United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (H-7508W)
EPA-738-F-93-010
September 1993

EPA R.E.D. FACTS

THYMOL

Pesticide Reregistration

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

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

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

Use Profile

Thymol is a constituent of oil of thyme, a naturally occurring mixture of compounds in the plant Thymus vulgaris L., or thyme. Thymol is an active ingredient in pesticide products registered for use as animal repellents, fungicides/fungistats, medical disinfectants, tuberculocides, and virucides. These products are used on a variety of indoor and outdoor sites, to control target pests including animal pathogenic bacteria and fungi, several viruses including HIV-I, and birds, squirrels, beavers, rats, mice, dogs, cats and deer. Products are liquids applied by spray, mop, brush-on, wipe-on dip, aerosol, immersion and spot treatment. Thymol also has many non-pesticidal uses, including use in perfumes, food flavorings, mouthwashes, pharmaceutical preparations and cosmetics.

Regulatory History

Thymol was initially registered as a pesticide in the United States in 1964 for use as a repellent for domestic animals. Currently, five end-use (and no manufacturing use) pesticide products containing the active ingredient

thymol are registered. Thymol, thyme essential oil and thyme (spice) are listed by the Food and Drug Administration (FDA) as foods for human consumption, as well as food additives. They are considered Generally Recognized as Safe or GRAS. (Please see 21 CFR 172.515, 182.10 and 182.20.)

Historically, certain thymol products and other liquid chemical germicides have been regulated both by EPA as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and by FDA as devices under the Federal Food, Drug, and Cosmetic Act (FFDCA). To resolve the confusion and burden of dual regulation, EPA and FDA signed a Memorandum of Understanding (MOU) on June 4, 1993, which clarifies the future regulation of these germicides. The MOU divides liquid chemical germicides used in conjunction with medical devices into two categories: sterilants, which will be regulated by FDA as devices, and general purpose disinfectants, which EPA will regulate as pesticides. Until rulemaking is completed to permanently vest jurisdiction over these categories, regulatory data need only be submitted to one Agency. For thymol, the conditions of reregistration must be fulfilled and required data must be submitted to EPA.

Human Health Assessment

Thymol is among those pesticides for which EPA believes a broadly reduced set of generic data requirements is appropriate for reregistration. The Agency, therefore, has waived most generic data requirements for thymol with the exception of studies that are considered essential, including additional information about chemical purity, and product chemistry studies. In evaluating thymol's potential risks to human health and the environment, EPA relied on information commonly available in scientific literature.

Thymol is a constituent of a mixture of organic compounds known to be rapidly degraded in the environment to elemental compounds by normal biological, physical and/or chemical processes that can reasonably be expected to exist where the pesticide is applied. As a pesticide, thymol repels vertebrate pests by a non-toxic mode of action, but is toxic to microorganisms. EPA is not aware of any adverse effects of thymol to humans or the environment when it is used in a manner prescribed by product labeling. The Agency has no significant incident reports involving thymol.

Toxicity data reported in available literature indicate that acute oral toxicity for rats and guinea pigs corresponds to Toxicity Category III (Category I

signals the highest degree of acute toxicity, and Category IV the lowest). The Material Safety Data Sheet (MSDS) for technical grade thymol notes that it is irritating to humans when exposed by inhalation, dermal or eye contact. The dermal risk to humans would be Toxicity Category III.

Exposures and health risks to people using currently registered products are expected to be relatively low. However, handling and use of the end-use products could involve greater exposure by the dermal and inhalation routes. Required product specific acute toxicity testing will enable the Agency to design appropriate labeling to address these potential exposure concerns.

The uses of thymol will result in negligible exposure of the environment and nontarget organisms. EPA concludes that the use of thymol as an active ingredient in currently-registered pesticide products should not result in unreasonable adverse effects to human health or the environment.

Additional Data Required

Although EPA has waived most generic studies for thymol, the Agency is requiring information on the manufacturing process and additional information about the characterization of the thymol used in the formulated products. EPA also is requiring product-specific data, including product chemistry, acute toxicity and efficacy studies, as well as revised Confidential Statements of Formula and revised labeling, for reregistration.

Product Labeling Changes Required

The labels of all registered pesticide products containing thymol must comply with EPA's current pesticide labeling requirements.

Regulatory Conclusion

The use of currently registered pesticide products containing thymol in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These thymol products will be reregistered once the required manufacturing process information, physical and chemical properties data, product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products containing other active ingredients will be reregistered only when the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) for thymol during a 60-day time period, as announced in a

Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), U.S. EPA, Washington, DC 20460, telephone 703-305-5805.

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

For more information about thymol or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, U.S. EPA, Washington, DC 20460, telephone 703-308-8000.

For information about reregistration of individual repellent products containing thymol, please contact Robert A. Forrest, Product Manager Team 14, Registration Division (7505C), OPP, U.S. EPA, Washington, DC 20460, telephone: 703-305-6600. For reregistration information on individual antimicrobial products, please contact Ruth G. Douglas, Product Manager Team 32, Registration Division (7505C), OPP, U.S. EPA, Washington, DC 20460, telephone: 703-305-7964.

REREGISTRATION ELIGIBILITY DECISION

Thymol

LIST C

CASE 3143

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

TABLE OF CONTENTS

THYMOL REREGISTRATION ELIGIBILITY DECISION TEAM iii

GLOSSARY OF TERMS AND ABBREVIATIONS v

EXECUTIVE SUMMARY vii

I. INTRODUCTION 1

II. CASE OVERVIEW 2
- A. Chemical Overview 2
- B. Use Profile 3
- C. Data Requirements 4
- D. Regulatory History 4

III. SCIENCE ASSESSMENT 5
- A. Product Chemistry Assessment 5
- B. Human Health And Environmental Assessment 5

IV. RISK MANAGEMENT AND REREGISTRATION ELIGIBILITY DECISION 7
- A. Determination of Reregistration Eligibility 7
  - 1. Eligible and Ineligible Uses 8
- B. Risk Management Decision 8

V. ACTIONS REQUIRED BY REGISTRANTS 9
- A. Technical Grade Information 9
  - 1. Generic Data Requirements 9
- B. End-Use Products 9
  - 1. Additional Product-Specific Data Requirements 9
  - 2. Labeling Requirements for End-Use Products 10
- C. Existing Stocks Information 10

VI. APPENDICES

Appendix A - Use Patterns Subject to Reregistration

Appendix B - Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

Appendix C - Citations Considered to be Part of the Data Base Supporting the Reregistration of Wood Oils and Gums

Appendix D - List of Available Related Documents

Appendix E - Pesticide Reregistration Handbook

Appendix F - Generic Data Call-In

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

Appendix G - Product Specific Data Call-In

Attachment A -	Chemical Status Sheet
Attachment B -	Product Specific DCI Response Forms (Form A) plus Instructions
Attachment C -	Requirements Status and Registrants' Response Forms (Form B) plus Instructions
Attachment D -	EPA Grouping of End Use Products for meeting Acute Toxicology Data Requirements.
Attachment E -	EPA Acceptance Criteria
Attachment F -	List of all Registrant(s) sent this DCI
Attachment G -	Cost Share/Data Compensation Forms

THYMOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Hawa Herzi	**Biological Analysis Branch**

Environmental Fate and Effects Division

William Schneider	**Science Analysis and Coordination Staff**

Health Effects Division

Arliene M. Aikens	**Chemical Coordination Branch**
Flora Chow	**Chemical Coordination Branch**
Tom McClintock	**Science Analysis Branch**

Registration Division

Amelia Acierto	**Registration Support Branch**
Ruth G. Douglas	**Antimicrobial Branch**
Robert A. Forrest	**Insecticide-Rodenticide Branch**
Joanne Hayes	**Registration Support Branch**
Daniel Peacock	**Insecticide-Rodenticide Branch**
Wallace Powell	**Antimicrobial Branch**

Special Review and Reregistration Division

Kathy Davis	**Accelerated Reregistration Branch**
Kathleen Depukat	**Accelerated Reregistration Branch**

Office of General Counsel:

Kevin Lee

Office of Compliance Monitoring:

Phyllis Flaherty

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CDC	Center for Disease Control
CFR	Code of Federal Regulations
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
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

mg/kg	Milligrams per Kilograms of Body Weight
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MSDS	Material Safety Data Sheets
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
RED	Reregistration Eligibility Decision Document
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.
USP	United States Pharmacopeia
w/w	Weight to Weight

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency (referred to as the "Agency" or "EPA") has completed its reregistration assessment of the available information on the pesticide active ingredient thymol. It has been determined that the currently registered uses will not cause unreasonable risk to humans or the environment and the products registered for these uses are eligible for reregistration.

