal Toxicity		waived
71-4	Avian Reproduction		waived
71-5	Simulated/Actual Field Testing		waived
72-1	Fish Acute Toxicity LC_{50}	A,B,C,D,K	GS0031-0004, GS0031-0005
72-2	Acute Toxicity to Invertebrates	A,B,C,D,K	GS0031-0002
72-3	Estuarine/Marine Toxicity	A,B,C,D,K	GS0031-0002

[2] Since sulfur is a required nutrient for all organisms and no avian hazards from the use of sulfur are known, this requirement is waived.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement	Use Pattern	Citation
72-4(a) Fish Early Life Stage		n/a
72-4(b) Aquatic Invertebrate Life Cycle		n/a
72-5 Fish Life Cycle		n/a
72-7 Simulated/Actual Field Testing		n/a
161-1 Hydrolysis		waived [3]
161-2 Photodegradation in Water		waived [3]
161-3 Photodegradation in Soil		waived [3]
161-4 Photodegradation in Air		waived [3]
162-1 Aerobic Soil Metabolism		waived [3]
162-2 Anaerobic Soil Metabolism		waived [3]

[3] Since sulfur is a natural component of the environment, and, in addition, has non-pesticidal applications, this testing requirement has been waived.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement	Use Pattern	Citation
162-3 Anaerobic Aquatic Metabolism		n/a [4]
162-4 Aerobic Aquatic Metabolism		n/a [4]
Effects of microbes on pesticides		n/a
Effects of pesticides on microbes		05018847, 05011773
Activated sludge metabolism		n/a
163-1 Leaching	A,B,C,D,H,I,K	05018847
163-2 Laboratory volatility		waived
163-3 Field volatility		waived
164-1 Terrestrial field dissipation		waived [5]

[4] Data not required because the use pattern indicates that the introduction of sulfur into an aquatic environment or forest ecosystem would not occur.

[5] Since sulfur is a natural component of the environment, and, in addition, has non-pesticidal applications, this testing requirement has been waived.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement	Use Pattern	Citation
164-2 Field dissipation and Aquatic impact		waived [6]
164-3 Forestry dissipation		waived [6]
164-4 Dissipation - Combination & Tank Mixes		waived
164-5 Long-term dissipation		waived
165-1 Confined rotational crops		waived
165-2 Field rotational crops		waived
165-3 Accumulation in irrigated crops		waived
165-4 Bioaccumulation in fish		waived [7]
165-5 Accumulation - Non-target		waived

[6] Data not required because the use pattern indicates that introduction of sulfur into an aquatic environment or forest ecosystem would not occur.

[7] This requirement is waived because sulfur is not expected to accumulate in fish.

APPENDIX A

Data Supporting Guideline Requirements for Reregistration of Sulfur

Requirement	Use Pattern	Citation
171-4(a) Metabolism in Plants		waived
171-4(b) Metabolism in Livestock		waived
171-4(c) Analytical Methods - Plant		waived
171-4(d) Analytical Methods - Livestock		waived
171-4(k) Cropfield Trials		waived
171-4(j) Meat, Milk		waived
171-4(e) Storage Stability		waived

APPENDIX B

SULFUR BIBLIOGRAPHY

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

GUIDE TO APPENDIX B

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 Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, 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 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. Note that, except for MRID 00009952, all of the data supporting the reregistration of sulfur came from public sources and are not compensable under FIFRA 3(c)(1)(D).

(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.

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Sulfur Bibliography

MRID	Citation
005011733	Badawy, F.H. (1978) Effect of sulfur application on sulfur-oxidizing bacteria and yield of two leguminous crops. Zentralblatt fuer Bakteriologie, Parasitenkunde, Infektionskrankheiten und Hygiene, Abteilung 2 133(1):54-58.
000009951	Baker, R.G. (1976) Report to Kocide Chemical Corporation: Acute Toxicity Studies with Flowable Sulfur (52% S w/w) 76-180: IBT No. 8530-09283. (Unpublished study received Sep 16, 1976 under 8901-19; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Kocide Chemical Corp., Houston, Tex.; CDL:229248-A)
GS0031-0002	Borthwich, P. and R.S. Stanley. Unpublished Laboratory Report. Definitive static bio-assay with Daphnia magna and Mysidipsis bahia exposed to Ortho Flotox. (U.S. EPA, Office of Research and Development, Environmental Research Laboratory, Gulf Breeze, FLA., October 1982).
005015875	Donohue, J. (1961) The structures of elemental sulfur. Pages 1-6, Inorganic Sulfur Compounds. Vol. 1. Elmsford, N.Y.: Pergamon Press.
000009932	Doull, J.; Cross, R. (1977) Acute Oral Toxicity of Chigg-Away and Its Ingredients in Adult Male Rats. (Unpublished study received May 2, 1977 under 36864-1; prepared by Univ. of Kansas Medical School, Dept. of Pharmacology, submitted by S.L. Chigg Laboratories, Kansas City, Mo.; CDL:230524-B)
GS0031-0003	Fink, R. Unpublished Laboratory Report. Eight day dietary LC_{50} - Bobwhite quail, Sulfur, Final Report. Wildlife International Ltd. (for U.S. EPA, Office of Research and Development, Environmental Research Laboratory, Corvalis, Oregon, October 4, 1982). (Fiche ID No. STOSUL02).

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MRID	Citation
005012348	Groves, A.B. (1946) Choosing a sulphur fungicide. Eastern Fruit Grower 8(12): 24, 27, 30-31.
005011817	Gruener, H. (1907) The vapor pressure of sulphur at low temperatures. Journal of the American Chemical Society 29: 1396-1402.
005012688	Meyer, B. (1976) The structures of elemental sulfur. Pages 287-317, In Advances in Inorganic Chemistry and Radiochemistry, Vol. 18. New York: Academic Press.
005013038	Murthy, K.S. (1974) Characterization of Sulfur Recovery in Oil and Natural Gas Production. Research Triangle Park, N.C.: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. (EPA-450/3-75-081; available from: NTIS, Springfield, VA; PB-248 602)
005011624	Nagy, Z.; Mile, I.; Antoni, F. (1975) The mutagenic effect of pesticides on Escherichia coli WP2 try. Acta Microbiologica Academiae Scientiarum Hungaricae 22(3): 309-314.
005018847	Toth, D.; Tomasovicova, D. (1979) Effect of pesticides on survival of Tetrahymena pyriformis in Danube water. Biologia (Bratislava) 34(3): 233-239.
005015159	Tuller, W.N. (1970) Elemental sulfur. Pages 1-88, In The Analytical Chemistry of Sulfur and Its Compounds: Part I. Edited by J.H. Karchmer. New York: Wiley-Interscience. (Chemical analysis, vol. 29. Edited by P.J. Elving and I.M. Kolthoff)
GS0031-0004	U.S. EPA. 1975. Report on the toxicity of Stauffer Chemical Companys OWL Superline Dusting Sulfur (99.5% a.i.) to bluegill sunfish. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static Jar, Test No. 916, 12/19/75, Unpublished Report (Fiche ID No. STOSUL03).

