



Reregistration Eligibility Decision (RED) ALIPHATIC ALCOHOLS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Frank Rubis at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Myers at (703) 308-8074.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

**SUMMARY OF INSTRUCTIONS FOR RESPONDING TO
THE REREGISTRATION ELIGIBILITY DECISION (RED)**

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified

limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements.** Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk (**RED-SRRD-PRB**)
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk (**RED-SRRD-PRB**)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

ALIPHATIC ALCOHOLS

LIST D

CASE 4003

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

TABLE OF CONTENTS

| | |
|--|-----------|
| ALIPHATIC ALCOHOLS REREGISTRATION ELIGIBILITY DECISION TEAM . . . | i |
| EXECUTIVE SUMMARY | v |
| I. INTRODUCTION | 1 |
| II. CASE OVERVIEW | 2 |
| A. Chemical Overview | 2 |
| B. Use Profile | 2 |
| C. Data Requirements | 11 |
| D. Regulatory History | 11 |
| III. SCIENCE ASSESSMENT | 13 |
| A. Physical Chemistry Assessment | 13 |
| B. Human Health Assessment | 14 |
| 1. Toxicology Assessment | 14 |
| a. Acute Toxicity | 14 |
| b. Subchronic Toxicity | 16 |
| c. Chronic toxicity | 17 |
| d. Carcinogenicity | 18 |
| e. Developmental/Reproductive Toxicity | 19 |
| f. Mutagenicity | 22 |
| g. Metabolism | 23 |
| h. Reference Dose | 23 |
| 2. Exposure Assessment | 24 |
| a. Dietary Exposure | 24 |
| b. Occupational and Residential | 24 |
| 3. Risk Assessment | 25 |
| a. Dietary | 25 |
| b. Occupational and Residential | 25 |
| C. Environmental Assessment | 25 |
| 1. Ecological Toxicity Data | 25 |
| a. Toxicity to Terrestrial Animals | 26 |
| b. Toxicity to Aquatic Animals | 26 |
| 2. Environmental Fate | 27 |
| a. Environmental Fate Chemistry | 27 |
| b. Environmental Fate Assessment | 27 |
| 3. Exposure and Risk Characterization | 27 |
| IV. RISK MANAGEMENT AND REREGISTRATION DECISION | 28 |
| A. Determination of Eligibility | 28 |

| | | |
|------|---|-----|
| B. | Determination of Eligibility | 28 |
| 1. | Eligibility Decision | 28 |
| 2. | Eligible and Ineligible Uses | 29 |
| C. | Regulatory Position | 29 |
| 1. | Labeling Rationale | 29 |
| | | |
| V. | ACTIONS REQUIRED BY REGISTRANTS | 30 |
| A. | Manufacturing-Use Products | 31 |
| 1. | Additional Generic Data Requirements | 31 |
| 2. | Labeling Requirements for Manufacturing-Use Products | 31 |
| B. | End-Use Products | 31 |
| 1. | Additional Product-Specific Data Requirements | 31 |
| 2. | Labeling Requirements for End-Use Products | 32 |
| C. | Existing Stocks | 32 |
| | | |
| VI. | APPENDICES | 35 |
| | APPENDIX A. Table of Use Patterns Subject to Reregistration | 37 |
| | APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision | 103 |
| | APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Aliphatic Alcohols | 113 |
| | APPENDIX D. List of Available Related Documents | 123 |
| | APPENDIX E. | 127 |
| | PR Notice 86-5 | 129 |
| | PR Notice 91-2 | 147 |
| | APPENDIX F. Product Specific Data Call-In | 153 |
| | Attachment 1. Chemical Status Sheet | 167 |
| | Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions | 169 |
| | Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions | 175 |
| | Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration | 179 |
| | Attachment 5. EPA Acceptance Criteria | 193 |
| | Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice | 207 |
| | Attachment 7. Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions | 209 |
| | APPENDIX G. FACT SHEET | 219 |

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GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|------------------|--|
| AE | Acid Equivalent |
| a.i. | Active Ingredient |
| ADI | Acceptable Daily Intake. A now defunct term for reference dose (RfD). |
| ARC | Anticipated Residue Contribution |
| CAS | Chemical Abstracts Service |
| CI | Cation |
| CNS | Central Nervous System |
| CSF | Confidential Statement of Formula |
| DFR | Dislodgeable Foliar Residue |
| DRES | Dietary Risk Evaluation System |
| DWEL | Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur. |
| 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 |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| GLC | Gas Liquid Chromatography |
| GM | Geometric Mean |
| GRAS | Generally Recognized as Safe as Designated by FDA |
| HA | Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur. |
| 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, air or feed, e.g., mg/L, mg/kg or ppm. |
| LD ₅₀ | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LD ₁₀ | Lethal Dose-low. Lowest Dose at which lethality occurs |
| LEL | Lowest Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOEL | Lowest Observed Effect Level |
| MATC | Maximum Acceptable Toxicant Concentration |
| MCLG | Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act. |
| µg/g | Micrograms Per Gram |
| mg/L | Milligrams Per Liter |
| MP | Manufacturing-Use Product |
| MPI | Maximum Permissible Intake |
| MOE | Margin of Exposure |
| NOEC | No effect concentration |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| N/A | Not Applicable |
| NPDES | National Pollutant Discharge Elimination System |
| NOEL | No Observed Effect Level |
| OP | Organophosphate |

GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|------------------|---|
| OPP | Office of Pesticide Programs |
| PADI | Provisional Acceptable Daily Intake |
| PAG | Pesticide Assessment Guideline |
| PAM | Pesticide Analytical Method |
| PHED | Pesticide Handler's Exposure Data |
| PPE | Personal Protective Equipment |
| ppb | Parts Per Billion |
| ppm | Parts Per Million |
| PRN | Pesticide Registration Notice |
| Q ₁ * | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RS | Registration Standard |
| SLN | Special Local Need (Registrations Under Section 24 (c) of FIFRA) |
| TC | Toxic Concentration. The concentration at which a substance produces a toxic effect. |
| TD | Toxic Dose. The dose at which a substance produces a toxic effect. |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TLC | Thin Layer Chromatography |
| TMRC | Theoretical Maximum Residue Contribution |
| torr | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions. |
| WP | Wettable Powder |
| WPS | Worker Protection Standard |

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal uses of aliphatic alcohols, ethanol and isopropanol, in the United States.

Aliphatic alcohols are used as components of a variety of commercial and household products including a sterilant, medical disinfectants, virucides, sanitizers, fungicides and plant regulators (ripeners). Ethanol is used with quaternary ammonium compounds for swimming pool water systems. Isopropanol is used in conjunction with quaternary ammonium compounds, phenolic compounds, glycols, methyl salicylate, and essential oils. It is also a component, in combination with one or more of the following active ingredients d-limonene, pyrethrins, piperonyl butoxide, d-cis trans phenothrin and oil of eucalyptus, for killing fleas and ticks, and other household insects. Both of these active ingredients are well known substances and have a wide range of human exposure uses. For example, ethanol is a constituent of some beverages for human consumption and isopropanol is the major ingredient in rubbing alcohol. The Agency has determined that ethanol and isopropanol as active ingredients in pesticide products will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration.