Thymol is a constituent of oil of thyme, a naturally occurring mixture of compounds in the plant Thymus vulgaris L., or thyme. Thymol, as used in pesticide products, may be applied as an animal repellant, a fungicide/fungistat, a medical disinfectant, a tuberculocide, or a virucide. The use sites include indoor residential, outdoor residential, indoor non-food, indoor medical, and terrestrial non-food/outdoor residential. Application methods include spray, mop, brush-on, wipe-on dip, aerosol, immersion and spot treatment.

All EPA registered thymol products are for non-food uses. Thymol, thyme essential oil and thyme (spice) are Generally Recognized As Safe (GRAS) and are listed by the U.S. FDA in Subchapter B-Food for human consumption (21 CFR §§ 172.515, 182.10 and 182.20).

Before reregistering the products containing thymol, the Agency is requiring that the manufacturing process and additional information on the physical and chemical properties of the extracted oil, product specific data, Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry, acute toxicity and efficacy testing for each registration. After reviewing these data and revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister the single product containing only thymol. The remaining four products cannot be reregistered until the Agency has determined that the other active ingredients in those products are also eligible for reregistration.

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 Agency of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for 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 eligibility of the registered uses of thymol. The document consists of six sections. Section I is the introduction. Section II describes thymol, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for thymol. Section V discusses the reregistration requirements for thymol. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

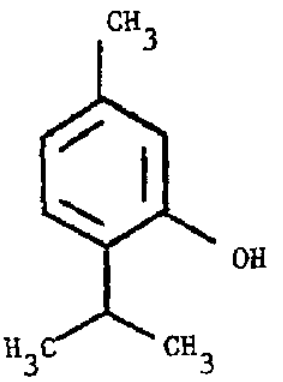
[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Thymol
- **Case Number:** 3143
- **Chemical Name:** 5-Methyl-2-(1-methylethyl)phenol
- **Synonyms:** 5-methyl-2-isopropyl-1-phenol; 1-methyl-3-hydroxy-4-isopropylbenzene; isopropyl-meta-cresol
- **Other Names:** Thyme camphor
Thymic acid
- **CAS Registry No.:** 89-83-8
- **Pesticide Chemical Code:** 080402
- **Empirical Formula:** $C_{10}H_{14}O$
- **Molecular Formula:** $(CH_3)_2CHC_6H_3(CH_3)OH$
- **Molecular Weight:** 150.21
- **Trade Names:** Thymocide
Topps
- **Structural Formula:**



B. Use Profile

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

For Thymol:

Type of Pesticide: Animal repellant, fungicide/fungistat, medical disinfectant, tuberculocide, virucide (antimicrobial)

Use Sites: Indoor Residential - bathroom premises/hard surfaces, household/domestic dwellings - contents and indoor premises, living/sleeping quarters

Outdoor Residential - fencerows/hedgerows, household/domestic dwellings - outdoor premises, refuse/solid waste containers (garbage cans)

Indoor Non-Food - commercial/institutional/industrial premises/equipment

Indoor Medical - hospital critical items (surgical instruments/pacemakers), hospital/medical institutions non-conductive floors, critical premises (burn wards), patient premises and other premises (human/veterinary)

Terrestrial Non-Food/Outdoor Residential - ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf and ornamental woody shrubs and vines

Target Pests: Animal pathogenic bacteria (G- and G+ vegetative), Pseudomonas spp., Mycobacterium spp. (Tubercle bacilli), animal pathogenic fungi (T. mentagrophytes), vaccinia virus, Herpes simplex viruses I and II, Influenza A3 (H3N2 - Hong Kong) and Influenza A2 - Hong Kong, HIV-I (Human Immunodeficiency Virus); birds, squirrels, beavers, rats, mice, dogs, cats, and deer

Formulation Types Registered: Soluble concentrate/liquid, liquid-ready to use

C. Data Requirements

The Agency has waived all generic data requirements except for manufacturing information and the physical and chemical properties for this active ingredient. The reason for this is described below in Section III. It has relied instead on general, commonly available information about thymol. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

Products containing thymol as an AI were originally registered in 1964 for use as a repellent for domestic animals. These have included products to repel dogs, cats, deer, beavers, rats, mice, birds, and tree squirrels. Subsequently, thymol-containing pesticide products have been registered for use as an acaricide, fungicide/fungistat, medical disinfectant, tuberculocide and virucide (antimicrobial). Currently, there are five products containing thymol as the pesticide ingredient for use as animal repellents or disinfectants. One product contains only the active ingredient thymol. The other four products contain one or two additional active ingredients. The concentration of thymol in these active products ranges from 0.027% to 13% (w/w). Thymol, thyme essential oil and thyme (spice) are Generally Recognized As Safe (GRAS) and are listed by the FDA in Subchapter B-Food for human consumption (21 CFR §§ 172.515, 182.10 and 182.20). Thymol is also used in perfumes, food flavorings, mouthwashes, disinfectants, pharmaceutical preparations and cosmetics.

Historically, certain thymol products and certain other liquid chemical germicides have been regulated both as pesticides under the Federal Insecticide, Fungicides and Rodenticide Act (FIFRA) and as devices under the Federal Food, Drug and Cosmetic Act (FFDCA). In an effort to resolve the confusion and burden of dual regulation, a Memorandum of Understanding (MOU) was signed on June 4, 1993 between EPA and the Food and Drug Administration (FDA). The objectives of the MOU are to (1) stimulate both Agencies to undertake rulemaking to permanently vest exclusive jurisdiction for certain categories of chemical germicides in each Agency and (2) serve as interim guidance designed to minimize duplicative regulatory requirements between the two Agencies until the rulemaking is complete.

The MOU separates the liquid chemical germicides into the following two categories based on their use patterns and efficacy claims: (1) sterilants and (2) general purpose disinfectants. Sterilants, under this agreement, refer to those chemical germicides used to reprocess reusable critical and semicritical devices as defined by the Centers for Disease Control (CDC). Critical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. Semicritical devices are those which contact intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter

normally sterile areas of the body. General disinfectants are defined as all remaining types of public health liquid chemical germicides bearing non-sterilant claims for use on non-critical surfaces.

The MOU outlines the future separate regulation of liquid chemical germicides as either pesticides under FIFRA or devices under FFDCA by granting each Agency primary jurisdiction over one of the two categories. All products which bear sterilant label claims and can be used on critical or semicritical surfaces will be regulated by FDA as devices. In addition, many sterilant products have claims which correspond to a high level disinfectant use pattern. These claims will also be regulated by FDA for the sterilant products. EPA will regulate the general purpose disinfectants.

Because the MOU does not change the statutory authority granted under FIFRA and FFDCA, both Agencies will continue to have jurisdiction over all liquid chemical germicides and will continue registration and premarket approval until rulemaking has been completed. However, the MOU reduces the regulatory burden by stating that the required data to support efficacy claims and product performance need only be submitted and reviewed by the Agency with primary jurisdiction as defined above. In the case of the thymol products, EPA has primary jurisdiction and the conditions of reregistration must be fulfilled and required data submitted as presented in Appendices F and G.

A copy of the signed EPA/FDA MOU is attached as Appendix D.

III. SCIENCE ASSESSMENT

A. Product Chemistry Assessment

Thymol (5-methyl-2-isopropyl-l-phenol) is a constituent of oil of thyme, a naturally occurring mixture of compounds in the plant Thymus vulgaris L., Monarda punctata L., Ptychotic coptica, or it can be produced synthetically.

The assessment of the manufacturing process and the physical and chemical properties are not complete. The Agency lacks generic product chemistry data on thymol which may be available in the literature, including patent information. The Agency is requiring registrants to provide manufacturing process information, and additional physical and chemical properties data on the active ingredient thymol, as well as, the Confidential Statement of Formula and labels (Appendix F) to confirm the chemical properties and purity of source(s) of thymol usesd in registered products.

B. Human Health And Environmental Assessment

EPA has developed a target data base, set forth in the regulations (40 CFR Part 158) and the Agency's Reregistration Phase 2 Technical Guidance Document to be

addressed for pesticide reregistration. These regulations and the guidance document specify the necessary data based on factors including use sites, potential environmental and human (dietary and occupational) exposures, product formulation types, and product application methods. Due to the diverse nature and characteristics of pesticide products and their uses subject to reregistration, the Agency also recognizes the necessity to modify the data requirements for specific pesticides, including waiving certain data requirements because such requirements are inappropriate or unnecessary for reregistration.