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Sulfur Bibliography

MRID	Citation
GS0031-0005	U.S. EPA. 1976. Report on the toxicity of Stauffer Chemical Companys OWL Superline Dusting Sulfur (99.5% a.i.) to bluegill sunfish. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static Jar, Test No. 917, 1/19/76, Unpublished Report (Fiche ID No. SIOSUL04).
005011811	West, J.R. (1950) Thermodynamic properties of sulfur. Industrial and Engineering Chemistry 42(4): 713-718.

APPENDIX C

PESTICIDE REREGISTRATION HANDBOOK

PESTICIDE REREGISTRATION HANDBOOK

HOW TO RESPOND TO THE

REREGISTRATION ELIGIBILITY DOCUMENT (RED)

OFFICE OF PESTICIDE PROGRAMS

ENVIRONMENTAL PROTECTION AGENCY

PRODUCT REREGISTRATION HANDBOOK

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PESTICIDE REREGISTRATION HANDBOOK

I. INTRODUCTION

A. Purpose and Content of this Handbook

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

Section I, this introduction, describes the contents of the Handbook, the Reregistration Eligibility Document and the reregistration process for products.

Section II contains instructions which must be followed by registrants of all registered products containing the active ingredient which is the subject of the RED.

Section III provides further instructions on the format, content and other aspects of generic data, product specific data and labels/labeling which may be required to be submitted. Further instructions and copies of forms are in the Appendix.

B. The Reregistration Eligibility Document (RED)

Registrants must read and follow both this Handbook and the accompanying RED which states the EPA's decision as to whether some or all pesticidal uses of a specific active ingredient are eligible for reregistration.

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

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

C. The Reregistration Process

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

If the RED declares that some or all uses of the chemical are eligible for reregistration, affected registrants must submit or cite any data and labels/labeling required for each product within 8 months of receiving the RED. EPA will review the submission for each product and decide whether to reregister it based on the following criteria:

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

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

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

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

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

II. INSTRUCTIONS FOR RESPONDING

A. How and When to Respond

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

Step 1. Are Expedited Label Changes Required? In some

instances, EPA may conclude that certain changes to product labels/labeling must be implemented rapidly. **If the RED requires expedited label/labeling changes, registrants must submit the items below by the deadline specified in the RED.** If expedited label changes are not required, go to Step 2.

a. **Application for Registration** (EPA Form 8570-1). Complete and sign the form. In Section II, insert **"Application for Expedited Amendment in Response to the Reregistration Eligibility Document for (insert case name for chemical)."** Applications for expedited label changes will be processed as applications for amended registration. **Use only an original application form with a red identifier number in the upper right-hand corner.**

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

Step 2. Are data required? **If the RED requires generic or product specific data, you must follow the directions in the data call-in notice in the RED. All registrants must respond for all products within 90 days of receipt; products for which an adequate response is not received on time will be subject to suspension.**

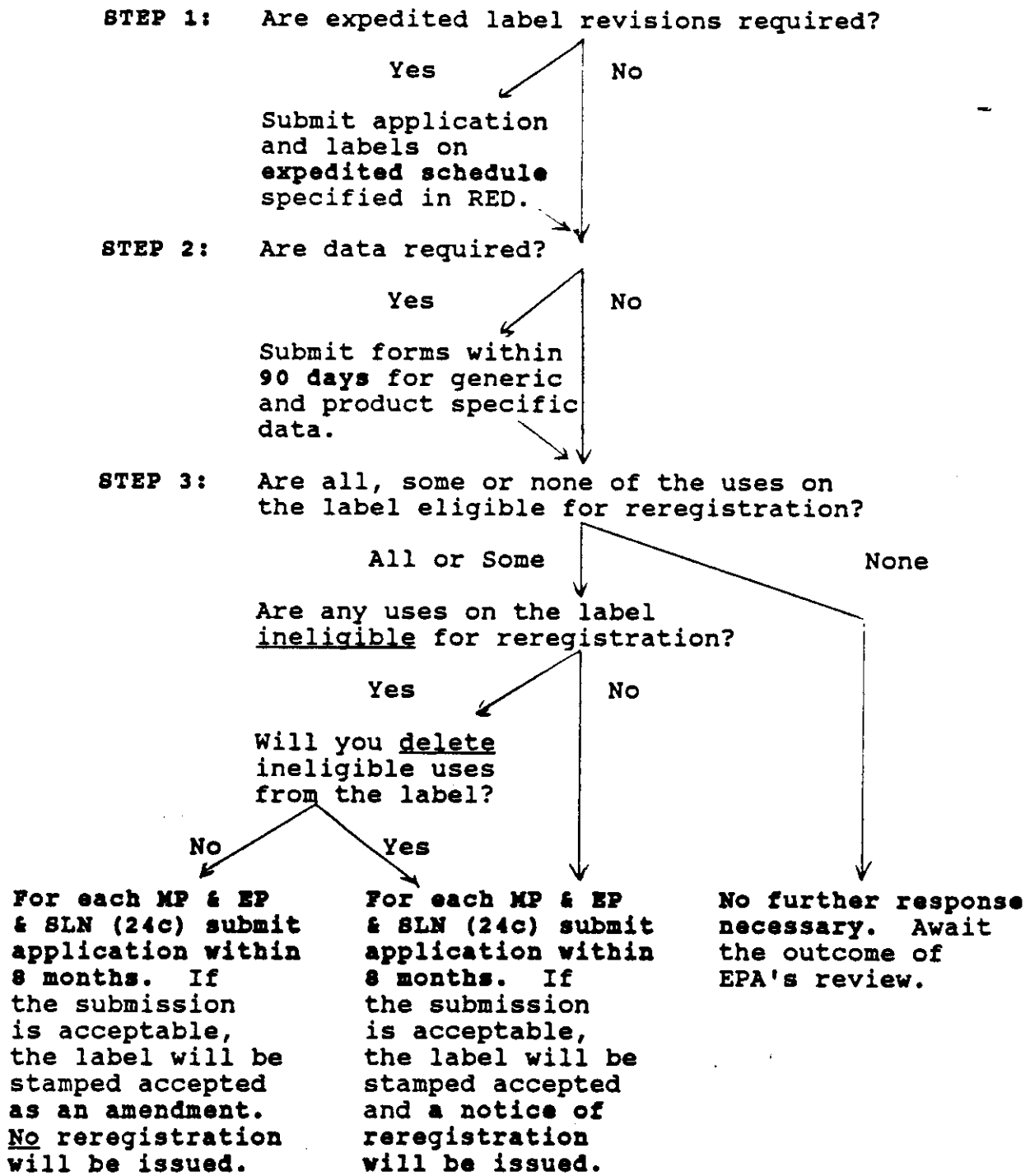
Step 3. Are **All, Some** or **None** of the Uses of a Chemical Eligible for Reregistration? If the RED states that some or all uses are eligible, follow these instructions. If no uses are eligible, no further response is necessary.