Before reregistering the products containing ethanol and isopropanol, the Agency is requiring that product specific data on acute toxicology, chemistry, and efficacy, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be 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 U.S. Environmental Protection Agency (referred to as "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 ethanol and isopropanol. The document consists of six sections. Section I is the introduction. Section II describes ethanol and isopropanol, 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 ethanol and isopropanol. Section V discusses the reregistration requirements for ethanol and isopropanol. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Ethanol
- **Chemical Name:** Ethyl Alcohol
- **Chemical Family:** Aliphatic Alcohol
- **CAS Registry Number:** 64-17-5
- **OPP Chemical Code:** 001501
- **Empirical Formula:** C₂H₅OH
- **Common Name:** Isopropanol
- **Chemical Name:** Isopropyl Alcohol
- **Chemical Family:** Aliphatic Alcohol
- **CAS Registry Number:** 67-63-0
- **OPP Chemical Code:** 047501
- **Empirical Formula:** C₃H₈O

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the registered uses of ethanol and isopropanol appears in Appendix A.

For ETHANOL:

Chemical Name: Ethyl Alcohol

Case Number: 4003

Chemical Code: 001501

CAS Reg Number: 64-17-5

Type of Pesticide:

Medical disinfectant, Virucide, Sanitizer, Algicide, Microbiocide/microbiostat (bacteria, fungi, and algae), Fungicide/fungistat, Fungicide (mold/mildew), Tuberculocide (with other chemicals, particularly phenols), Plant regulator, component of formaldehyde-based sterilant.

Use Sites:

Aquatic Non-Food Residential:

Domestic/Commercial Nonpotable Water (Waterbed Water)(whirlpools)

Indoor Food:

Citrus Fruits

Pear

Avocado

Banana

Papaya

Melons

Tomato

Grain/Cereal/Flour Bins - Empty

Grain/Cereal/Flour Elevators - Empty

*Poultry (Egg/Meat)

Egg Handling Equipment (Commercial)

Egg Handling Rooms (Commercial)

Egg Packing Plants (Commercial)

Household/Domestic Dwellings Indoor Food Handling Areas

Food Processing Plant Premises (Nonfood Contact)

Dairies/Cheese Processing Plant Premises (Nonfood Contact)

Feed Mills/ Feed Processing Plants

Meat Processing Plant Premises (Nonfood Contact)

Poultry Processing Plant Premises (Nonfood Contact)

Fish/Seafood Processing Plant Premises (Nonfood Contact)

Food Processing Plant Equipment (Food Contact)

Meat Processing Plant Equipment (Food Contact)

Poultry Processing Plant Equipment (Food Contact)

Eating Establishments Food Handling Areas (Food Contact)

Eating Establishments Food Serving Areas (Food Contact)

Eating Establishments Equipment/Utensils (Food Contact)

Food/Grocery/Marketing/Storage/Distribution Facility Premises

Food Dispensing Equipment/Vending Machines

Food Stores/Markets/Supermarkets Premises
Food Marketing/Storage/Distribution Equipment/Utensils (Food Contact)

Indoor Non-Food:

Tobacco/Cigar/Cigar Wrapping

*Goats (wool/angora animal)

*Mink

*Nutria

*Rabbits

*Fox

*Specialized Animals (zoo animals)

*Dogs (Show/Military/Special)

Animal Kennels/Sleeping Quarters (Commercial)

*Donkeys

*Horses (Show/Race/Special/Ponies)

*Mules (Work)

*Animals (Laboratory/Research)

*Cats (Laboratory/Research)

*Rodents, Wild (Captured for Sale)

*Sheep

Commercial Transportation Facilities-Nonfeed/Nonfood

Tobacco Processing Plant Premises/Equipment

Eating Establishments Food Handling Areas (Nonfood Contact)

Eating Establishments Food Serving Areas (Nonfood Contact)

Commercial/Institutional/Industrial Premises/Equipment (Indoor)

Commercial/Institutional/Industrial Floors

Leather/Leather Products

Textiles/Textile Fibers/Cordage

Felt/Furs/Feathers/Felt Products

Laundry (Drycleaning)

Dust Mops/Cloths/Tool Covers/Dusters (Laundry/Dryclean)

Laundry (Commercial)

Diapers (Commercial Laundry)

Carpets (Commercial Sanitizer)

Laundry Equipment

Refuse/Solid Waste Transportation Facilities/Handling Equipment

Museum Collections (Preserved Animal/Plant Specimens)

Upholstery (Hospital/Commercial)

Indoor Medical:

Household Sickrooms Premises/Contents/Utensils

Hospitals/Medical Institutions Premises (Human/Veterinary)

Ambulances

Hospitals/Medical Institutions Critical Premises (Burn Wards)

Hospitals/Medical Institutions Patient Premises
Hospitals/Medical Institutions Noncritical Premises
Hospital Critical Items (Surgical Instruments/Pacemakers)
Hospital Noncritical Items (Bedpans/Furniture)
Hospitals/Medical Institutions Nonconductive Floors
Barber/Beauty Shop Instruments (Shavers/Scissors)
Barber/Beauty Shop Equipment (Barber Chair/Cabinets)
Morgues/Mortuaries/Autopsy/Embalming Room Premises
Morgues/Mortuaries/Autopsy/Embalming Equipment
Morgues/Mortuaries/Autopsy/Embalming Instruments
Upholstery (Hospital/Commercial)
Carpets (Hospital Sanitizer)
Biological Specimens (Organs/Tissues/Milk Samples)
Cupidors/Spittoons
Air Treatments (Hospital)

Indoor Residential:

*Cats (Adults/Kittens)
*Dogs/Canines (Adults/Puppies)
*Monkeys
*Birds
Pet Living/Sleeping Quarters
*Rodents (Guinea pigs/Hamsters/Gerbils/Mice/Rats)
*Rabbits
Fish (Aquaria)
*Amphibians
*Reptiles
Household/Domestic Dwellings Indoor Premises
Household/Domestic Dwellings Contents
Human Clothing (Insect and Mold/Mildew Control)
Human Face Gear
Human Footwear
Human Headgear
Human Dentures/Toothbrushes/Mouthpieces
Human Camping Equipment
Human Grooming Instruments (Brushes, Combs)
Laundry (Household/Coin-Operated)
Diapers (Household/Coin-Operated Laundry)
Carpets (Household Sanitizer)
Toilet Bowls (Interior Surfaces)
Toilet Tanks/Water Closets Water
Urinals (Interior Surfaces)
Bathroom Premises/Hard Surfaces
Portable/Chemical Toilets/Latrine Buckets

Vehicular Holding Tanks
Diaper Pails (Empty)
Refuse/Solid Waste Containers (Garbage Cans)
Refuse/Solid Waste Transportation Facilities/Handling Equipment
Household Trash Compactor/Food Disposals
Incinerators
Air Treatments (Commercial/Household)

Terrestrial Non-Food Crop:
Refuse/solid Waste Sites (Outdoor)

*Premises of specified animal is the specific site on the label.