The case specific approach to waiving individual data requirements has served to identify the appropriate data requirement sets for pesticide products. Further, the Agency believes there is a category of pesticide active ingredients for which a broadly reduced set of data requirements are appropriate for reregistration. Specifically, products in this category would be exempt from the generic data requirements for toxicology, human exposure, ecological effects, and environmental fate on the active ingredient. The Agency believes there are considerations which, when taken together, can form the basis for a conclusion that such a reduction in data requirements is appropriate for a particular pesticide active ingredient, while not compromising human health or environmental safety.

There are, however, certain data requirements which are essential and not likely to be waived. Basic product identity/chemistry information on the active ingredient and formulated products is required for pesticides in this category so that the Agency has reasonable certainty of the pesticide's identity and chemical and physical characteristics. Also, product specific acute toxicology studies are required for the Agency to determine appropriate product labeling for potential hazards to those who handle or apply such products. However, these toxicology studies may also be waived if an assessment of the product formulation, including the inert ingredients, indicates that such studies are unnecessary to prescribe appropriate labeling. Efficacy studies may be required on formulated products if those product labels specify a public health use.

In considering thymol for reregistration eligibility the Agency believes it is an active ingredient that should be considered for this broad waiver of the generic data requirements. The considerations that lead the Agency to this conclusion are presented below.

Thymol is a component of many non-pesticidal consumer products currently marketed in the United States. Thymol is listed as a food additive by the Food and Drug Administration (21 CFR 172.515; synthetic flavoring substances and adjuvants). Thymol is rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the pesticide is applied. As a pesticide, it repels vertebrate pests by a non-toxic mode of action. The phenols of thymol are considered GRAS as set forth in 21 CRF 172.515 (synthetic flavoring substances and adjuvants). EPA is not aware of any adverse effects

of the active ingredient to humans or the environment in the literature when used in a manner prescribed in end-use product labeling. There have been no significant incident reports.

Thymol toxicity data reported in available literature cite acute oral LD_{50} values as 980 mg/kg and 880 mg/kg for the rat and guinea pig, respectively (Sax, 1984). The acute oral toxicity reported for the rat and guinea pig, correspond to Toxicity Category III. The Material Safety Data Sheet (MSDS) for the manufacture of technical grade thymol cites human health effects as irritating when exposed by inhalation, dermal or eye contact. The MSDS also estimates a human ingestion LD_{50} at two grams of the synthetic thymol (99% w/w). Based upon an estimated thymol dermal toxicity LD_{50} of greater than 2000 mg/kg, the dermal toxicity category would be Toxicity Category III.

Exposures and, therefore, health risks to people using currently registered products are expected to be relatively low. The product specific acute toxicity testing will indicate appropriate labeling to address potential exposure concerns.

No ecological or environmental data were submitted to support reregistration of thymol. The Agency expects that there will be low exposure to the environment and to nontarget organisms.

Based on these factors the Agency does not believe generic data are necessary to determine whether the currently registered uses of this active ingredient pose unreasonable risks to humans or the environment. Therefore, EPA is not requiring the submission of additional generic data for the active ingredient thymol other than the identity and physical and chemical properties. However, EPA is requiring the submission of product specific data (chemistry, acute toxicity and efficacy) to characterize the products and ensure their efficacy of public health uses. The Agency believes that, based on the above factors, the registered uses of thymol do not pose unreasonable risks to humans or the environment.

IV. RISK MANAGEMENT AND REREGISTRATION ELIGIBILITY DECISION

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. As discussed above, the Agency has determined that the set of generic requirements that would normally be applicable to thymol are not necessary for the Agency to reach a decision on potential risks and reregistration eligibility. Thymol meets the criteria in the Agency document entitled "Guidance for Making Determinations to Reduce Data Requirements" (Appendix D). The criteria thymol passed to become a reduced data RED are: (1) Thymol is recognized as a significant component of a common human food; (2) Thymol is widely distributed

in commerce and available to the general public throughout the U.S. for non-pesticidal uses; (3) Thymol has no data submitted under Section 6(a)(2) of FIFRA; (4) The Agency is not aware of any adverse effects of thymol when used in a manner prescribed in end-use product labeling; (5) There have been no significant incident reports for thymol; (6) There is no indication in the literature, as provided by the registant, that thymol poses adverse effects in humans or to the environment when used in a manner prescribed in end-use product labeling; (7) There is negligible human and environmental exposure to thymol as a result of pesticidal use patterns, e.g., low use rate and frequency of application, or product applied in confined or contained manner; and (8) Thymol can be presumed non-persistent based on knowledge of its composition, e.g., organic material known to be rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the thymol is applied. (See Appendix B).

The Agency has concluded from its review of this information that thymol can be used without resulting in unreasonable adverse effects to human health and the environment. The Agency, therefore, finds that all products containing thymol as an active ingredient as the sole active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

Although the Agency has found that all uses of thymol are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing thymol, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligible and Ineligible Uses

Based on its review of generic information for thymol, the Agency has determined that products labeled for all uses of thymol are eligible for reregistration. The Agency can reregister the single product containing only thymol once the Agency has reviewed the data and labeling requested in this RED and found them to be in accordance with section 3(c)(5) of FIFRA. Each of the remaining four products can be reregistered when the Agency had determined its eligibility for reregistration based on a review of generic data for the product's other active ingredients and its compliance wilth section 3(c)(5).

B. Risk Management Decision

In consideration of the above information about thymol, the Agency finds no reason to impose new risk reduction measures for currently registered uses. The Agency will however, assess the need for product specific risk reduction measures upon receipt of data that are being required under the Product Specific Data Call-in Notice appended to this document.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both technical grade and end-use products. There are currently no manufactured use products registered.

A. Technical Grade Information

1. Generic Data Requirements

The generic data base supporting the reregistration of products containing thymol for the eligible uses (Section II and Appendix A) has been reviewed and determined to be incomplete. Registrants are required to submit the technical chemistry data corresponding to Series 61 and Series 62 for the analysis and certification of product ingredients. If the product is a USP grade, a copy of USP analysis with citation of the analytical method used and certification would satisfy the requirement for Series 62.

The Confidential Statement of Formula (CSF) must be supported by analytical data. Registrants of end-use products using unregistered sources of thymol are required to submit the data on the physical and chemical characteristics of thymol from the Material Safety Data Sheet (MSDS) for the product may be compiled by the registrant in the format required by the FIFRA Accelerated Reregistration Phase 3 Technical Guidance, specifically PR Notice 86-5 to satisfy some of the requirements of Series 63. The generic data requirements are listed in Appendix F, the Generic Data Call-in Notice.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Based on consideration of the above information for the active ingredient thymol, all currently registered uses of products containing thymol 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 on the active ingredient has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Previous data submissions must be reviewed to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment E) and if not, commit

to conduct new studies. If it is believed that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants' Responses Form provided for each product.

It is the responsibility of the registrant(s) to ensure that their source product is registered (i.e., not cancelled) and the registration numbers are current. If the source product is unregistered, the registrant must provide the data base, Series 61, 62 and 63 for that source product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and described in the Pesticide Reregistration Handbook.

C. Existing Stocks Information

Existing stocks may generally be distributed and products sold bearing old labels/labeling for 26 months from the date of the issuances of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell thymol products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED.

VI.
APPENDICES

APPENDIX A

Table of Use Patterns Subject to Reregistration

APPENDIX A - Case 3143, [THYMOL] Chemical 080402 [Thymol]

Application Type / Application Timing / Application Equipment / Surface Type / Efficacy Influencing Factor (Antimicrobials Only)	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED USES										
Site: Bathroom Premises/Hard Surfaces (Use Group: INDOOR RESIDENTIAL)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
contact and/or surface treatment, NA, cloth, hard organic soil (5%)	L-RTU	270 W	270 W	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Commercial/Institutional/Industrial Premises/Equipment (Use Group: INDOOR NON-FOOD)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Hospital Critical Items (Surgical Instruments/Pacemakers) (Use Group: INDOOR MEDICAL)										
immersion, NOL, NOL, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Hospital/Medical Institutions Non-Conductive Floors (Use Group: INDOOR MEDICAL)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Hospitals/Medical Institutions Critical Premises (Burn Wards) (Use Group: INDOOR MEDICAL)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.