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

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

b. **Five (5) copies of revised draft label and labeling.** Refer to the RED for labeling changes specific to the active ingredient, follow the instructions in Section III.C. of this Handbook and refer to the Appendix of this Handbook for guidance on current requirements for labels and labeling. If there are **ineligible uses** on the label or labeling, you may delete such uses and avoid all requirements and consequences associated with ineligible uses (e.g, generic data requirements, cancellation,

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



suspension, etc.). If you delete certain uses now and those uses become eligible for reregistration later, you must submit an amendment application to add those uses back to the label.

c. **Product Specific Data. You must follow the instructions in the Data Call-In Notice in the RED and in Section III of this Handbook. Responses to the data call in are due within <u>90 days</u> and the data are due within <u>8 months</u>.**

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

If no uses of the chemical are eligible for reregistration, no response is necessary (except as may be required under Step 1 or 2). EPA will notify you when the ineligible status of those uses has been resolved. Uses of an active ingredient may be declared ineligible for reregistration for two possible reasons:

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

--Additional generic data are required.

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

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

B. Where to Respond

By U.S. Mail:

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

By express mail or by hand delivery:

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

Use the following distribution codes, as applicable:

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

RED/RD-XXX (where XXX is the case code for the chemical)-- use this distribution code for all responses pertaining to or containing **product specific data**. Such responses would include expedited labeling amendments, 90-day responses to product specific data requirements, hard copies of product specific data and applications for reregistration.

IMPORTANT NOTE: These mailing addresses and distribution codes must be used to assure the timely receipt and processing of your submissions. Use of other addresses or codes may cause significant delay to the receipt and handling of your submissions.

III. SUBMISSION OF DATA AND LABELS/LABELING

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

A. Generic Data

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

necessary to confirm EPA's assessment of that chemical.

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

B. Product Specific Data

Product specific data may be required for the reregistration of every pesticide product in three areas--product chemistry, acute toxicity and efficacy. Instructions concerning product specific data and labels/labeling follow. In addition, the instructions in the data call-in notice in the RED must be followed.

1. Product Chemistry

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

a. Data

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

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

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

b. Inert Ingredients

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

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

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

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

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

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

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

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

2. <u>Acute Toxicity</u>

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

If feasible, EPA will group products that are similar with respect to their acute toxicity so that one set of tests can support reregistration of each group of products. This approach would impose the least amount of testing necessary to adequately support the registration and labeling for pesticide products. The main benefits of this approach would be to minimize the need for animal testing, reduce the expense to registrants to generate the tests and decrease the resources EPA must spend on reviewing data. Registrants would contact other registrants with products in the same "batch" to decide whether to provide or depend on one set of data; alternatively, registrants could choose to conduct their own studies. All deadlines for submission of acute toxicity testing must be met, whether batching is appropriate or not.

3. Product Performance

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

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

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

a. Efficacy Data Submission Waiver Policy

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

efficacious when used in accordance with commonly accepted pest control practices."

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

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

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

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

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

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

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

C. Labels and Labeling

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

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

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

3. Labeling changes required by Pesticide Regulatory (PR) Notices, regulations or other decisions (such as Special Reviews) issued by EPA which are relevant to the pesticide. If such notices, regulations or decisions are in effect at the time of your application for reregistration, your product's labeling must reflect the required changes. Some existing notices are referred to in section B. of the appendix. However, registrants are responsible for complying with all applicable notices and regulations as they are issued by EPA.

APPENDIX

A. Confidential Statement of Formula and Instructions

B. Instructions for Label Contents

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

D. Label Regulations (40 CFR 156.10)

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

Form Approved OMB No 2070-0060 Approval expires 9-30-90

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No /File Symbol

5. EPA Product Mgr/Team No

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 2-85) Previous editions are obsolete.

Original and second copy to EPA

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. INSTRUCTIONS FOR LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. The sample label formats that follow this section generally show where these statements are to be placed.

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

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)]

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. [40CFR 156.10(h)(1)(i)].

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

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

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

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use,

and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

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

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

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

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

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

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

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

    c. A summary statement of the terms of restriction must appear directly below this reason statement on the front panel. If use is restricted to certified applicators, the following statement is required: "For retail sale

to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification." The RED will specify what statement must be used.

2. Some but not all uses restricted. If the 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.

Item 10A. REENTRY STATEMENT - If a restricted entry interval (REI) has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

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

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

COLLATERAL LABELING

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

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

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

(6) A copy of the Registration Standard;

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

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

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

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

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

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

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

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

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

§ 155.34 Notice of availability.

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

(1) Concerns a previously unregistered active ingredient; or

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

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

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

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

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

§ 156.10 Labeling requirements.

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

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

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

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

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

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

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

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

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

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

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

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

(ii) All required label text must:

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

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

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

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

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

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

(i) Is false or misleading, or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 paragraph (j) of this section immediately under the heading "Directions for Use."

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

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

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

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

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

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

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

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

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

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

(B) Rotational crop restrictions.

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

(D) [Reserved]

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

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

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

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

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

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

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

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

PART 157—PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A—[Reserved]

Subpart B—Child-Resistant Packaging

Sec.
157.20 General.
157.21 Definitions.
157.22 When required.
157.24 Exemptions.
157.27 Unit packaging.
157.30 Voluntary use of child-resistant packaging.
157.32 Standards.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING ACUTE TOXICOLOGY DATA REQUIREMENTS FOR REREGISTRATION

EPA

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

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name 0031 Sulfur Chemical # and Name 077501 Sulfur EPA Reg. No. 4-62	3. Date and Type of DCI PRODUCT SPECIFIC ID#

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	2 yrs	3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-14	Oxidizing/Reducing Action					ALL	E P	8 mos.	
63-15	Flammability					ALL	E P	8 mos.	
63-16	Explodability					ALL	E P	8 mos.	
63-17	Storage stability					ALL	E P	8 mos.	
63-18	Viscosity					ALL	E P	8 mos.	
63-19	Miscibility					ALL	E P	8 mos.	
63-20	Corrosion characteristics					ALL	E P	8 mos.	
63-21	Dielectric breakdown voltage					ALL	E P	8 mos.	
81-1	Acute oral toxicity					ALL	E P	8 mos.	
81-2	Acute dermal toxicity					ALL	E P	8 mos.	
81-3	Acute inhal. toxicity					ALL	E P	8 mos.	
81-4	Primary eye irritation					ALL	E P	8 mos.	
81-5	Primary dermal irritation					ALL	E P	8 mos.	
81-6	Dermal sensitization					ALL	E P	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one) Date