Target Pests:

Bacteria:

Odor-causing bacteria, Airborne bacteria, *Staphylococcus aureus*, *Staphylococcus aureus* (penicillin resistant methicillin & gentamicin), *Pseudomonas aeruginosa*, *Pseudomonas cepacia*, *Pseudomonas putida*, *Mycobacterium tuberculosis*, *Mycobacterium tuberculosis var. bovis*, *Mycobacterium smegmatis*, *Salmonella choleraesuis*, *Salmonella schottmuelleri* (paratyphoid B), *Salmonella enteritidis*, *Salmonella typhosa*, *Salmonella paratyphi*, *Escherichia coli*, *Shigella paradysenteriae*, *Shigella dysenteriae*, *Shigella flexneri*, *Streptococcus pyogenes*, *Streptococcus hemolyticus*, *Streptococcus salivarius*, *Streptococcus faecalis*, *Proteus mirabilis*, *Proteus vulgaris*, *Neisseria gonorrhoeae*, *Neisseria elongata*, *Enterobacter aerogenes*, *Klebsiella pneumoniae*, *Corynebacterium diphtheriae*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Serratia marcescens*, *Acinetobacter calcoaceticus*, *Chlamydia psittaci*

Fungi:

Mold and mildew, *Penicillium glaucus*, *Aspergillus niger*, *Trichophyton mentagrophytes*, *Candida albicans*

Viruses:

Influenza A2/Hong Kong (myxovirus) and Japan 305/57, Influenza B (Hong Kong 5/72), Herpes Simplex Types 1 and 2, Adenovirus Types 2 and 5, Vaccinia (poxvirus), Infectious Canine Hepatitis Virus, HIV-1 Virus, Canine Distemper, Canine Parvovirus ATCC VR-2006, Poliovirus Type 1 (Mahoney Strain), Rhinovirus Type 39, Respiratory Syncytial Virus, Echovirus Type 12, Rotavirus (Wa), Poliovirus Type 1, Hepatitis A Virus, Parainfluenza Type 2, Cytomegalovirus, Influenza Type B, Adeno Type 2, Coxsackie B3, Polio Type 2, Rhino Type 16, Parainfluenza Type 3, Influenza A/J305, Parainfluenza 1 (Sendai), Influenza A2 (Aichi)

Formulation Types Registered:

Type: End use, Manufacturing use.

Form: Pressurized liquid, Ready to use liquid, Soluble concentrate/liquid.

Methods and Rates of Application:

Types of Treatment:

Antimicrobials:

Spray, Surface treatment, Premise treatment, Water related surface treatment, Transportation vehicle treatment, Immersion, Aerosol application.

Plant regulator:

Stored commodity fumigation as ripening agent (citrus fruits, pear, avocado, banana, papaya, melons, tomato, flue-cured tobacco/cigar/cigar wrapping).

Equipment:

Antimicrobials:

Aerosol can, Sprayer, Pump spray bottle, Automatic aerosol dispenser, Hand held sprayer.

Plant regulator:

Catalytic generator of ethylene gas (citrus fruits, pear, avocado, banana, papaya, melons, tomato, tobacco/cigar/cigar wrapping).

Timing:

Antimicrobials:

Not specified.

Plant regulator:

Postharvest (citrus fruits, pear, avocado, banana, papaya, melons, tomato, tobacco/cigar/cigar wrapping).

Rate of Application:

Antimicrobials:

For all surfaces (including food contact surfaces and upholstery), air treatments, and water-related surface treatment: From 169200 to 820000 ppm active ingredient.

Plant regulator (ethanol is converted to ethylene by dehydration in an ethylene generator):

Produce ripening---one quart product used in a 4000 to 8000 cubic feet ripening room produces 20-1200 ppm ethylene over a period of 16 hours.

Tobacco---use 2 quarts product in 1500-2500 cubic foot curing barn for 12 hours, immediately after filling barn. Use an additional 2 quarts as required. [Label did not state ethylene ppm to be expected.]

Use Practices Limitations:

Do not use on polished wood furniture or on rayon fabrics. Do not get product on foods/drinks/feeds or surfaces that they may contact; protect polished wood furniture, rayon fabrics, foods/drinks/feeds or surfaces during treatment by removing or covering them. Any contaminated food/drink/feed contact surfaces should be washed with a suitable cleaning product and rinsed with potable (drinking) water before using. Treat food/drink/feed processing areas only when the facility is not in operation.

For ISOPROPANOL

Chemical Name: Isopropyl Alcohol

Case Number: 4003

Chemical Code: 047501

CAS Reg Number: 67-63-0

Type of Pesticide:

Disinfectant, Bacteriostat, Sanitizer, Microbiocide/microbiostat (bacteria and algae), Fungicide, Fungicide/fungistat, Virucide, Tuberculocide, component of insecticides, acaricides, and a repellent in combination with one or more of the following active ingredients: d-limonene, pyrethrins, piperonyl butoxide, d-cis trans phenothrin and oil of eucalyptus.

Use Sites:

Aquatic Non-Food Industrial:

Commercial/Industrial Water Cooling Systems

Outdoor Residential:

Pet Living/Sleeping Quarters

Indoor Food:

Eating Establishments Food Handling Areas (Food Contact)

Dairies/Cheese Processing Plant Equipment (Food Contact)

Dairies/Cheese Processing Plant Premises (Nonfood Contact)
Eating Establishments Equipment/Utensils (Food Contact)
Eating Establishments Food Serving Areas (Food Contact)
Food Marketing/Storage/Distribution Equipment/Utensils (Food Contact)
Food Processing Plant Equipment (Food Contact)
Food Processing Plant Premises (Nonfood Contact)
Household/Domestic Dwellings Indoor Food Handling Areas

Indoor Non-Food:

Commercial Transportation Facilities-Nonfeed/Nonfood
Commercial/Institutional/Industrial Premises/Equipment (Indoor)
Commercial/Institutional/Industrial Floors
Laundry Equipment
Animal Kennels/Sleeping Quarters (Commercial)**
Eating Establishments Food Handling Areas (Nonfood Contact)
Eating Establishments Food Serving Areas (Nonfood Contact)
Eating Establishments Non-Food Areas (Nonfood Contact)

Indoor Medical:

Household Sickrooms Premises/Contents/Utensils:
Hospital/Medical Institutions Premises (Human/Veterinary)
Hospital Critical Items (Surgical Instruments/Pacemakers)
Hospital Semicritical Items (Catheters/Inhalation Equipment)
Hospital Noncritical Items (Bedpans/Furniture)
Hospital/Medical Institutions Non-Conductive Floors
Air treatments (Hospital)
Barber/Beauty Shop Instruments (Shavers/Scissors)
Hospital/Medical Institutions Critical Premises (Burn Wards)
Hospital/Medical Institutions Noncritical Premises
Hospital/Medical Institutions Patient Premises

Indoor Residential:

Cats (Adults/Kittens)*
Dogs/Canines (Adults/Puppies)*
Pet Living/Sleeping Quarters**
Household/Domestic Dwellings Indoor Premises**
Household/Domestic Dwellings Contents
Residential Floors
Human Bedding/Mattresses
Human Footwear
Toilet Bowls (Interior Surfaces)
Urinals (Interior Surfaces)
Bathroom Premises/Hard Surfaces
Diaper Pails (Empty)

Refuse/Solid Waste Containers (Garbage Cans)
Air treatments (Commercial/Household)
Human Headgear

*Isopropanol is only a component of an insecticide/acaricide/repellent at this site.

*Isopropanol has antimicrobial activity as well as being a component of insecticide/acaricide/repellent products at this site.

Pests:

Salmonella choleraesuis, Salmonella schottmuelleri, Salmonella typhosa, Staphylococcus aureus, Pseudomonas aeruginosa, Trichophyton mentagrophytes (Trichophyton interdigitale), Streptococcus spp., Escherichia coli, Klebsiella pneumoniae, Shigella flexneri, Proteus vulgaris, Enterobacter aerogenes, Mycobacterium tuberculosis, Candida albicans, Aspergillus niger, Mycobacteria, Odor-causing bacteria, Slime-forming bacteria and fungi, Mold and mildew, Herpes Simplex I Virus, Herpes Simplex II Virus, Influenza A₁ Virus (Hong Kong), Influenza A₂ Virus, Vaccinia Virus, HIV-1 (AIDS Virus), component of insecticide/acaricide/repellent which act against ticks, fleas, roaches, bedbugs, ants, silverfish, lice, sowbugs, centipedes, firebrats, and mites.