APPENDIX A - Case 3143, (THYMOL) Chemical 080402 [Thymol]

Application Type / Application Timing / Application Equipment / Surface Type / Efficacy Influencing Factor (Antimicrobials Only)	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Pattern Limitations
USES ELIGIBLE FOR REREGISTRATION										
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Hospitals/Medical Institutions Patient Premises (Use Group: INDOOR MEDICAL)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Hospitals/Medical Institutions Premises (Human/Veterinary) (Use Group: INDOOR MEDICAL)										
brush-on, NOL, brush, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
mop, NOL, mop, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
wipe-on, NOL, cloth, hard organic soil (5%)	SC/L L-RTU	270 W	508 V	NS	NS	NS	NS	NA	NA	Preclean claim.
Site: Household/Domestic Dwellings Contents (Use Group: INDOOR RESIDENTIAL)										
spot treatment, when needed, pump spray bottle	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
Site: Household/Domestic Dwellings Outdoor Premises (Use Group: OUTDOOR RESIDENTIAL)										
spot treatment, when needed, brush	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
spray, when needed, sprayer	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
Site: Ornamental and/or Shade Trees (Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL)										
spot treatment, when needed, brush	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
spray, when needed, sprayer	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
Site: Ornamental Herbaceous Plants (Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL)										
soak, bulbs, glove	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
soak, seed, glove	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
soak, foliar, sprayer	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
Site: Ornamental Lawns and Turf (Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL)										

APPENDIX A - Case 3143, [THYMOL] Chemical 080402 [Thymol]											
Application Type / Application Timing / Application Equipment / Surface Type / Efficacy Influencing Factor (Antimicrobials Only)	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations		Use Pattern Limitations
								Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION										
spray, foliar, sprayer	L-RTU	NA	0.00282 lb. 1K sq. ft.	NS	NS	NS	NS	NA	NA	NS
Site: Ornamental Woody Shrubs and Vines (Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL)										
spray, foliar, sprayer	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS
Site: Refuse/Solid Waste Containers (Garbage Cans) (Use GRoup: OUTDOOR RESIDENTIAL)										
spot treatment, when needed, sprayer	L-RTU	NA	NA	NS	NS	NS	NS	NA	NA	NS

Abbreviations used:

Header: ppm a.i. - parts per million of active ingredient; Max. # Apps. - maximum number of applications
Max. # Apps. @ Max. Rate - maximum number of applications at maximum rate
Min. Interval Between Apps. @ Max. Rate (Days) - minimum interval between applications at maximum rate (in days)

Form: L-RTU - Ready-to-use Liquid; SC/L - Soluble Concentrate/Liquid
Rate: W - parts per million of active ingredient calculated by weight; V - parts per million of active ingredient calculated by volume
In general: NOL - not specified on the label; NA - not applicable; NS - not specified

APPENDIX B

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case anything covered by this Reregistration Eligibility Decision. It contains generic data requirements that apply to anything in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

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 appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Thymol

REQUIREMENT		USE PATTERN	CITATION
PRODUCT CHEMISTRY			
61-1	Chemical Identity	All	REQUIRED
61-2a	Start. Mat. & Mnfg. Process	All	REQUIRED
61-2b	Formation of Impurities	All	REQUIRED
62-1	Preliminary Analysis	All	REQUIRED
62-2	Certification of Limits	All	REQUIRED
62-3	Analytical Method	All	REQUIRED
63-2	Color	All	SATISFIED[1]
63-3	Physical State	All	SATISFIED[1]
63-4	Odor	All	SATISFIED[1]
63-5	Melting Point	All	SATISFIED[1]
63-6	Boiling Point	All	SATISFIED[1]
63-7	Density	All	SATISFIED[1]
63-8	Solubility	All	REQUIRED
63-9	Vapor Pressure	All	SATISFIED[1]
63-10	Dissociation Constant	All	SATISFIED[1]
63-11	Octanol/Water Partition	All	SATISFIED[1]
63-12	pH	All	SATISFIED[1]
63-13	Stability	All	REQUIRED
63-14	Oxidizing/Reducing Action	All	REQUIRED
63-15	Flammability	All	REQUIRED
63-16	Explodability	All	REQUIRED
63-17	Storage Stability	All	REQUIRED
63-18	Viscosity	All	REQUIRED
63-19	Miscibility	All	REQUIRED
63-20	Corrosion Characteristics	All	REQUIRED

2

[2] Data contained in a letter dated 3/12/92 from the source manufacturer

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Thymol

REQUIREMENT	USE PATTERN	CITATION
ECOLOGICAL EFFECTS		
71-1a Acute Avian Oral - Quail/Duck	All	WAIVED
71-2a Avian Dietary - Quail	All	WAIVED
71-2b Avian Dietary - Duck	All	WAIVED
72-1a Fish Toxicity Bluegill	All	WAIVED
72-1c Fish Toxicity Rainbow Trout	All	WAIVED
72-2a Invertebrate Toxicity	All	WAIVED
122-1a Seed Germination/Seedling Emergence	All	WAIVED
122-1b Vegetative Vigor	All	WAIVED
122-2 Aquatic Plant Growth	All	WAIVED
TOXICOLOGY		
81-1 Acute Oral Toxicity - Rat	All	WAIVED
81-2 Acute Dermal Toxicity - Rabbit/Rat	All	WAIVED
81-3 Acute Inhalation Toxicity - Rat	All	WAIVED
81-4 Primary Eye Irritation - Rabbit	All	WAIVED
81-5 Primary Dermal Irritation - Rabbit	All	WAIVED
81-6 Dermal Sensitization - Guinea Pig	All	WAIVED
84-2a Gene Mutation (Ames Test)	All	WAIVED
84-2b Structural Chromosomal Aberration	All	WAIVED
84-4 Other Genotoxic Effects	All	WAIVED

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Thymol

REQUIREMENT	USE PATTERN	CITATION
ENVIRONMENTAL FATE		
160-5 Chemical Identity	All	WAIVED
161-1 Hydrolysis	All	WAIVED
161-2 Photodegradation - Water	All	WAIVED
161-3 Photodegradation - Soil	All	WAIVED
162-1 Aerobic Soil Metabolism	All	WAIVED
162-2 Anaerobic Soil Metabolism	All	WAIVED
162-3 Anaerobic Aquatic Metabolism	All	WAIVED
163-1 Leaching/Adsorption/Desorption	All	WAIVED
164-1 Terrestrial Field Dissipation	All	WAIVED
165-1 Confined Rotational Crop	All	WAIVED

APPENDIX C

THYMOL BIBLIOGRAPHY

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

GUIDE TO APPENDIX C

1. CONTENTS 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 Decision. 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, are 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 also attempted 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 whenever a 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 identifying 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 standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, 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 the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained 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 the 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. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands 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.

REFERENCES

Code of Federal Regulations, Title 21, Part 172, Section 515, revised as of July 1, 1992. Published by the Office of the Federal Register National Archives and Records Administration, Washington, DC, U.S.A.

Code of Federal Regulations, Title 21, Part 182, Sections 10 and 20, revised as of July 1, 1992. Published by the Offices of the Federal Register National Archives and Records Administration, Washington, DC, U.S.A.

Gunether, E., The Essential Oils, Vol. III., D. Van Nostrand Co., Inc.

Material Safety Data Sheets: 10/23/85, Ruger Chemical Co. Inc.

The Merck Index; An Encyclopedia of Chemicals, Drugs, and Biologicals. Windholz, Martha, Ed. et al., Tenth Edition. Published in 1983 by Merck and Company, Rahway, New Jersey, U.S.A.

Sax, N. I., (1984), Dangerous Properties of Industrial Materials, Van Nostrand Reinhold Co., p. 2580.

APPENDIX D

List of Available Related Documents

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

1. Detailed Label Usage Information System (LUIS) Report

2. Thymol RED Fact Sheet

3. PR Notices 86-5 and 91-2 (included in these appendices). These notices pertain to the correct submission of the data and label ingredient statements.

4. June 4, 1993 Memorandum of Understanding between FDA and EPA; Notice regarding matters of mutual responsibility - Regulation of liquid chemical germicides intended for use on medical devices (included in these appendices).