EPA

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

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address

2. Case # and Name **0031 Sulfur**
Chemical # and Name
077501 Sulfur
EPA Reg. No. **4-62**

3. Date and Type of DCI
PRODUCT SPECIFIC
ID#

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1 yr	2 yrs	3 yrs	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	Product Identity					ALL	EP	8 mos.	
61-2(a)	Begin. mat. & mfg. proc.					ALL	EP	8 mos.	
61-2(b)	Discussion of impurities					ALL	EP	8 mos.	
62-1	Preliminary analysis					ALL	EP	8 mos.	
62-2	Certification of limits					ALL	EP	8 mos.	
62-3	Analytical method					ALL	EP	8 mos.	
63-2	Color					ALL	EP	8 mos.	
63-3	Physical state					ALL	EP	8 mos.	
63-4	Odor					ALL	EP	8 mos.	
63-5	Melting point					ALL	EP	8 mos.	
63-6	Boiling point					ALL	EP	8 mos.	
63-7	Density, bulk density or sp. gr.					ALL	EP	8 mos.	
63-8	Solubility					ALL	EP	8 mos.	
63-9	Vapor pressure					ALL	EP	8 mos.	
63-10	Dissociation constant					ALL	EP	8 mos.	
63-11	Oct/Water partition coef.					ALL	EP	8 mos.	
63-12	pH					ALL	EP	8 mos.	
63-13	Stability					ALL	EP	8 mos.	

10. Certification
I certify that the statements that 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.
Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed **"Certification With Respect To Data Compensation Requirements" form.**

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form.** I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date **(Developing Data)**. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly **(Cost Sharing)**. I am submitting a **copy of this agreement** and a completed **"Certification With Respect To Data Compensation Requirements" form.** I understand that this option is available **only** for acute toxicity or certain efficacy

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

Product Specific Data

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

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

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

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

ATTACHMENT C

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

EPA

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

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

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

1. Company name and Address	2. Case # and Name 0031 Sulfur Chemical # and Name 077501 Sulfur	3. Date and Type of DCI PRODUCT SPECIFIC

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

8. Certification
I certify that the statements that 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.
Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes.**" If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)** and complete and submit the **"Generic Data Exemption" form**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**"

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**" If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

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

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

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

ATTACHMENT B

PRODUCT-SPECIFIC DATA CALL-IN RESPONSE FORM

ATTACHMENT A

SULFUR: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This attachment, the Data Call-In Status Sheet, contains an overview of data required by this Notice, and point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, (3) Attachment C, the Requirements Status and Registrant's Response Form, and (4) Attachment G, the Cost Share and Data Compensation Forms in replying to this sulfur Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for sulfur are contained in the Requirements Status and Registrant's Response, Attachment C.

The Agency has concluded that additional data on sulfur are needed for specific products. No additional generic data are required. The required additional data are listed in Attachment C. These data are needed to complete the reregistration of sulfur products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database for sulfur, please call Eric Feris through the Federal Information Relay Service at 1-800-877-8339. When the operator answers, have him call Mr. Feris at (703) 308-8048.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Carl Grable, (703) 557-1900.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Carl Grable, PM Team 21
Fungicide/Herbicide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460
RE: SULFUR

ATTACHMENT A

DATA CALL-IN CHEMICAL STATUS SHEET

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

Sincerely yours,

Allan S. Abramson, Acting Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Product-Specific Data Call-In Response Form
C - Requirements Status and Registrant's Response Form for the Product Specific Data Call-In
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms for Product Specific Data, and Product Specific Data Report Form

Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

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

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

Requests for voluntary cancellation received <u>after</u> the 90 day response period required by this Notice will not result in the

offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

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

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

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

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

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

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

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

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

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

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or

parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii). A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

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

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

registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

(ii). Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii). Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv). Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v). A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi). A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii). For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the

the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3, Offer to Share in the Cost of Data Development -- The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4, Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5, Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6, Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

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

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

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

2. Product Specific Data

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

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

Option 1, Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2, Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on

protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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

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

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

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " '[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

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

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

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

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the

development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

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

description of any problems encountered since the last progress report.

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

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

Option 2, Agreement to Share in Cost to Develop Data -- If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study.
In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full

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

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

b. Satisfying the Product Specific Data Requirements of this Notice. There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 7 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Document.

d. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose this option, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

e. Request for Generic Data Waivers. Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

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

required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 557-2126.

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

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

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data

The options for responding to this Notice for generic data are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

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

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

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

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

b. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

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

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

The Attachments to this Notice are:

A - Data Call-In Chemical Status Sheet
B - Product-Specific Data Call-In Response Form
C - Requirements Status and Registrant's Response Form for the Product Specific Data Call-In
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

APPENDIX D

DATA CALL-IN NOTICE

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

DATA CALL-IN NOTICE

APR 16 1991

CERTIFIED MAIL

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Dear Sir or Madam:

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

1. how you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment B, (for generic data) and Attachment C (for product specific data), Requirements Status and Registrant's Response Form, (see section III-B); or

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

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

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

Printed on Recycled Paper

EPA'S BATCHING OF SULFUR END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION (4-15-91).

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient sulfur, the Agency has batched products which can be considered similar with respect to acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g. signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of his/her own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the group as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar with respect to acute toxicity and the formulation has not been significantly altered since submission and acceptance of the acute toxicology data.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options:

Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the group from citing his/her studies and offering to cost share (Option 3) those studies.

The following table shows 18 batches including 167 products containing the active ingredient sulfur. Note that another 74 products were either considered not to be similar with respect to acute toxicity, or the Agency lacked sufficient information for decision making and were not placed into any batch. Registrants of the products not listed are responsible for meeting the acute toxicity data requirements for each product.

The Agency is requiring that data submitted to support batch one or six must include a complete battery of acute toxicity studies on any product within that particular numerical batch and a separate eye irritation study for a product within each lettered sub-batch. For example, if a complete battery of six acute toxicity studies is submitted on a product in sub-batch 1A, then a single eye irritation study must also be submitted on any one of the products in sub-batch 1B.

Table

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient	Formulation Type
1A	239-15	90	Wettable Powder
	802-16	90	Wettable Powder
1B	6330-13	40	Dust
	6330-14	20	Dust
	6330-15	10	Dust
2	279-242	99.5	Dust
	279-1721	98	Dust
	506-172	100	Candle
	2935-48	98	Dust
	2935-92	97	Wettable Powder
	3095-28	100	Candle
	5481-122	98	Dust
	5481-167	97	Wettable Powder
	5967-65	98	Dust
	6325-14	99.9	Manufacturing Use Product
	9018-8	98	Dust
	10163-77	98	Dust