Formulation Types Registered:

Type: End use, Manufacturing use.

Form: Ready to use liquid, Pressurized liquid, Impregnated material, Soluble concentrate/liquid.

Methods and Rates of Application:

Types of Treatment:

Spray, Mop, Sponge-on, Wipe-on, Surface treatment, Pour-on, Aerosol application, Animal treatment (spray), Animal bedding/litter treatment, Enclosed premise treatment, Indoor premise treatment, Wipe-on/wiper treatment, Immersion, Water treatment (recirculating system).

Equipment:

Aerosol can, Pump spray bottle, Sprayer, Mop, Sponge, Mist sprayer, Cloth, Swab, Atomizing type sprayer, Not specified.

Timing:

Not specified.

Rate of Application:

Generally, for disinfection of hard and porous surfaces 242370 to 757100 ppm active ingredient for ready to use and pressurized liquid products, and 2713 to 10606 ppm active ingredient for the liquid/soluble concentrate product. For sanitizing air - 385000 to 600000 ppm active ingredient. For water cooling systems, 8.4 to 13 ppm active ingredient (intermittent slug initial) and 2.8 to 4.2 ppm active ingredient (intermittent slug subsequent).

Use Practices Limitations:

Not recommended for use on aluminum. Do not pour used solution back into the stock bottle. Do not use on polished wood furniture or rayon fabrics. Avoid spraying lacquered or shellacked surfaces.

C. Data Requirements

The data required to support the uses of ethanol and isopropanol are identified in Appendix B. This includes all data requirements identified by the Agency for currently registered uses.

D. Regulatory History

Ethanol and isopropanol were registered in the United States as early as 1948 as active ingredients in indoor disinfectants. Currently, 73 ethanol and 67 isopropanol products are registered for use as hard surface treatment disinfectants, sanitizers and mildewcides. Ethanol products are also registered for use as a plant regulator (ripeners). There have not been any Data Call-Ins issued for these chemicals.

Ethanol and isopropanol can be considered to function as inert ingredients (40 CFR 153.139(a)). This determination is made on a case-by-case basis involving the following four parameters. First, ethanol and isopropanol when present in multiple active products (except products formulated with quaternary ammonium compounds) at percentages lower than 30% are not considered to be active ingredients, but rather inert. Second, ethanol and isopropanol when present in quaternary ammonium compound products at percentages greater than 5% are considered to be active ingredients. Third, ethanol and isopropanol when present in quaternary ammonium compound products at percentages less than 5% are considered to be inert ingredients. Fourth, all products which list only ethanol or isopropanol as active ingredients in the ingredient statement, regardless of percentage, are considered to be active ingredients and not inerts.

Historically, certain products containing ethanol or isopropanol, and certain other liquid chemical germicides have been regulated both as pesticides under the Federal Insecticide, Fungicide 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), and amended on June 20, 1994. The MOU has been mailed to registrants as an attachment to Pesticide Regulation (PR) Notice 94-4, signed on June 30, 1994. 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 of 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 that 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, and describes how each Agency will have primary jurisdiction over one of the two categories. All products that 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 that 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.

PR Notice 94-4 discusses the MOU in greater detail. The PR Notice contains specific labeling statements that are also included in Part V of this RED.

The other three chemicals in the aliphatic alcohols case, methanol, propyl alcohol, and tert-butyl alcohol are not being supported in reregistration. Products containing these chemicals have been either voluntarily cancelled or the registrants have been permitted to declare these alcohols as inert ingredients in formulations.

These unsupported chemicals, when or if someone decides to support any one of them, will be required to go through the registration process as new chemicals.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical/chemical characteristics of ethanol and isopropanol are described below:

| | |
|---------------------|---|
| <u>Ethanol:</u> | |
| Chemical Structure: | $\begin{array}{c} \text{H} \quad \text{H} \\ \quad \\ \text{H} - \text{C} - \text{C} - \text{H} \\ \quad \\ \text{H} \quad \text{OH} \end{array}$ |
| Molecular Weight | 46.1 g/mole |
| Color | Clear colorless |
| Physical State | Liquid |
| Odor | Characteristic, alcoholic odor |
| Boiling point | 78.5 °C |
| Specific gravity | 0.789 at 20 °C |
| Solubility | miscible in water |
| Vapor pressure | 43.9 mm Hg at 20 °C |
| Stability | Stable |

| | |
|---------------------|--|
| <u>Isopropanol:</u> | |
| Chemical Structure | $\begin{array}{c} \text{H} \quad \text{H} \quad \text{H} \\ \quad \quad \\ \text{H} - \text{C} - \text{C} - \text{C} - \text{H} \\ \quad \quad \\ \text{H} \quad \text{OH} \quad \text{H} \end{array}$ |
| Molecular Weight | 60.1 g/mole |
| Color | Clear colorless |
| Physical State | Liquid |
| Odor | Characteristic, alcoholic odor |
| Boiling point | 82.5 °C |
| Specific gravity | 0.785 at 20 °C |
| Solubility | miscible in water |
| Vapor pressure | 96 mm Hg at 20 °C |
| Stability | Stable |

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for the aliphatic alcohols, ethanol and isopropanol, is adequate and will support reregistration eligibility.

a. Acute Toxicity

Ethanol

Acute toxicity studies for ethanol are summarized in Table 1. No dermal sensitization studies were available.

Table 1

| STUDY | RESULT | CATEGORY |
|--|---|----------|
| Acute oral Rat ^a Mouse ^a | LD ₅₀ : 7060 mg/kg 7500 mg/kg | IV IV |
| Acute inhalation Rat ^a Mouse ^a | LC ₅₀ : 38 mg/L (10 hr) 39 mg/L (4 hr) | IV IV |
| Primary eye irritation - Rabbit ^b | Mild iritis, chemosis, redness | IV |
| Primary dermal irritation - Rabbit ^b | Nonirritating | IV |

^a Sax and Lewis (1989a)

^b Guess (1970)

In an acute neurotoxicity study, (Broxup *et al.*, 1989) male Sprague-Dawley rats were orally gavaged once with ethanol at 0, 0.2, 1, or 5 ml/kg (0, 0.16, 0.79, or 3.95 mg/kg). During the FOB (Functional Observational Battery), decreased incidence of rearing, flaccid body tone, and reduced extensor thrust, toe pinch and tail pinch reflexes were observed. At 5 mg/kg, motor activity was significantly decreased.

Isopropanol

Acute toxicity studies for isopropanol are summarized in Table 2. No dermal sensitization studies were available.