APPENDIX E

Pesticide Reregistration Handbook
PR Notices 86-5 and 91-2
Memorandum of Understanding Between FDA/EPA

PESTICIDE REGISTRATION HANDBOOK

PR Notice 86-5

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

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

		Text Page	Example Page
A.	Organization of the Submittal Package	3	17
B.	Transmittal Document	4	11
C.	Individual Studies	4	
	C. 1 Special Considerations for Identifying Studies	5	
D.	Organization of each Study Volume	6	17
	D. 1 Study Title Page	7	12
	D. 2 Statement of Data Confidentiality Claims (based on FIFRA §10(d)(1))	8	13
	D. 3 Confidential Attachment	8	15
	D. 4 Supplemental Statement of Data Confidentiality Claims (other than those based on FIFRA §10(d)(1))	8	14
	D. 5 Good Laboratory Practice Compliance Statement	9	16
E.	Reference to Previously Submitted Data	9	
F.	Physical Format Requirements & Number of Copies	9	
G.	Special Requirements for Submitting Data to the Docket	10	

****

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

+Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

+Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
12	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

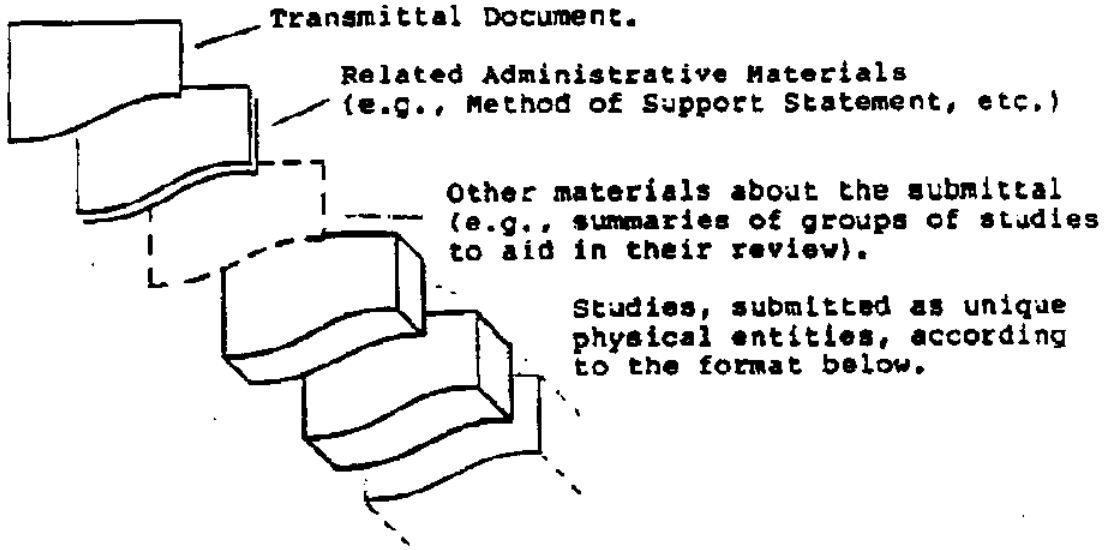
Example 3.

The submltter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

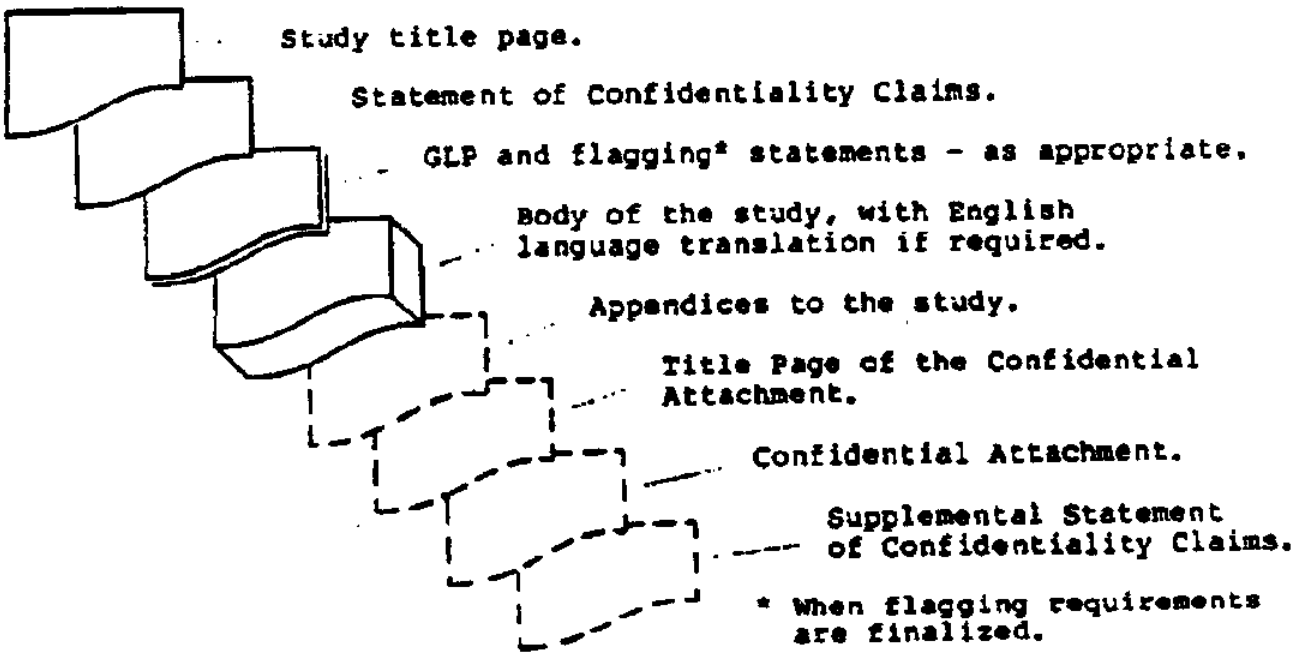
Submitter_____

ATTACHMENT 7.

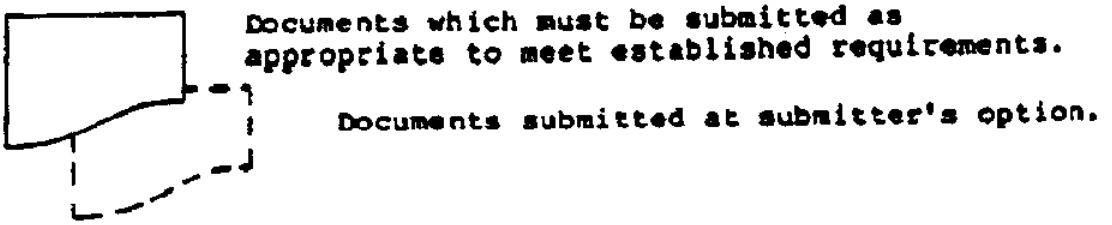
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in

the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

FDA/EPA MEMORANDUM OF UNDERSTANDING
Notice Regarding Matters of Mutual Responsibility - Regulation of Liquid Chemical Germicides Intended for Use on Medical Devices

Memorandum of Understanding
Between
The Food and Drug Administration, Public Health Service,
Department of Health and Human Services
and
The Environmental Protection Agency

Notice Regarding Matters of Mutual Responsibility - Regulation of Liquid Chemical Germicides Intended for Use on Medical Devices

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) clarifies jurisdiction between the two agencies in the regulation of certain liquid chemical germicides. These liquid chemical germicides are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This MOU also embodies the agreement of the two agencies to undertake certain rulemakings in order to eliminate duplicative regulation of certain types of liquid chemical germicides. This MOU includes the agencies' interim agreement to simplify and coordinate their regulatory and enforcement activities in shared areas of jurisdiction affecting these types of products pending the conclusion of these rulemakings.

II. STATUTORY AUTHORITIES

A. FDA Authorities

The FD&C Act grants FDA authority to regulate devices as defined in 21 U.S.C. §321(h). Under section 321(h), the term "device" includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is intended to cure, mitigate, treat, or prevent disease in man, or is intended to affect the structure or any function of the body of man. Liquid chemical germicides intended for use in conjunction with a variety of articles that fit within the statutory definition of "device," such as operating instruments, medical examining tables, hospital scales, and other hospital equipment, also fall within the definition of "device", because they are considered accessories to these devices.

Unless liquid chemical germicides used in conjunction with devices were commercially distributed prior to May 28, 1976,[3] manufacturers of these products, under 21 U.S.C. §360(k) [section 510(k) of the FD&C Act] are required to submit a premarket notification to FDA before they market their products. Before these products can be legally marketed, FDA must grant marketing clearance by (1) issuance of an order in response to a section 510(k) submission which exempts the device from the FD&C Act's premarket approval requirements, or (2) approval of a premarket approval application. In granting marketing clearance by issuance of a section 510(k) order exempting a liquid chemical germicide from premarket approval, FDA must find that the device is "substantially equivalent," as the term is defined in 21 U.S.C. §360c(i)(1)(A), to a predicate device that does not require premarket approval. Section 513 of the FD&C Act authorizes FDA to exempt products from premarket notification requirements for which there is a reasonable assurance of safety and effectiveness. At present, no chemical germicides that are used with devices have been exempted from premarket notification requirements.

In regulating liquid chemical germicides used with devices, FDA is exercising its responsibilities under the FD&C Act for ensuring that devices are safe and effective for their intended uses. The FD&C Act provides enforcement authority to FDA to pursue regulatory actions, including seizure, injunction, prosecution, and civil penalties.