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient	Formulation Type
	10163-141	98.5	Dust
	10182-142	98	Dust
	10182-143	98	Dust
	10182-144	97	Wettable Powder
	10951-9	98	Dust
	11169-9	98	Dust
	11656-2	97	Dust
	11656-3	98	Wettable Powder
	36476-1	98	Dust
	45002-11	98	Dust
	45002-12	97	Wettable Powder
	49668-1	99.1	Dust
	49668-3	99.1	Dust
	49832-6	99.9	Manufacturing Use Product
	51036-138	98	Powder
	63840-2	95	Wettable Powder
3.	6325-15	53	Flowable
	9779-276	52	Liquid
	10163-135	52	Liquid
	19713-39	52	Flowable
	19713-87	65	Flowable
	19713-266	52	Liquid
	19713-282	65	Liquid
	49832-5	53	Liquid
4.	279-42	69	Dust
	279-47	81.3	Wettable Powder
	279-126	84	Dust
	34704-323	53	Dust
	34704-325	83	Wettable Powder
	34704-428	60	Dust
5.	400-363	52.4	Flowable
	769-484	51.2	Flowable
	5905-437	52	Liquid

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient	Formulation Type
	6325-16	70	Liquid
	10182-151	51.1	Flowable
	22555-2	52	Liquid
	22555-6	64	Flowable
	34704-70	52	Flowable
	34704-123	67	Liquid
	37429-1	53.1	Flowable
	42697-17	0.4	Liquid
	45002-18	52	Flowable
	45115-2	52	Flowable
	45115-50	65	Flowable
	49668-4	53	Liquid
	49832-7	70	Liquid
	51036-16	52	Liquid
	55146-51	52	Flowable
6A	5905-289	90	Wettable Powder
	5905-350	90	Micronized
	9779-283	91	Wettable Powder
	10107-140	95	Dust
	19713-238	90	Wettable Powder
	49668-2	94	Wettable Powder
	50383-25	95	Wettable Powder
	51036-14	90	Wettable Powder
	51036-137	83.7	Dust
	51036-147	93.0	Dust
6B	16-136	90	Wettable Powder
	279-363	90	Wettable Powder
	279-387	92	Wettable Powder
	400-222	93	Dust
	400-223	93	Wettable Powder
	769-191	90	Wettable Powder
	769-478	93	Dust
	829-163	90	Wettable Powder
	869-39	90	Wettable Powder
	5905-288	93	Dust
	6325-11	95	Dust
	6325-13	90	Wettable Powder
	6720-444	90	Wettable Powder
	7401-188	90	Dust
	8590-621	92	Wettable Powder
	33955-112	92	Wettable Powder
	49832-1	92	Wettable Powder
	49832-3	90	Wettable Powder
	49832-4	90	Wettable Powder

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient		Formulation Type
	51036-10	90		Wettable Powder
	51061-11	90		Wettable Powder
	51036-57	90		Wettable Powder
	51036-58	90		Wettable Powder
	54401-2	90		Wettable Powder
	55429-1	90		Wettable Powder
	56644-1	90		Wettable Powder
6C	5481-300	83.16		Dust
	5905-422	90		Dust
	6023-45	80		Dust
	11656-53	73.5	Sulfur	Dust
		0.064	Bt*	
	45002-10	80		Wettable Powder
	54401-1	90		Wettable Powder
6D	279-49	31		Wettable Powder
	2935-246	60		Dust
	2935-399	25	Sulfur	Dust
		0.064	Bt*	
	11169-6	51	Sulfur	Dust
		0.064	Bt*	
	11656-52	39		Dust
7.	192-49	45	Sulfur	Smoke Cartridge
		45	Potassium Nitrate	
	358-137	34.8	Sulfur	Smoke Cartridge
		46.2	Potassium Nitrate	
	10551-1	34.8	Sulfur	Smoke Cartridge
		46.2	Sodium Nitrate	
	36210-5	34.8	Sulfur	Smoke Cartridge
		46.2	Potassium Nitrate	
	56228-2	10.8	Sulfur	Smoke Cartridge
		43.4	Sodium Nitrate	
8.	279-1392	42	Sulfur	Dust
		3.3	Endosulfan	

Bt* = *Bacillus thuringiensis*

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient		Formulation Type
	279-1618	50	Sulfur	Dust
		3	Endosulfan	
	279-2522	50	Sulfur	Dust
		5	Endosulfan	
	3468-28	50	Sulfur	Dust
		3	Endosulfan	
9.	572-62	25	Sulfur	Wettable Powder
		10	Methoxychlor	
		6	Malathion	
		5.9	Captan	
	655-616	10	Sulfur	Dust
		8.8	Methoxychlor	
		5	Malathion	
		4.7	Captan	
	828-236	25	Sulfur	Liquid
		9	Methoxychlor	
		6	Malathion	
		5.8	Captan	
10.	34704-384	50	Sulfur	Dust
		9.8	Captan	
	34704-344	26.2	Sulfur	Dust
		11.5	Captan	
11.	400-276	50	Sulfur	Dust
		15	Copper	
	34704-393	25	Sulfur	Dust
		15	Copper	

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient		Formulation Type
12.	400-277	50	Sulfur	Dust
		6	2,6-Dichloro-4-nitroanaline	
	2935-403	25	Sulfur	Dust
		6	2,6-Dichloro-4-nitroanaline	
	10951-4	69	Sulfur	Dust
		6	2,6-Dichloro-4-nitroanaline	
13.	802-324	22.5	Sulfur	Dust
		0.5	Rotenone	
	7401-433	10.0	Sulfur	Dust
		1.0	Rotenone	
14.	10370-154	10	Sulfur	Dust
		3.9	Zineb	
		4	Carbaryl	
	33955-456	20	Sulfur	Dust
		5.2	Zineb	
		3	Carbaryl	
15.	769-110	71.7	Sulfur	Wettable Powder
		3.6	Parathion	
	769-242	86	Sulfur	Wettable Powder
		1.5	Parathion	
	769-518	50	Sulfur	Flowable
		5	Parathion	

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient		Formulation Type
	5481-246	70 3.8	Sulfur Parathion	Dust
	5481-290	6 1	Sulfur Parathion	Dust
	5481-297	20 2	Sulfur Parathion	Dust
	5481-299	73.2 1.5	Sulfur Parathion	Dust
	5481-329	55 2.7	Sulfur Parathion	Dust
	5905-284	75 3.6	Sulfur Parathion	Wettable Powder
	34704-327	53 3	Sulfur Parathion	Wettable Powder
	34704-334	68.7 3.8	Sulfur Parathion	Wettable Powder
	51036-47	75 3.8	Sulfur Parathion	Wettable Powder
	51036-46	54.5 2.7	Sulfur Parathion	Wettable Powder
16.	602-701	10 5	Sulfur Carbaryl	Dust
	769-349	75 10	Sulfur Carbaryl	Dust
	829-151	70 5	Sulfur Carbaryl	Dust

Table (Continued)