Table 2

| STUDY | RESULT | CATEGORY |
|---|--|----------------|
| Acute oral Rat ^a Mouse ^b | LD ₅₀ : 4384 mg/kg 3600 mg/kg | III III |
| Acute dermal ^c | LD ₅₀ : 16.37 mg/kg | IV |
| Acute inhalation Rat ^d ♂ ♀ Rat ^e | LC ₅₀ : 46.7 mg/L (8 hr) 55.3 mg/L (8 hr) 68.5 mg/L (4 hr) | IV IV IV |
| Primary eye irritation - Rabbit ^{f,g} | Slight/Moderate | III, IV |
| Primary dermal irritation - Rabbit ^h | Nonirritating | IV |

^a Ivett (1991a)^b Sax and Lewis (1989b)^c Union Carbide Corp. (1967)^d Laham *et al.* (1980)^e BASF (1989)^f Griffith *et al.* (1980)^g Kennah *et al.* (1989)^h Nixon *et al.* (1975)

In an acute neurotoxicity study (Gill and Hurley, 1991), Fischer 344 rats were exposed for six hours in a whole body chamber to air only (control) or to isopropanol vapors at concentrations of 500, 1500, 5000, or 10000 ppm. Motor activity and Functional Observational Battery (FOB) were evaluated. No deaths occurred during the study. Motor activity was decreased in a dose-dependent manner in 1500, 5000 and 10000 ppm males and in 5000 and 10000 ppm females, with severe effects at 10000 ppm. FOB findings included narcosis at 10000 ppm and central nervous system sedation at 5000 ppm. FOB findings at 10000 ppm included prostration, decreased arousal and muscle tone, hypothermia, abnormal respiration and loss of righting reflex. At 24 hours, hind leg splay and hypothermia were still observed, otherwise recovery was essentially complete. Based on the results of this study, the NOEL for neurobehavioral effects was at 500 ppm in males and 1500 ppm in females. The LOEL was 1500 ppm in males (decreased motor activity) and 5000 ppm in females (decreased motor activity and FOB changes).

b. Subchronic Toxicity

Ethanol

In a 12-week oral study, male Sprague-Dawley rats were given drinking water containing 3.26 M ethanol (Kager *et al.*, 1974). During the course of the study, the animals consumed an average of 10.2 g of alcohol/kg/day. Compared to controls, treated animals showed decreased mean body weights. A high degree of fatty degeneration occurred in the livers of 10/12 treated animals. Other than the fatty changes in the liver, no other gross or histopathological changes were observed.

In a 21-day dermal study (Phillips *et al.*, 1972), human volunteers were continuously exposed to ethanol-saturated patches under an occlusive dressing. No dermal irritation was noted through day 14, very slight edema and erythema was noted from days 15 to 18, and well defined edema and erythema was noted from days 19 to 21.

In a 90-day aerosol inhalation study, several species of animals (rats, guinea pigs, rabbits, monkeys and dogs) were exposed continuously to ethanol vapors at 86 mg/m³ (Coon *et al.*, 1970). No deaths or clinical signs of toxicity were observed during the study; all hematology results were within normal limits. Histopathology findings were negative also.

Isopropanol

In a subchronic inhalation study (Burleigh-Flayer *et al.* 1991, 1994), rats and mice were exposed to isopropanol vapors at concentrations of 0 (air only), 100, 500, 1500, or 5000 ppm for 6 hr/day, 5 days/week, for 13 weeks. No treatment-related deaths occurred. During the actual exposure, clinical signs in some 1500 and 5000 ppm rats and mice included ataxia, narcosis, and hypoactivity, and lack of startle response was also present in 5000 ppm animals. Following exposure at 500 or 1500 ppm, some rats showed perinasal encrustations. At 5000 ppm, there were also periocular swelling, ataxia and paresis. Following exposure at 5000 ppm, some mice showed hypoactivity and ataxia. After an initial decrease in mean body weight during Week 1, increases in body weight were observed at some dose levels in rats and female mice. At 5000 ppm, increased absolute liver weights were observed in male and female rats and female mice. However, no histopathological changes were present, suggesting an adaptive rather than toxic effect. Hyaline droplets were present in the

kidneys of all male rats, and the severity of the lesion generally increased with increasing dose. In a nine-day range-finding inhalation exposure study in rats, hyaline droplet nephropathy was also observed in male rats in the 1000 and 5000 ppm groups (Burleigh-Flayer *et al.*, 1990). Subsequent immunohistochemical evaluation of the kidneys did not reveal any differences in the distribution of alpha_{2u}-globulin, suggesting that the accumulation of this protein is not associated with hyaline droplet formation (Fowler and Martin, 1994). Based on these results, the systemic NOEL was 500 ppm in rats and mice, and the systemic LOEL was 1500 ppm in rats and mice.

In a subchronic inhalation neurotoxicity study (Burleigh-Flayer *et al.*, 1991, 1994), rats were exposed to isopropanol vapors at concentrations of 0 (air only), 100, 500, 1500, or 5000 ppm for 6 hr/day, 5 days/week for 13 weeks. FOB, motor activity, and neuropathology were evaluated. No treatment-related changes were noted in the FOB or neuropathological evaluations. Motor activity was increased in 5000 ppm female rats at 9 and 13 weeks, and full recovery did not occur until 42 days post-treatment. In a subsequent inhalation study (Burleigh-Flayer and Hurley, 1994), increased motor activity was also observed in female rats exposed to 5000 ppm isopropanol for 13 weeks.

c. Chronic toxicity

Ethanol

In a chronic oral study (Boughton, 1944), male albino rats were treated with 5% ethanol (2.1 ml/kg/day) in drinking water for 304 days. No treatment related mortalities occurred during the study. Decreased mean body weights were evident throughout the study. At Week 36, the mean body weight of ethanol-treated animals was decreased by 30%, compared to controls. Ethanol-treated animals showed decreased activity and impaired maze learning ability.

In a chronic dermal toxicity study (Boughton, 1944), a 50% aqueous solution of ethanol was applied to the facial area of male albino rats for 187 days. No treatment-related effects were noted.

Isopropanol

In a chronic feeding study (Boughton, 1944), male albino rats were treated with 5% isopropanol (1.87 ml/kg/day, 1470 mg/kg/day) in drinking water for 304 days. No treatment-related mortalities occurred

during the study. Decreased mean body weights were evident throughout the study. At Week 36, the mean body weight of isopropanol-treated animals was 29% lower than control animals. Isopropanol-fed animals showed decreased activity and impaired maze learning ability.

In a chronic dermal toxicity study (Boughton, 1944), a 50% aqueous solution of isopropanol was applied to the facial area of male albino rats for 187 days. No treatment-related effects were noted.

d. Carcinogenicity

Ethanol

A 1982 review of the toxicity of ethanol did not reference any studies pertaining to the carcinogenic potential of ethanol (Clayton and Clayton, 1982). A literature search conducted in March 1994 of the Registry of Toxic Effects of Chemical Substances indicated that ethanol was an equivocal tumorigenic agent. An International Agency of Research in Cancer review, conducted in 1988, concluded that the animal data were inadequate to evaluate carcinogenic risk in man. The Agency review of the literature indicates that carcinogenic effects are not expected from the uses of ethanol.

Isopropanol

In a carcinogenicity study, rats were exposed to isopropanol vapors at concentrations of 0 (filtered air), 500, 2500, or 5000 ppm for 6 hr/day, 5 days/week for 105 weeks (Burleigh-Flayer and Benson, 1994). Treatment-related gross pathological changes consisted of an increased incidence of granular kidneys of mid- and high-dose males at the interim sacrifice and mid-dose males at terminal sacrifice; no treatment-related gross lesions were noted in female rats. Male rats, which died or were sacrificed *in extremis* during the study, had increased incidences of thickened stomachs, granular kidneys and color change of the kidneys at 2500 and 5000 ppm. Female rats had increased incidences of thickened stomachs at 5000 ppm and granular kidneys at 2500 and 5000 ppm. Histopathological examinations revealed an increased incidence of nonneoplastic kidney lesions (mineralization, tubular dilation, glomerulosclerosis, interstitial nephritis, interstitial fibrosis, hydronephrosis and transitional cell hyperplasia) of 2500 and 5000 ppm males and females. A secondary effect of the renal lesions was an increased incidence of mineralization observed in other tissues. Neoplastic lesions consisted of interstitial cell adenomas, which were

present at frequencies of 64.9, 77.3, 86.7 and 94.7% for the 0, 500, 2500 and 5000 ppm groups, respectively. This lesion was attributed to marked hyperplasia rather than autonomous growth. Based on the results of this study, the NOEL for systemic toxicity was 500 ppm in males and females, and the LOEL for systemic toxicity was 2500 ppm in males and females. Evidence of carcinogenicity was not found.