B. EPA Authorities

Liquid chemical germicides, including those regulated as devices, are also under the authority of the EPA under FIFRA. Before a pesticide product may be lawfully sold or distributed in commerce, the product must be registered by EPA pursuant to FIFRA section 3, or otherwise exempted from the requirements of FIFRA. A registration is a license allowing a pesticide product to be sold and distributed for specified uses in accordance with specified use instructions, precautions, and other terms and conditions. Liquid chemical sterilants are included among the various types of antimicrobial products that are currently subject to FIFRA.

A pesticide product may be registered or remain registered only if it meets the statutory standard for registration. Among other things, a pesticide must perform its intended pesticidal function without causing "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)). "Unreasonable adverse effects on the

[3] Devices marketed prior to May 28, 1976 are grandfathered from the FD&C Act's premarket notification requirements. Neither FDA nor EPA are aware of any currently marketed products that are exempt under this grandfather provision. Should any exist, they are not covered by this Memorandum of Understanding.

environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide" (FIFRA section 2(bb)).

The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of initial or continued registration. FIFRA section 6 provides EPA with various regulatory tools that the Administrator may use if it appears that the product no longer satisfies the statutory criteria for registration. If appropriate, EPA may require modifications to the terms and conditions of registration, such as deletion of particular uses or revisions to labeling, as an alternative to regulatory outcomes such as cancellation, suspension, or emergency suspension. FIFRA also provides enforcement authority to EPA to pursue actions, including issuance of stop sale, use, or removal orders when there is reason to believe a pesticide is in violation of FIFRA. Additionally, EPA has authority to seek the assessment of civil administrative penalties as well as institute seizure and criminal actions for violations of FIFRA.

FIFRA section 25(b) authorizes the Administrator to exempt pesticides from FIFRA through regulation if the Administrator determines that the pesticide is "adequately regulated by another Federal agency" or is "of a character which it is unnecessary to be subject to this Act in order to carry out the purposes of this Act."

III. REGULATORY RESPONSIBILITIES AND DEFINITIONS

For the purposes of this agreement, liquid chemical germicides that are used in conjunction with medical devices are divided into two product categories: (1) sterilants and (2) general purpose disinfectants. Sterilants, for purposes of this agreement, means those chemical germicides used to reprocess reusable critical and semicritical devices[2]. Critical devices are devices that are introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. These critical devices must be sterile. Semicritical devices are those which contact intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. For these devices, sterilization is desirable

[2] This definition is consistent with the definition of these terms used by the Centers for Disease Control and Prevention (CDC). Block, S.S. 1991. Disinfection, Sterilization, and Preservation. 4th Edition. Philadelphia, Lea & Febiger.

but not mandatory. These devices must be subjected at least to a high level disinfection[3] process using a sterilant, but for a shorter time than that required for sterilization.

The second category of liquid chemical germicides are general purpose disinfectants. General purpose disinfectants, for purposes of this agreement, means those chemical germicides used to reprocess noncritical devices and medical equipment surfaces[4]. Noncritical devices and medical equipment surfaces must be subjected to intermediate or low level disinfection[5].

FDA's priority is to confirm the efficacy and safety of sterilants used to reprocess critical and semicritical devices which pose the greatest risk of disease transmission. This includes assuring that they do not adversely affect device performance or pose a hazard to the patient/user. Historically, EPA has assessed the effective performance of all chemical germicides and addressed health and safety issues their use.

The FD&C Act and FIFRA have overlapping regulatory schemes for liquid chemical germicides used on devices. **The objective of this MOU is to minimize redundant regulation of these products by FDA and EPA while assuring that the safety and efficacy requirements of both statutes are met.** This affects three areas: data requirements for obtaining approval, procedures for obtaining approval, and compliance.

In determining whether the FD&C Act's and FIFRA's statutory and regulatory requirements are met, EPA and FDA will utilize the data requirements and performance standards referenced in FDA's current Guidance on the Content and Format of Premarket Notification Submission for Liquid Chemical Germicides, FDA premarket notification regulations at 21 CFR Part 807, Subpart E, EPA data requirements regulations at 40 CFR Part 158, and EPA's Subdivision G, Product Performance Guidelines.

Since the EPA registration requirements for general purpose disinfectants parallel the requirements necessary to receive marketing clearance for general purpose disinfectants under section 510(k) of the FD&C Act, fulfillment of EPA's registration

---

[3] "High level disinfectant" and "high level disinfection" are terms of are used by the public health community. FDA recognizes "high level disinfectant" as a separate or subcategory of sterilants. EPA does not register "high level disinfectants" as separate antimicrobial pesticides, but instead may register uses of germicides that correspond with uses in FDA's "high level disinfection" category.

[4] This definition is consistent with the definition of the term used by CDC.

[5] "Low and intermediate level disinfectants" are terms of art used by the public health community. FDA recognizes "low and intermediate level disinfection" as subcategories of general purpose disinfectants. EPA does not register low level and intermediate level disinfectants, but has corresponding germicide classes.

requirements fulfills FDA's section 510(k) requirements for those products.

The EPA efficacy data requirements for liquid chemical sterilants, including those with high level disinfectant uses, are fulfilled by FDA's section 510(k) requirements or premarket approval requirements. Therefore, premarket clearance by FDA fulfills certain EPA registration requirements for liquid chemical sterilants, insofar as efficacy and product performance are concerned. FDA premarket clearance does not satisfy EPA's chemistry, toxicology, and ecological effects requirements.

IV. AGREEMENT

The Administrator of the Environmental Protection Agency and the Commissioner of the Food and Drug Administration agree that until exemptions referred to in Section V occur, the following division of responsibility will govern the activities of the agencies in the regulation of liquid chemical germicides that are intended for use on devices:

A. Regulatory Responsibilities

1. FDA will be primarily responsible for the premarket review of safety and efficacy requirements for liquid chemical germicides that are sterilants[6] intended for use on critical or semicritical devices. Examples of critical devices are laparoscopes, surgical instruments, heart-lung oxygenators, and transfer forceps. Examples of semicritical devices are gastrointestinal endoscopes, endotracheal tubes, cystoscopes, anesthesia breathing circuits, and vaginal specula. FDA will also be primarily responsible for premarket review of contact lens solutions.

2. EPA will be primarily responsible for premarket review of liquid chemical germicides that are general purpose disinfectants[7] intended for use on devices other than critical

---

[6] If a liquid chemical sterilant product has subordinate claims such as tuberculocidal or virucidal, these claims also will be regulated by FDA.

[7] Procedures described in Paragraph 4 only apply to liquid chemical germicide products that do not contain <u>any</u> sterilant claims. If a liquid chemical germicide product contains both sterilant and general purpose disinfectant claims, registration will proceed according to the procedures described in Paragraph 3. If the registrant of a general purpose disinfectant product registered by EPA subsequently applies for registration of a sterilant claim, registration of that product must proceed under procedures described in Paragraph 3 and the existing EPA registration will become void upon FDA's clearance of the product.

or semicritical devices. Examples of noncritical devices are wheel chairs, medical beds, stands, certain operating room surfaces, medical lamps, dental units, and stethoscopes.

3. FDA marketing clearance through the section 510(k) process or approval through the premarket approval process of sterilants will satisfy certain requirements for registration under FIFRA Section 3. Upon submission to EPA by the applicant of an order issued by FDA granting marketing clearance or approval for a liquid chemical germicide that is a sterilant, EPA will consider the efficacy data requirements for registration to be satisfied, and will promptly determine whether the other requirements for registration are satisfied.

4. EPA registration of liquid chemical germicides that are used as disinfectants for devices, except sterilants, will satisfy the criteria necessary to establish substantial equivalence as defined in 21 U.S.C. §360c(i)(1)(A). For this category of liquid chemical germicides, submission by the manufacturer to FDA of a copy of the EPA correspondence granting registration will satisfy FDA's requirement for a premarket notification under 21 U.S.C. §360(k). Upon receipt of this information from the manufacturer of a liquid chemical germicide in this category, FDA will issue an order finding the product substantially equivalent to a predicate device that does not require premarket approval. This order will allow the device to be legally marketed without an approved FDA premarket approval application.

5. As part of the EPA registration process, EPA will require registrants of liquid chemical germicides, other than sterilants that have received FDA premarketing clearance or approval, to put the following statement on their product labels:

> "This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

B. <u>Compliance Responsibilities</u>

1. FDA will be responsible for all sampling and all efficacy testing of liquid chemical sterilants intended for use on critical and semicritical devices and for instituting appropriate enforcement and/or regulatory action against any products that do not comply with the FD&C Act.

   Upon request, EPA will provide FDA with copies of the latest accepted labeling and the name and location of the production site for each product FDA intends to sample.