Batch No.	EPA Reg. No.	% Sulfur & Any Other Active Ingredient		Formulation Type
	2935-308	50	Sulfur	Dust
		10	Carbaryl	
	5481-111	50	Sulfur	Dust
		10	Carbaryl	
	5481-254	20	Sulfur	Dust
		5	Carbaryl	
	5481-309	50	Sulfur	Dust
		5	Carbaryl	
	5481-327	50	Sulfur	Dust
		3	Carbaryl	
	7401-81	40	Sulfur	Dust
		10	Carbaryl	
	7401-334	2	Sulfur	Dust
		2	Carbaryl	
	11656-75	50	Sulfur	Dust
		10	Carbaryl	
17.	2935-407	92		Wettable Powder
	45115-77	92		Wettable Powder
18.	4581-373	80		Wettable Powder
	7969-61	80		Wettable Powder
	9288-1	80		Wettable Powder
	45115-76	80		Dust
	55947-48	80		Flowable

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

51 Product Identity and Composition
52 Analysis and Certification of Product Ingredients
53 Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Name of technical material tested (include product name and trade name, if appropriate)
2. ___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3. ___ Name and upper certified limit for each impurity or each group of impurities present at ≥ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%
4. ___ Purpose of each active ingredient and each intentionally-added inert
5. ___ Chemical name from Chemical Abstracts Index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6. ___ Molecular, structural, and empirical formulas, molecular weight or weight range, and company assigned experimental or internal code numbers for each active ingredient
7. ___ Description of each beginning material in the manufacturing process
   - ___ EPA Registration Number (if registered; for other beginning materials, the [illegible]
   - ___ Name and address of manufacturer or supplier
   - ___ Brand name, trade name or commercial designation
   - ___ Technical specifications or data sheets by which manufacturer or supplier [illegible] composition, properties or toxicity
8. ___ Description of manufacturing process
   - ___ Statement of whether batch or continuous process
   - ___ Relative amounts of beginning materials and order in which they are added
   - ___ Description of equipment
   - ___ Description of physical conditions (temperature, pressure, humidity) [illegible] each step and the parameters that are maintained
   - ___ Statement of whether process involves intended chemical reactions
   - ___ Flow chart with chemical equations for each intended chemical reaction
   - ___ Duration of each step of process
   - ___ Description of purification procedures
   - ___ Description of measures taken to assure quality of final product
9. ___ Discussion of formation of impurities based on established chemical theory addressing each impurity which may be present at ≥ 0.1% or was found at ≥ 0.1% by product [illegible] and (2) certain toxicologically significant impurities (see #3)

Criteria marked with a * are supplemental and may not be required for every study.

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration and certified limits.
3. Name and upper limit for all impurities present at ≥ 0.1% and those toxicologically significant impurities present at <0.1%.
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at ≥ 0.1%
2. ___ Degree of accountability or closure ≥ [illegible]
3. ___ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples: nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus [illegible] polyhalogenated dibenzodioxins and dibenzofurans) [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]
4. ___ Complete and detailed description of each step in analytical method used to analyze above samples
5. ___ Statement of precision and accuracy of analytical method used to analyze above samples
6. ___ Identities and quantities (including mean and standard deviation) provided for each active ingredient
7. ___ Upper and lower certified limits proposed for each active ingredient and intentional inert along with explanation of how the limits were determined
8. ___ Upper certified limit proposed for each impurity present at ≥ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined
9. ___ Analytical methods to verify certified limits of each active ingredient and impurities [illegible] not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described
10. ___ Analytical methods (as discussed in #9) to verify certified limits validated as to [illegible] precision and accuracy

Criteria marked with a * are supplemental and may not be required for every study.

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Number of representative samples analyzed for all active ingredients and all impurities present at ≥ 0.1%.

2. Degree of accountability or closure in analyses in item #1.

3. Chemical names of toxic impurities which were analyzed for levels <0.1%.

4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.

5. Statement of precision and accuracy of method(s) in item #4.

6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.

7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.

8. Proposed upper certified limit for each impurity present at >=0.1% and certain toxicologically significant impurities at <0.1% with brief explanation of how limits were determined.

9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).

10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

- ___ Verbal description of coloration (or lack of it)
- ___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

- ___ Verbal description of physical state provided using terms such as "solid, [illegible] volatile liquid"
- ___ Based on visual inspection at about 20-25°C

63-4 Odor

- ___ Verbal description of odor (or lack of it) using terms such as "garlic-like, [illegible] characteristic of aromatic compounds"
- ___ Observed at room temperature

63-5 Melting Point

- ___ Reported in °C
- ___ Any observed decomposition reported

63-6 Boiling Point

- ___ Reported in °C
- ___ Pressure under which B.P. measured reported
- ___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

- ___ Measured at about 20-25°C
- ___ Density of technical grade active ingredient reported in g/ml or the spec[illegible] liquids reported with reference to water at 20°C. [Note: Bulk density of [illegible] products may be reported in lbs/ft³ or lbs/gallon.]

63-8 Solubility

- ___ Determined in distilled water and representative polar and non-polar s[illegible] including those used in formulations and analytical methods for the pes[illegible]
- ___ Measured at about 20-25°C
- ___ Reported in g/100ml (other units like ppm acceptable if sparingly solu[illegible]

Criteria marked with a * are supplemental and may not be required for every study.

63-9 Vapor Pressure

- ___ Measured at ≈25°C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25°C)
- ___ Experimental procedure described
- ___ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

- ___ Experimental method described
- ___ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

- ___ Measured at about 20-25°C
- ___ Experimentally determined and description of procedure provided (preferred [illegible] 45 Fed. Register 77350)
- ___ Data supporting reported value provided

63-12 pH

- ___ Measured at about 20-25°C
- ___ Measured following dilution or dispersion in distilled water

63-13 Stability

- ___ Sensitivity to metal ions and metal determined
- ___ Stability at normal and elevated temperatures
- ___ Sensitivity to sunlight determined

Criteria marked with a * are supplemental and may not be required for every study.

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Description of color.
2. Description of physical state.
3. Description of odor.
4. Indication of melting point (in °C).
5. Indication of boiling point (in °C).
6. Indication of density, bulk density, and specific gravity.
7. Indication of solubility.
8. Indication of vapor pressure.
9. Indication of dissociation constant.
10. Indication of octanol/water partition coefficient.
11. Indication of pH.
12. Description of stability.