In a second carcinogenicity study, mice were exposed to isopropanol vapors at concentrations of 0 (filtered air), 500, 2500, or 5000 ppm for 6 hr/day, 5 days/week for 78 weeks (Burleigh-Flayer and Wagner, 1993). Gross examination revealed increased incidence of abnormal stomach contents in all treated mice at the interim sacrifice. At terminal sacrifice an increased incidence of seminal vesicle enlargement was noted in 5000 ppm males. This lesion was also noted in 2500 and 5000 ppm males that died or were sacrificed *in extremis* during the study. Histopathological examination revealed dilation of the seminal vesicles of 2500 and 5000 ppm males, and 5000 ppm females showed increased incidence of renal tubular dilation. All treated mice also showed an increased incidence of renal tubular proteinaceous material. Other nonneoplastic lesions included mucosal cell hyperplasia within the glandular portion of the stomach, congestion of the adrenal gland and extramedullary hematopoiesis and hemosiderosis of the spleen. The study indicated that none of these findings are of biological significance. There were no increases in the frequencies of neoplastic lesions. Based on the results of this study, the NOEL for systemic toxicity was 500 ppm in males and females.

e. Developmental/Reproductive Toxicity

Ethanol

Ethanol is generally recognized as a human developmental neurotoxicant (Rees *et al.* 1990). Jones and Smith (1973) and Jones *et al.* (1973) initially described Fetal Alcohol Syndrome, that results from the effects of chronic maternal alcohol consumption on the fetus. The effects of this syndrome include altered prenatal growth and morphogenesis, characterized, in part, by severe growth retardation, mental retardation and microencephaly. Meyer and Riley (1986) extensively reviewed the behavioral teratology of alcohol and describe transient delays in development, such as age-dependent deficits in activity, delays in maturational indices (eye opening, incisor eruption), increased open field activity, and learning deficits. The effects listed here are generally associated with high (grams/day, oral) maternal consumption of ethanol. Given that OSHA has established the threshold

limit value at 1000 ppm (10 hour, time weighted average), the human risk to ethanol exposure in an industrial environment appear to be minimal.

Isopropanol

Rats were orally gavaged with aqueous solutions of isopropanol, at dosages of 0, 400, 800 or 1200 mg/kg/day, on days 6 through 15 of gestation (Tyl *et al.*, 1990a). Maternal toxicity consisted of two (8%) deaths at 1200 mg/kg and one (4%) death at 800 mg/kg. At 800 and 1200 mg/kg, fetal body weights were significantly reduced. Based on the results of this study the NOEL for systemic maternal toxicity was 400 mg/kg/day. The NOEL for developmental toxicity was 400 mg/kg/day.

In another developmental toxicity study, New Zealand White rabbits were orally gavaged with isopropanol, at dosages of 0, 120, 240 or 480 mg/kg/day, on days 6-18 of gestation (Tyl *et al.*, 1990b). Maternal toxicity consisted of increased mortality (4/15, 26.7%) at 480 mg/kg/day, significantly decreased mean body weights during dosing, and decreased corrected maternal body weight change. No other treatment-related differences were noted. Based on the results of this study, the NOEL was 240 mg/kg/day for systemic maternal toxicity and 480 mg/kg/day for developmental toxicity. The LOEL was 480 mg/kg/day for systemic toxicity, and greater than 480 mg/kg/day for developmental toxicity.

In an inhalation developmental toxicity study, Sprague-Dawley rats were exposed to high vapor concentrations of isopropanol (0, 3500, 7000, or 10000 ppm) 7 hr/day on gestation days 1-19 (Nelson *et al.*, 1988). At 10000 ppm, the mean number of implants/dam and the number of live implants/litter were significantly reduced, and there was a significant increase in the number of resorptions/litter. At all treatment levels, the mean fetal body weights were significantly reduced. The incidence of total fetal (but not litter) skeletal malformations was increased at 7000 and 10000 ppm. Based on the results of the study, a NOEL for developmental toxicity was not obtained, since the lowest dose (3500 ppm) produced slight decreases in the mean fetal body weights.

In a developmental neurotoxicity study, timed-pregnant Sprague-Dawley rats were orally gavaged with isopropanol at dosages of 0, 200, 700 or 1200 mg/kg/day from day 6 of gestation through postpartum day 21 (RTI, 1991). For maternal animals, one high-dose animal died.

There were no other clinical signs of toxicity present. Maternal body weight and food consumption were not altered by treatment. No treatment-related differences in the litter indices or sexual maturation were observed. Behavioral tests did not reveal any differences that could be attributed to treatment. At necropsy, maternal and pup organ weights and incidence of pup histological findings were comparable between control and treatment groups. Based on these findings, the NOEL for developmental neurotoxicity in rats was established at greater than 1200 mg/kg/day.

In a two-generation reproduction study, rats were treated by oral gavage with aqueous solutions of isopropanol at 0, 100, 500 or 1000 mg/kg/day (Exxon, 1992). For parental animals, no treatment-related differences were noted in the incidence of clinical signs, mortality, body weights or food consumption. High-dose, and to a lesser extent mid-dose, parental animals showed increases in the absolute and/or relative liver and/or kidney weights. No treatment-related histopathological lesions were noted in parental females, and treated P₁ and P₂ males had increased incidence of hyaline droplet nephropathy. During the first two days postpartum, F₁ offspring showed increased mortality compared to controls, however, no clinical signs of toxicity were present. Gross pathological examination on postnatal day 21 did not reveal any biologically meaningful differences between control and treated offspring from either generation. Based on the results of this study, the NOEL for systemic toxicity was 500 mg/kg/day, and no reproductive toxicity was noted at the highest dose tested (1000 mg/kg/day).

f. Mutagenicity

Ethanol

A summary of mutagenicity study results for ethanol is presented in Table 3.

Table 3

| MUTAGENICITY TEST ^a | RESULT |
|--|----------|
| Rodent dominant lethal | Positive |
| Aspergillus-forward mutation; sister chromatid exchange-clonal assay | Negative |
| Cell transformation-RLV F344 rat embryo | Negative |
| <i>In vitro</i> cytogenetics- nonhuman; mammalian micronucleus | Negative |
| <i>N. crassa</i> -aneuploidy; histidine reversion (Ames Test) | Negative |
| <i>In vitro</i> sister chromatid exchange-human lymphocytes | Negative |
| <i>In vitro</i> sister chromatid exchange-nonhuman; sperm morphology-mouse | Negative |

From USEPA Genetox Program 1988.

Isopropanol

A summary of mutagenicity study results for isopropanol is presented in Table 4.

Table 4

| MUTAGENICITY TEST | RESULT |
|---|----------|
| Cell transformation-SA7/SHE; <i>N. crassa</i> aneuploidy ^a | Negative |
| <i>In vitro</i> mouse micronucleus test ^b | Negative |
| CHO/HGPRT forward gene mutation assay ^c | Negative |

^a From USEPA Genetox Program 1988.