To the extent allowed under 21 U.S.C. § 331j, 21 U.S.C. §360(j)(c), 42 U.S.C. §263g(d), 42 U.S.C. 263i(e), and 21 C.F.R. Part 20, FDA will share all safety and efficacy test results, labeling changes, and upon EPA request, any other information obtained during FDA enforcement/regulatory actions relating to liquid chemical sterilants. EPA may use this information to determine whether the registrant has complied with FIFRA. On the basis of this information, EPA may determine that further regulatory action under FIFRA, including cancellation of the product's registration, is warranted.

2. EPA will be responsible for the sampling and efficacy testing of all general purpose chemical germicides that are intended for use on devices other than critical and semicritical devices, and for instituting appropriate enforcement and/or regulatory action against any such chemical germicide that does not comply with FIFRA. EPA will refer labels and other evidence concerning inefficacious liquid chemical germicides intended for use on medical devices other than critical or semicritical to FDA for complementary action under the FD&C Act.

3. Each agency will provide assistance upon request to support compliance activities and litigation by the other Agency in cases involving liquid chemical germicides that are intended for use on devices. Assistance will be requested in accordance with applicable procedures, statutory and regulatory requirements including compliance with regulations of 21 CFR Part 20, through the liaison officers listed below. Assistance may include provision of sampling, inspection and audit data, expert witnesses, certified statements, and affidavits.

   Each Agency may consult with the other at any time to determine if the initiation of regulatory and/or enforcement action against a liquid chemical germicide in lieu of or concurrently with the other agency's action is appropriate.

   This Memorandum of Understanding has no effect on any pending investigations or enforcement or regulatory actions undertaken by EPA pursuant to FIFRA or by FDA pursuant to the FD&C Act.

C. Coordination of Activities

To ensure the continued coordinated regulatory, compliance, and enforcement activities for liquid chemical germicides intended for use on devices, an EPA/FDA interagency committee is established. The Directors of the EPA's Registration Division and the Compliance Division, Office of Prevention, Pesticides, and Toxic Substances, and of FDA's Center for Devices and Radiological Health, Office of Compliance and Surveillance, will serve as joint chairpersons who will designate their respective agency members of the committee. The committee will meet at a minimum of twice each fiscal year.

V. FUTURE RULEMAKINGS TO ELIMINATE DUPLICATIVE AGENCY REVIEW

EPA will initiate a rulemaking proceeding under section 25(b) of FIFRA to exempt liquid chemical sterilant products from regulation under FIFRA. EPA believes that the efficacy data requirements and product performance standards for liquid chemical sterilants are fulfilled by FDA's section 510(k) requirements or premarket approval requirements. When such exemption becomes effective, FDA and EPA will cease to follow procedures described in Paragraph IV, A.3. and these products will be subject solely to the regulatory and enforcement requirements and procedures of FDA, and EPA will no longer register such products. To the extent EPA receives information regarding such products, it will share such information with FDA.

FDA will initiate a rulemaking proceeding to classify liquid chemical germicides used on devices under section 513 of the FD&C Act. FDA believes that EPA's requirements under FIFRA for liquid chemical germicides that are intended for use on medical devices that are not critical or semicritical devices parallel the FD&C Act's requirements under section 510(k) of the Act. Accordingly, FDA will recommend to its classification advisory panel that liquid chemical germicides intended for use on devices that are not critical or semicritical devices be exempted from premarket notification requirements under section 510(k) of the FD&C Act. When any such exemption becomes effective, FDA and EPA will cease to follow the procedures in paragraph IV. A. 4. To the extent FDA obtains any information regarding such products, it will share the information with EPA.

VI. NAME AND ADDRESS OF PARTICIPATING PARTIES

A. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

B. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

VII. LIAISON OFFICERS

A. For the Food and Drug Administration

Sterilization and Toxicology Project Officer
(currently: Dr. Virginia Chamberlain)
Office of Compliance and Surveillance
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville, MD 20850
Telephone: (301) 427-1131

For the Environmental Protection Agency:

Antimicrobial Program Branch Chief
(currently: Juanita Wills)
Registration Division
Antimicrobial Program Branch (H7505C)
401 M Street, S.W.
Washington, DC 20460
Telephone: (703) 305-6661

VIII. PERIOD OF AGREEMENT

This agreement becomes effective upon acceptance by both parties. It may be modified by mutual written consent or terminated by either party upon a thirty (30) day advance written notice to the other party. The parties agree to evaluate the agreement every three (3) years, at which time either party would have the option of renewing, modifying, or canceling the agreement.

APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY

By

Title Acting Assistant Administrator

Date June 4, 1993

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By

Title Associate Commissioner for Regulato Affair

Date June 4, 1993

APPENDIX F

Generic Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) 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(s). 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 D; or,

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

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.

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 time frames provided.

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)].

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

A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) 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.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In

Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

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

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

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

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

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

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

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

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

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

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data --

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

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

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

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

affected registration(s).

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

Option 2, Agreement to Share in Cost to Develop Data --

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

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit

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

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

Option 4. Submitting an Existing Study --

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw 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(7), means "any material derived from a test system for examination or analysis."

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

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

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

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

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

Option 5. Upgrading a Study --

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

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

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

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

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

D. REQUESTS FOR DATA WAIVERS

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

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) 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(s) 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(s) 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(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales

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

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

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), 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.

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

c. Total direct production cost of product(s) containing the active ingredient(s) 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.

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

e. 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.

f. 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.

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

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

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), 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(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

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

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

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

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

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

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

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.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

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

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

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

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

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 Federal Insecticide, Fungicide, and Rodenticide 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(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Peter Caulkins

Dan Barolo, Director
Special Review
and Reregistration Division

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address

SAMPLE

2. Case # and Name
3143 Thymol
Chemical # and Name 080402
Thymol

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1 *	Chemical Identity					all	TGAI	8 mos.	
61-2(a) *	Begin. mat. & mnfg. proc					all	TGAI	8 mos.	
61-2(b) *	Discussion of Impurities					all	TGAI	8 mos.	
62-1 *	Preliminary Analysis					all	TGAI	8 mos.	
62-2 *	Certification of limits					all	TGAI	8 mos.	
62-3 *	Analytical Method					all	TGAI	8 mos.	
63-8	Solubility					all	TGAI/PAI	8 mos.	
63-13 *	Stability					all	TGAI	8 mos.	
63-14 *	Oxidizing/Reducting Action					all	TGAI	8 mos.	
63-15 *	Flammability					all	TGAI	8 mos.	
63-16 *	Explodability					all	TGAI	8 mos.	
63-17 *	Storage stability					all	TGAI	8 mos.	
63-18 *	Viscosity					all	TGAI	8 mos.	
63-19 *	Miscibility					all	TGAI	8 mos.	
63-20 *	Corrosion characteristics					all	TGAI	8 mos.	

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
3143 Thymol
Chemical # and Name
080402 Thymol

GUIDELINE	COMMENT
61-1	A Confidential Statement of Formula (CSF) and label are required.
61-2(a)	A brief discussion as to how this product is produced must be submitted. Material Safety Data Sheet for this product and ingredients may be submitted.
61-2(b)	A brief discussion on the possible impurities must be submitted. Please discuss the absence or presence of impurities.
62-1	If the product is a USP grade, a copy of the USP certification indicating the analytical method used for determination would be sufficient to satisfy all Series 62 requirements.
62-2	See comment for 62-1 above.
62-3	See comment for 62-1 above.
63-13	The data submitted should include the stability of the product with metals and metal ions, sunlight and normal and elevated temperatures. Storage stability data should not be confused with stability (63-13). Any analytical data on a product should be interpreted. (i.e., analysis of unknown concentrations should be accompanied with calculations and/or final data).
63-14	The MSDS for this product would suffice to satisfy this requirement.
63-15	See comment for 63-14 above.
63-16	See comment for 63-14 above.

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

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
3143 Thymol
Chemical # and Name
080402 Thymol

GUIDELINE	COMMENT
63-17	Storage stability data should not be confused with stability (63-13). Any analytical data on the product should be interpreted. (i.e., analysis of unknown concentrations should be accompanied with calculations and/or final data).
63-18	See comment for 63-14 above.
63-19	See comment for 63-14 above.
63-20	See comment for 63-14 above.

Attachment A

Chemical Status Sheet

THYMOL: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing thymol.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of thymol. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment D).

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for thymol are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on thymol are needed for technical grade of the active ingredient. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible thymol products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific database of thymol, please contact Frank Rubis at (703) 308-8184.

If you have any questions regarding the product generic data requirements and procedures established by this Notice, please contact Kathleen Depukat at (703) 308-8587.