SUBDIVISION F

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81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2.* ____ At least 5 young adult rats/sex/group
3. ____ Dosing, single oral may be administered over 24 hrs.
4.* ____ Vehicle control if other than water.
5. ____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6. ____ Individual observations at least once a day.
7. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8. ____ Individual daily observations.
9.* ____ Individual body weights.
10.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing.
7. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
8. See items 6 and 7
9. Summarization of body weights
10. Summarization of gross necropsy
11. Significance of changes from the Acceptance Criteria

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2.* ____ At least 5 animals/sex/group
3.* ____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4. ____ Dosing, single dermal.
5. ____ Dosing duration at least 24 hours.
6.* ____ Vehicle control, only if toxicity of vehicle is unknown.
7. ____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8. ____ Application site clipped or shaved at least 24 hours before dosing
9. ____ Application site at least 10% of body surface area.
10. ____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. The number of animals/sex/dose
3. Weight range of animals
4. Verification of single, dermal exposure
5. Duration of dermal exposure
6. Statement of vehicle control
7. Doses tested and results
8. Preparation of application site
9. Area of application site (percent body surface)
10. Occlusion of test material on application site
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.* ____ At least 5 young adult rats/sex/group
4.* ____ Dosing, at least 4 hours by inhalation.
5.* ____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6. ____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7. ____ Monitor rate of air flow
8. ____ Monitor actual concentrations of test material in breathing zone.
9. ____ Monitor aerodynamic particle size for aerosols.
10. ____ Doses tested, sufficient to determine a toxicity catagory or a limit dose (5 mg/L actual concentration of respirable substance).
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. Statement of the inhalability of test substance
3. The number of animals/sex/dose
4. Duration of inhalation exposure
5. Number of chamber air changes/hour and the percent oxygen content of chamber air
6. Ranges for chamber air temperature and relative humidity
7. Air flow rate
8. Analytical concentrations of test material in breathing zone
9. Results of aerosol particle-size determination
10. Doses tested (or limit dose of 5mg/L or highest attainable)
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3. *____ 6 adult rabbits
4. ____ Dosing, instillation into the conjunctival sac of one eye per animal.
5. *____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6. ____ Solid or granular test material ground to a fine dust.
7. ____ Eyes not washed for at least 24 hours.
8. ____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9. *____ Individual observations for the entire day of dosing.
10. *____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State of material is corrosive, cause severe dermal irritation or has a pH of <2 or >11.5
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual observations for entire day of dosing
10. Individual observations for entire day of dosing and individual daily observations afterwards, until eyes are normal or for 21 days
11. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.* ____ 6 adult animals.
4. ____ Dosing, single dermal.
5. ____ Dosing duration 4 hours.
6. ____ Application site shaved or clipped at least 24 hour prior to dosing.
7. ____ Application site approximately 6 cm^2.
8. ____ Application site covered with a gauze patch held in place with nonirritating tape
9. ____ Material removed, washed with water, without trauma to application site
10. ____ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.* ____ Individual observations for the entire day of dosing.
12.* ____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD-50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for entire day of dosing.
12. Individual observations for entire day of dosing and individual daily observations thereafter
13. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3. ____ One of the following methods is utilized:
   - ____ Freund's complete adjuvant test
   - ____ Guinea pig maximization test
   - ____ Split adjuvant technique
   - ____ Buehler test
   - ____ Open epicutaneous test
   - ____ Mauer optimization test
   - ____ Footpad technique in guinea pig
   - ____ Other test accepted by OECD (specify)_____
4. ____ Complete description of test
5. *____ Reference for test.
6. ____ Test followed essentially as described in reference document.
7. *____ Positive control included.

Criteria marked with a * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive or has pH <2 or >11.5).
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

81-7 Acute Neurotoxicity in the Hen

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Study performed on an organophosphate cholinesterase inhibiting compound.
2. ____ Technical form of the active ingredient tested.
3.* ____ Positive control utilized.
4. ____ Species utilized, domestic laying hen 8-14 months of age.
5. ____ Dosing oral by gavage or capsule (dermal or inhalation may be used).
6. ____ An acute oral LD_{50} is determined.
7. ____ Dose tested equal to an acute oral LD_{50} or a limit test of 5000 mg/kg.
8.* ____ Dosed animals may be protected with atropine and/or 2-PAM.
9. ____ Sufficient test animals so that at least 6 survive.
10. ____ Negative (vehicle) control group of at least 6 hens
11.* ____ Positive control of at least 4 hens. (if used)
12. ____ Test dose repeated if no signs of delayed neurotoxicity observed by 21 days after dosing.
13. ____ Observation period 21 days after each dose.
14. ____ Individual daily observations.
15. ____ Individual body weights.
16.* ____ Individual necropsy not required.
17. ____ Histopathology performed on all animals. Tissue to be fixed *in situ* preferably using whole animal perfusion techniques. At least three sections of each of the following tissues
    - ____brain, including medulla oblongata
    - ____spinal cord; upper cervical, mid-thoracic and lumbro-sacral regions
    - ____tibial nerve; proximal regions and branches
    - ____sciatic nerve

Criteria marked with a * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF REGISTRANTS SENT THIS DATA CALL-IN NOTICE

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0031 Sulfur
Chemical # and Name
077501 Sulfur

Company Name	Additional Name	Address	City & State	Zip
BONIDE CHEMICAL CO. INC.		2 WURZ AVE.	YORKVILLE NY	13495
DRAGON CORPORATION		BOX 7311	ROANOKE VA	24019
DEXOL INDUSTRIES		1450 W 228TH ST	TORRANCE CA	90501
CHEVRON CHEMICAL COMPANY	REGISTRATION & REGULATORY AFFAIRS	940 HENSLEY STREET	RICHMOND CA	94804
FMC CORP.	PRODUCT REGISTRATION ACG	2000 MARKET STREET	PHILADELPHIA PA	19103
NOTT MANUFACTURING COMPANY INC		BOX 685	PLEASANT VALLEY NY	12569
UNIROYAL CHEMICAL COMPANY INC.		74 AMITY ROAD	BETHANY CT	06525
STAUFFER CHEMICAL COMPANY		1200 S. 47TH ST.	RICHMOND CA	94804
TEGWEST COMPANY	AGENT FOR: WALCO-LINK CO.	BOX 2220	GREELEY CO	80632
ROCKLAND CORPORATION		686 PASSAIC AVENUE BOX 809	WEST CALDWELL NJ	07007
PURINA MILLS, INC.		BOX 66812	ST LOUIS MO	63166
PRINCE AGRI PRODUCTS, INC		ONE PRINCE PLAZA	QUINCY IL	62301
PRENTISS DRUG & CHEMICAL COMPANY I		21 VERNON ST._C.B. 2000	FLORAL PARK NY	11001
SURECO, INC.	ROYALGARD PRODUCTS CO(SUBSIDIARY)	BOX 938	FORT VALLEY GA	31030
CHAS H. LILLY CO.		7737 N.E. KILLINGSWORTH	PORTLAND OR	97218
SOUTHERN AGRICULTURAL INSECTICIDES		BOX 218	PALMETTO FL	34220
GREEN LIGHT COMPANY		P.O. BOX 17985	SAN ANTONIO TX	78217
COOKE LABORATORY PRODUCTS	SUBSIDIARY OF THE CHAS. H. LILLY C	7737 N.E. KILLINGSWORTH	PORTLAND OR	97218
LEFFINGWELL	C/O UNIROYAL CHEMICAL CO., INC.	74 AMITY ROAD	BETHANY CT	06525
GRIFFIN CORPORATION		BOX 1847	VALDOSTA GA	31603
CONAGRA PET PRODUCTS CO.		1405 CUMMINGS DRIVE	RICHMOND VA	23220
HAPPY JACK INC		BOX 475	SNOW HILL NC	28580
WILBUR ELLIS CO.		BOX 16458	FRESNO CA	93755
PIC CORPORATION		23 SOUTH ESSEX AVE.	ORANGE NJ	07050
SCHALL CHEMICAL INC		120 N. BROADWAY	MONTEVISTA CO	81144
AGCHEM DIVISION-PENNWALT CORP.		THREE PARKWAY, ROOM 619	PHILADELPHIA PA	19102
AMVAC CHEMICAL CORP		4100 EAST WASHINGTON BLVD	LOS ANGELES CA	90023
HELENA CHEMICAL CO		5100 POPULAR AVENUE - SUITE 3200	MEMPHIS TN	38137
MOYER PRODUCTS, INC.		BOX 5434	FRESNO CA	93755
STOKER COMPANY		BOX 907	IMPERIAL CA	92251
GEORGIA GULF SULFUR CORPORATION		700 NORTH OAK BOX 1165	VALDOSTA GA	31603