^c Young (1990)

^b Ivett (1991b)

g. Metabolism

Ethanol

The metabolism of ethanol has been well described in the literature. The first step, oxidation to acetaldehyde, may involve various enzymes that act as mediators during alcohol metabolism. Alcohol dehydrogenase is a soluble enzyme found in high concentrations in the liver that appear to play the major role in alcohol metabolism. NAD is the coenzyme, and the products are NADH and acetaldehyde. A second enzyme capable of converting ethanol to acetaldehyde is catalase which uses hydrogen peroxide to perform the oxidation. Since there is very little peroxide available to support this reaction, it accounts for no more than 10 percent of ethanol metabolism. A third enzyme is the NADPH-dependent microsomal ethanol oxidizing system, that with oxygen as a cosubstrate results in the oxidation of ethanol to acetaldehyde. Acetaldehyde is further metabolized to acetate via a NAD-dependent reaction with acetaldehyde dehydrogenase.

Isopropanol

The absorption, metabolism, tissue distribution, and excretion of [¹⁴C]-isopropanol were studied in rats and mice (Slauter *et al.*, 1994). Animals were treated either intravenously or by inhalation. Rats were also orally gavaged. In both rats and mice, no marked differences were noted between sexes or route of administration. Total cumulative excretion ranged from 78 to 97%, with exhaled volatile organic compounds (unmetabolized isopropanol and acetone) and CO₂ accounting for most of the radioactivity. Small amounts of radioactivity were found in the urine (3 - 8%) and feces (0.5 - 1.5%). Urinary metabolites consisted of unmetabolized isopropanol, acetone and a metabolite tentatively identified as the isopropyl glucuronic acid.

From pharmacokinetic analysis, the elimination half-life was 0.6 to 2 hr. At the high oral dose (3000 mg/kg) the half-lives ranged from 4.0 to 6.8 hr in females and males, respectively.

h. Reference Dose

There are registered food uses for ethanol and isopropanol as a plant regulator (ripeners). However, dietary exposure is not expected from the use patterns of ethanol and isopropanol. Therefore, Reference Doses (RfD) were not established for the active ingredients.

2. Exposure Assessment

Aliphatic alcohols are used as components of a variety of commercial and household products including a sterilant, medical disinfectants, virucides, sanitizers, fungicides, and plant regulators. Application sites include: indoor food, indoor nonfood, indoor residential, and indoor medical sites (such as surfaces, equipment and utensils in medical facilities, eating and food-handling/processing establishments, veterinary institutions and kennels, and crack and crevice treatment of home/commercial institutions or transportation facilities). Isopropanol is a component used in combination with known insecticidal/acaricidal or repellent activity, of products used as insecticides/acaricides/repellent on cats and dogs and in and around kennels and non-food areas of homes.

Concentrations of the active ingredients range from approximately 5% to 92% in the various formulations. Antimicrobial application methods include surface wipes, spray, mop, sponge-on, wipe-on, pour-on, immersion, aerosol, and closed system uses for commercial/industrial water cooling systems. Application equipment includes surface swipes, pump spray bottle, aerosol sprays, power and hand-held sprayers.

The uses of aliphatic alcohols may result in high dermal and inhalation exposures; however, the risk from exposures to these active ingredients is considered to be incidental when compared to the frequent intentional human exposures. Therefore, an occupational/residential exposure risk assessment is not required.

a. Dietary Exposure

Dietary exposure is not expected from the use patterns of ethanol and isopropanol.

b. Occupational and Residential

The registered uses of aliphatic alcohols may result in high dermal and inhalation exposures during mixer/loader and applicator use of aliphatic alcohol products, especially when power sprays are used. However, the risk from exposures to these active ingredients is considered to be incidental when compared to the frequent intentional human exposures.

3. Risk Assessment

a. Dietary

Dietary exposure is not a concern for the aliphatic alcohols when used as a plant regulator (ripeners). Dietary exposure is not expected from this use. A dietary risk assessment is not required.

b. Occupational and Residential

The Agency has determined that an occupational/residential exposure risk assessment is required for active ingredients if: (1) certain toxicological criteria are triggered and (2) there is an exposure risk for handlers (mixers, loaders, applicators, etc.) during use or for persons entering treated sites immediately after completion of product applications, especially in the use of sanitizers.

Based on the acute toxicities and usage patterns for the active ingredients in this reregistration case, the Agency has determined the toxicological criteria are not triggered and that the exposure risk, from the active ingredients, for handlers and reentry workers is not significant when compared to the frequent intentional human exposures. (EPA's OPP Less Than Lifetime Committee, November 2, 1994). Both active ingredients in this reregistration case have a history of extensive human exposure. Therefore, an occupational/residential exposure risk assessment is not required for the uses of aliphatic alcohols in this reregistration case.

The Agency review of the literature concluded that there is no expectation of developmental or reproductive effects from the potential dermal and inhalation exposures from the registered uses of the aliphatic alcohols as described in this reregistration case.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency relied on data available from its Toxicology Data Base and published literature to review the toxicity of ethanol and isopropanol to mammalian and aquatic species.

a. Toxicity to Terrestrial Animals

Table 5

| Species | LD50 | Source | Conclusion |
|------------------|------------|-----------------------------|-----------------------|
| Rat: ethanol | 7060 mg/kg | Agency Toxicology Data Base | practically non-toxic |
| Rat: isopropanol | 4384 mg/kg | Agency Toxicology Data Base | practically non-toxic |

These results demonstrate that ethanol and isopropanol are practically non-toxic to the rat on an acute basis.

b. Toxicity to Aquatic Animals

(1) Acute Toxicity Data for Ethanol

Table 6

| Species | % ai | Results | MRID | Conclusion ¹ |
|--------------------------|---------|------------------|-----------------------------|-------------------------|
| rainbow trout | 100% | LC50 = 13000 ppm | MRID 40098001 | practically non-toxic |
| fathead minnow | 95% | LC50 = 14200 ppm | Brooke, et al. ² | practically non-toxic |
| Daphnia | unknown | LC50 > 100 ppm | Ewell, et al. ³ | practically non-toxic |
| Palaemonetes kadiakensis | 100% | LC50 > 250 ppm | MRID 40098001 | practically non-toxic |

¹ for material tested

² Brooke, L.T., et al., Acute Toxicities of Organic Chemicals to Fathead Minnows, Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, 1994.

³ Information obtained secondarily from EPA's Office of Pollution Prevention and Toxics.

These results show that ethanol is practically non-toxic to the rainbow trout, fathead minnow, Daphnia, and Palaemonetes kadiakensis (glass shrimp).

(2) Aquatic Toxicity Data for Isopropanol.

Table 7

| Species | % ai | Results | Author | Conclusion ¹ |
|----------------|---------|-----------------|-----------------------------|-------------------------|
| fathead minnow | 99.8% | LC50 = 6550 ppm | Brooke, et al. ² | practically non-toxic |
| <u>Daphnia</u> | unknown | EC50 = 2280 ppm | Hermen ³ | practically non-toxic |

¹ for material tested

² Brooke, L.T., et al., Acute Toxicities of Organic Chemicals to Fathead Minnows, Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, 1994.

³ Information obtained secondarily from EPA's Office of Pollution Prevention and Toxics.

These results show that isopropanol is practically non-toxic to the fathead minnow and Daphnia.

2. Environmental Fate

The Agency relied on information from the open chemical literature to characterize the environmental fate of ethanol and isopropanol.

a. Environmental Fate Chemistry

Aliphatic alcohols are organic chemical compounds in which the carbon atoms are linked in open chains and that contain a hydroxyl (-OH) group. There are two principal ways to manufacture the simple alcohols: by hydration of alkenes obtained from the cracking of petroleum and by fermentation of carbohydrates.