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

Kathleen Depukat
Accelerated Reregistration Branch (H7508W)
Special Review and Reregistration Division
Office of Pesticide Programs
401 M Street, S.W.
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: THYMOL

Attachment B

Generic DCI Response Forms (Form A) plus Instructions

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

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, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, DC 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item

2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

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

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

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

Attachment C

Requirements Status and Registrants' Response Forms (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

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

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

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

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

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

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

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active

	Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

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

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as

outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The

person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Attachment D
List of Registrant(s) sent this DCI

APPENDIX G

Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific 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 C, Requirements Status and Registrant's Response Form, (see section III-B); or

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

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

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
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, and Product Specific Data Report Form

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. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. 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 product specific 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 time frames provided.

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for 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.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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 chose 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. 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 and Attachment C. 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 or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). 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.

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

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

2. 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 of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

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

III-C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 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 time frame (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.

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. 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 -- 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 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. 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 -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 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 cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to

anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

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

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

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

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, as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

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

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

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

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

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

Response Form:

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

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

IV-C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(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.

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A- Data Call-In Chemical Status Sheet
B- 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, and Product Specific Data Report Form

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

DATA CALL-IN RESPONSE

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

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	3143 Thymol	PRODUCT SPECIFIC

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

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

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
3143 Thymol

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					C K MNO	EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					C K MNO	EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					C K MNO	EP	8 mos.	
62-1	Preliminary analysis (1,4)					C K MNO	EP	8 mos.	
62-2	Certification of limits (1,5)					C K MNO	EP	8 mos.	
62-3	Analytical method (1)					C K MNO	EP	8 mos.	
63-2	Color					C K MNO	EP	8 mos.	
63-3	Physical state					C K MNO	EP	8 mos.	
63-4	Odor					C K MNO	EP	8 mos.	
63-7	Density					C K MNO	EP	8 mos.	
63-8	Solubility					C K MNO	EP	8 mos.	
63-12	pH (9)					C K MNO	EP	8 mos.	

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

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
3143 Thymol

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-14	Oxidizing or reducing action (10,50)					C K MNO	EP	8 mos.	
63-15	Flammability (11)					C K MNO	EP	8 mos.	
63-16	Explodability (12,50)					C K MNO	EP	8 mos.	
63-17	Storage stability					C K MNO	EP	8 mos.	
63-18	Viscosity (13)					C K MNO	EP	8 mos.	
63-20	Corrosion characteristics					C K MNO	EP	8 mos.	
63-21	Dielectric breakdown voltage (15,50)					C K MNO	EP	8 mos.	
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,37)					C K MNO	EP	8 mos.	
81-2	Acute dermal (1)					C K MNO	EP	8 mos.	
	toxicity-rabbit/rat								
81-3	Acute inhalation toxicity-rat (3)					C K MNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit (2)					C K MNO	EP	8 mos.	
81-5	Primary dermal irritation (1,2)					C K MNO	EP	8 mos.	
81-6	Dermal sensitization (4)					C K MNO	EP	8 mos.	
	Efficacy - Antimicrobial Agents - Public								
	Health Uses								
	Medical, Dental, Mortuary, and								

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

Date

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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
3143 Thymol

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Allied Environments								
91-2,3	AOAC use-dilution method (1,2)					MN	EP	8 mos.	
91-2	AOAC fungicidal test (1,2)					MN	EP	8 mos.	
91-2	AOAC tuberculocidal activity method (1,2)					MN	EP	8 mos.	
91-2	Virucidal activity study (1,2)					MN	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (50,51,52)					C JK	EP	8 mos.	
96-14	Rodent repellents on tree seeds (50,51,52)					C JK	EP	8 mos.	
96-18	Domestic dog and cat repellents (50,52)					K O	EP	8 mos.	
96-19	Browsing animal repellents (50,51,52)					C JK	EP	8 mos.	

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

Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3143 Thymol

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
15 Required if end-use product is liquid and is to be used around electrical equipment.
50 Not required for vertebrate repellent products (EPA Reg. Nos. 11715-211 and 45735-2).

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3143 Thymol

Footnotes (cont.):

applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Efficacy - Antimicrobial Agent

1 Efficacy data for antimicrobial agents that claim to control pest microorganisms that may pose a threat to human must be submitted.
2 Comparative product performance data are required to be developed and maintained in the registrant's file and must be submitted to the Agency on a case-by-case basis for risk/benefit analyses such as for public interest findings and cases of special review.

Efficacy - Vertebrate Control Agents

50 Due to questions concerning the effectiveness of vertebrate animal repellents and the suitability of label directions for such products, registrants of vertebrate pesticides containing Thymol must indicate the studies upon which the claims made for their products are based. Such studies in EPA's data base may be cited by MRID number or accession number. Studies not in EPA's data base must be submitted in the appropriate format. If no efficacy data are available to substantiate the claims made for their products, registrants must commit to generate such data, delete the relevant claims, or request voluntary cancellation of their registrations.
51 Efficacy data are needed to support the following claims made for this product, EPA Reg. No. 45735-2: protection of ornamental trees and shrubs from damage by deer and beavers; protection of flowers from damage by deer; protection of seeds and bulbs from consumption or damage by representative types of tree squirrels (e.g., Sciurus spp.) and representative granivorous birds (e.g., house sparrows, house finches, horned larks, Icterid blackbirds, etc.); protection of garbage from disturbance by dogs, cats, Norway rats, house mice; and protection of poles, fences, outdoor furniture, etc. from dogs, Norway rats, house mice, and tree squirrels (Sciurus spp.). Any additional claims sought (e.g., protection of poles and siding from damage by woodpeckers) must be supported by adequate product performance data before they can be added to the label.
52 Registrants who choose to develop efficacy data to maintain their registrations are strongly advised to submit protocols for their proposed studies. These protocols should be submitted as soon as possible as the need to run new studies does not extend the "8-months" deadline for submitting or citing efficacy data. Applicable sections of the Guidelines and appropriate specialists within the Office of Pesticide Programs should be consulted in developing test protocols. For guidance in developing protocols for efficacy tests of vertebrate control agents, contact Dr. William W. Jacobs at 703-305-6406.

ATTACHMENT A

CHEMICAL STATUS SHEET

THYMOL: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing thymol.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of thymol. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this thymol Product Specific Data Call-In (Attachment G). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for thymol are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on thymol are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible thymol products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of thymol, please contact Kathleen Depukat at (703) 308-8587.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Frank Rubis at (703) 308-8184.

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

Frank Rubis
Planning and Reregistration Branch (H7508W)
Special Review and Reregistration Division
Office of Pesticide Programs
401 M Street, S.W.
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **THYMOL**

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A) PLUS INSTRUCTIONS

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 reregistration numbers of your source (s); 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 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.

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORMS (Form B) PLUS INSTRUCTIONS

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 guidelines 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 patters (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 Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement 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. I understand that this option is available on for acute toxicity or certain efficacy 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 my 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 require 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 upgrade (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 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) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant'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 require 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 chosen. I also understand that the deadline for submission of data as specified by the original data cal-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.

ATTACHMENT D

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

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING THYMOL FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient thymol, the Agency considered batching products. This process involves grouping similar products for purposes of 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.).

However, batching of products containing thymol was not possible after considering the available information described above. Table I lists all the end-use products containing thymol. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their products. 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 for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is cited, the registrant must clearly identify the material tested by its EPA registration number.

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 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). Since the end-use products containing thymol could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Containing Thymol

EPA REG. NO.	% of Thymol & Other Active Ingredients	Formulation Type
11715-211	1.300 0.065 Bitrex	aerosol
34810-18	13.00	liquid
34810-19	7.00 7.00 Ortho-phenyl phenol	liquid
34810-22	0.027 0.027 Ortho-phenyl phenol	liquid
45735-2	0.035 0.065 Benzyldiethyl [(2,6-Xylycarbomyl)methyl] ammonium saccharide	liquid

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	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 $\geq$ 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 any 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 following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes 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) controlled in 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 (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

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 $\geq$ 0.1%.

2.____ Degree of accountability or closure $\geq$ ca 98%.

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 nitrites; 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 analyzed ingredient.

7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.

8.____ Upper certified limit proposed for each impurity present at $\geq$ 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 (latter 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 their precision and accuracy.

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, granular, 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, 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 <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

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 method-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

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
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 an * are supplemental and may not be required for every study.

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
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.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
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 ($\pm 2°$), 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 category 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.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
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 daily observations.

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
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 hours 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 daily observations.

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
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.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

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

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

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	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)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

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

Please fill in blanks below.

Company Name	Company Number
Chemical Name	EPA Chemical Number

I Certify that:

1. For each study cited in support of 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 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 section 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 he active ingredient listed on this form (Cite-All Method or Cite-All option under the Selective Method). (Also sign the General Offer to Pay below.)

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

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of 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 reregistration of my products, to th extent required by FIFRA section 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	