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0031 Sulfur
Chemical # and Name
077501 Sulfur

Company Name	Additional Name	Address	City & State	Zip
WALLACE C. THARP	UNIVERSAL DIATOMBSINC	410 12TH ST NW	ALBUQUERQUE NM	87102
SOUTHERN MILL CREEK PRODUCTS		5414 NORTH 56TH STREET	TAMPA FL	33610
VOLUNTARY PURCHASING GROUP, INC.		P. O. BOX 460	BONHAM TX	75418
BASF CORPORATION	AGRICULTURAL CHEMICALS GROUP	BOX 13528	RESEARCH TRIANGLE PARK	27709
AGWAY, INC.-CROP SERVICES		BOX 4933	SYRACUSE NY	13221
BREA AGRICULTURAL SERVICE, INC.	SUBSIDIARY OF UNION OIL CO. OF CAL	BOX 201059	STOCKTON CA	95201
CAL-AG ENTERPRISES, INCORPORATED		P. O. BOX 666	DINUBA CA	93618
SUNNILAND CORPORATION		BOX 1697	SANFORD FL	32771
RIVERSIDE/TERRA CORPORATION		BOX 171376	MEMPHIS TN	38187
CORN BELT CHEMICAL COMPANY		BOX 410	MCCOOK NE	69001
GOWAN COMPANY		BOX 5569	YUMA AZ	85366
ICI AMERICAS INC.		NEW MURPHY ROAD & CONCORD PIKE	WILMINGTON DE	19897
ATLAS CHEMICAL CORPORATION		BOX 141	CEDAR RAPIDS, IA	52406
BRITZ FERTILIZERS, INC.		BOX 366	FIVE POINTS CA	93624
CONTRA COSTA COUNTY DEPT. OF AGRIC		161 JOHN GLEN DRIVE	CONCORD CA	94520
SAN JOAQUIN SULPHUR COMPANY, INC		BOX 700	LODI CA	95241
WESTERN FARM SERVICE, INC.		3075 CITRUS CIRCLE, SUITE 195	WALNUT CREEK CA	94598
HUBBARD CHEMICALS		224 W. BATTLE ST. BOX 174	TALLADEGA AL	35160
DREXEL CHEMICAL COMPANY		BOX 9306	MEMPHIS TN	38109
STOLLER CHEMICAL COMPANY INC.		8582 KATY FREEWAY, SUITE 200	HOUSTON TX	77024
PBI GORDON CORP		BOX 4090	KANSAS CITY MO	64101
PLATTE CHEMICAL COMPANY		419 18TH ST. (80632) BOX 667	GREELEY CO	80632
ORGANIC CONTROL INC.		5132 VENICE BLVD.	LOS ANGELES CA	90019
PIERSON LABORATORIES INC.		BOX 157	SALUDA NC	28773
BOLD CORPORATION		BOX 1463	TIFTON GA	31793
CALIFORNIA DEPT OF HEALTH SERVICES		5545 E SHIELDS AVE	FRESNO CA	93727
TODHUNTER, MANDAVA & ASSOC	AGENT FOR: SAFER, INC.	1625 K ST N W SUITE 975	WASHINGTON DC	20036
C. LEON DAVIS		ROUTE 2 BOX 295	PIKEVILLE NC	27863
BACTEC CORP	AGENT FOR: CUPROQUIM S.A.	9601 KATY FREEWAY, SUITE 350	HOUSTON TX	77024
ALLJACK & CO.		377 AMELIA	PLYMOUTH MI	48170
LANDIS INTERNATIONAL INC.	AGENT FOR: INTERNATIONAL CHEMICALS	BOX 5126	VALDOSTA GA	31603

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0031 Sulfur
Chemical # and Name
077501 Sulfur

Company Name	Additional Name	Address	City & State	Zip
SUNBELT CHEMICAL INC.		HIGHWAY 31 WEST	ATMORE AL	36502
MEAGLEY, PHILIPS, LYTLE, HITCHCOCK	AGENT FOR: WILSON LABORATORIES INC	3400 MARINE MIDLAND CENTER	BUFFALO NY	14203
FERMENTA ASC CORPORATION		5966 HEISLEY ROAD BOX 8000	MENTOR OH	44061
MICRO-FLO CO.		BOX 5948	LAKELAND FL	33807
LANDIS INTERNATIONAL, INC		BOX 5126	VALDOSTA GA	31603
LYKES AGRI SALES, INC.		BOX 1758	DADE CITY FL	33526
AGTROL CHEMICAL PRODUCTS		7322 SOUTHWEST FREEWAY, SUITE 1400	HOUSTON TX	77074
CONTINENTAL SULFUR COMPANY		7500 SAN FELIPE, SUITE 410	HOUSTON TX	77063
SANDOZ CROP PROTECTION CORORATION		1300 EAST TOUHY AVENUE	DES PLAINES IL	60018
USDA/APHIS/ADC		BOX 25266	DENVER CO	80225
SECURITY PRODUCTS COMPANY OF DELAW	D.B.A. SECURITY PRODUCTS CO	485 OAK PLACE SUITE 370	ATLANTA GA	30349
DR. T'S NATURE PRODUCTS, INC.		MT. OLIVE RD	PELHAM GA	31779
VALENT U.S.A. CORPORATION		1333 NORTH CALIFORNIA BOULEVARD BO	WALNUT CREEK CA	94596
THE LAND, EPCOT CENTER		BOX 10,000	LAKE BUENA VISTA FL	32830
RNA CORPORATION		1715 S. CAESAR	FRESNO CA	93727

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS AND PRODUCT-SPECIFIC DATA REPORT FORM

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS**	Form Approved OMB No. 2070-0106 Approval Expires 12-31-92

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

   _____

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

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

Signature	**Date**
Name and Title (Please Type or Print)	

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

Signature	**Date**
Name and Title (Please Type or Print)	

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 Approval Expires 12-31-92

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	**Date of Offer**

Certification:

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

Certify that:

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

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Chemical Name	EPA Chemical Number

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

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. 158.120 Product Chemistry					
61-1	Identity of Ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	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. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit /rat/g.pig				
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