Ethanol and isopropanol are flammable liquids. Both chemicals are miscible with water and with many organic solvents. The high solubility of the chemicals in water is due to the hydrogen bond that can exist between an alcohol molecule and a water molecule.

b. Environmental Fate Assessment

Ethanol and isopropanol are highly volatile liquids. They are expected to be stable in water under typical use conditions. The Agency does not anticipate significant exposure to the environment from the remaining supported uses (mostly indoor except for pet living quarters; and discharge of treated water from waterbeds and whirlpools; and refuse/solid waste sites) of the aliphatic alcohols.

3. Exposure and Risk Characterization

Estimated environmental concentrations (EECs) were not established for the use patterns for ethanol and isopropanol. Results from the Agency's toxicology data base and the published literature show that these alcohols are practically non-toxic to mammals and the aquatic species tested. The majority of registered uses for ethanol and isopropanol being supported for reregistration are mostly for indoor use. The only outdoor uses are for pet living quarters (isopropanol) and refuse/solid waste sites (ethanol). In addition, both alcohols are highly volatile, which supports the conclusion that exposure to terrestrial organisms would be extremely minimal.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of ethanol and isopropanol and to determine that ethanol and isopropanol can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing ethanol and/or isopropanol as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency based its reregistration eligibility determination upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that all uses of ethanol and isopropanol 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 ethanol and isopropanol if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients ethanol and isopropanol, the Agency has sufficient information on the health effects and on their potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that ethanol and isopropanol products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the

environment. Therefore, the Agency concludes that products containing ethanol and isopropanol for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of ethanol and isopropanol are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for ethanol and isopropanol. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Labeling Rationale

The registered uses of these aliphatic alcohols may result in high dermal and inhalation exposures during mixer/loader and applicator use of aliphatic alcohol products, especially when power sprays are used. However, the risk from exposures to these active ingredients is considered to be incidental when compared to the frequent intentional human exposures.

Mixer/loader/applicator PPE

For each end-use product, PPE requirements for pesticide handlers are established during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.
2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):
 - In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.
 - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

The EPA concludes there are no specific acute toxic or adverse effects from exposures to registered uses of aliphatic alcohols (ethanol and isopropanol), for handlers which warrant the establishment of active-ingredient-based minimum PPE.

Post-Application Exposures

There are several types of potential exposures to persons after application is complete. These include:

- 1). Potential exposure, especially inhalation exposure, to industrial/manufacturing workers immediately after aliphatic alcohol use.
- 2). Potential exposure, especially inhalation exposure, to products containing aliphatic alcohol immediately after such products are used.

Post-application dermal exposures to aliphatic alcohols, excluding ethanol used to generate ethylene, are expected to be minimal, because both active ingredients evaporate rapidly.

Although there is potential inhalation exposure following applications of the aliphatic alcohols in this reregistration case, the establishment of active-ingredient-based post-application entry restrictions and personal protective equipment specifications are not warranted. This conclusion is based on the absence of toxicological concerns when the uses are compared to the frequent intentional human exposures.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ethanol and isopropanol for the above eligible uses has been reviewed and determined to be substantially complete.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by MP registrant."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility

has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes 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 Response Form provided for each product.

Where new efficacy studies must be conducted, the registrant may refer to Subdivision G of EPA's Pesticide Assessment Guidelines. Subdivision G is available from National Technical Information Service (a fee will be charged); the order number is PB83-153924.

2. Labeling Requirements for End-Use Products

In compliance with PR Notice 94-4, the following statement must be added to the label of each product, except for sterilants, that is registered for treatment of any medical device or medical equipment surface:

"This product is not to be used as a terminal sterilant/high level disinfectant 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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (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 ethanol and isopropanol 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. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

**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 Aliphatic Alcohols covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Aliphatic Alcohols 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 Ethanol

| REQUIREMENT | USE PATTERN | CITATION(S) |
|--------------------------|-----------------------------|-----------------|
| PRODUCT CHEMISTRY | | |
| 61-1 | Chemical Identity | CGLMNO 42705601 |
| 61-2A | Start. Mat. & Mnfg. Process | CGLMNO 42705601 |
| 61-2B | Formation of Impurities | CGLMNO 42705601 |
| 62-2 | Certification of limits | CGLMNO 42705602 |
| 63-2 | Color | CGLMNO 42705603 |
| 63-3 | Physical State | CGLMNO 42705603 |
| 63-4 | Odor | CGLMNO 42705603 |
| 63-5 | Melting Point | CGLMNO 42705603 |
| 63-6 | Boiling Point | CGLMNO 42705603 |
| 63-7 | Density | CGLMNO 42705603 |
| 63-8 | Solubility | CGLMNO 42705603 |
| 63-9 | Vapor Pressure | CGLMNO 42705603 |
| 63-10 | Dissociation Constant | CGLMNO 42705603 |
| 63-11 | Octanol/Water Partition | CGLMNO Waived |
| 63-12 | pH | CGLMNO 42705603 |
| 63-13 | Stability | CGLMNO 42705603 |
| 63-14 | Oxidizing/Reducing Action | CGLMNO 42705603 |
| 63-15 | Flammability | CGLMNO 42705603 |
| 63-16 | Explosibility | CGLMNO 42705603 |

Data Supporting Guideline Requirements for the Reregistration of Ethanol

| REQUIREMENT | USE PATTERN | CITATION(S) |
|----------------------------------|---|--------------------|
| 63-17 | Storage stability | CGLMNO Waived |
| 63-18 | Viscosity | CGLMNO 42705603 |
| 63-19 | Miscibility | CGLMNO 42705603 |
| 63-20 | Corrosion characteristics | CGLMNO 42705603 |
| <u>ECOLOGICAL EFFECTS</u> | | |
| 72-1A | Fish Toxicity Bluegill | CGLMNO 40098001 |
| 72-1C | Fish Toxicity Rainbow Trout | CGLMNO 40098001 |
| 72-2A | Invertebrate Toxicity | CGLMNO * |
| 72-3A | Esturine/Marine Toxicity Fish | CGLMNO * |
| <u>TOXICOLOGY</u> | | |
| 81-1 | Acute Oral Toxicity - Rat | CGLMNO * |
| 81-3 | Acute Inhalation Toxicity - Rat | CGLMNO * |
| 81-4 | Primary Eye Irritation - Rabbit | CGLMNO * |
| 81-5 | Primary Dermal Irritation - Rabbit | CGLMNO * |
| 82-1A | 90 Day Feeding - Rodent | CGLMNO * |
| 82-2 | 21 Day Dermal | CGLMNO * |
| 82-4 | 90 Day Inhalation | CGLMNO * |
| 83-1A | Chronic Feeding Toxicity - Rodent | CGLMNO 00031038 |
| 83-3A | Developmental Toxicity - Rat | CGLMNO * |
| 84-2A | Gene Mutation (Ames Test) | CGLMNO * |

Data Supporting Guideline Requirements for the Reregistration of Ethanol

| REQUIREMENT | | USE PATTERN | CITATION(S) |
|--------------------|--|--------------------|--------------------|
| 84-2B | Structural Chromosomal Aberration | CGLMNO | * |
| 84-4 | Other Genotoxic Effects | CGLMNO | * |
| 85-1 | General Metabolism | CGLMNO | * |

*** These guidelines were satisfied by studies in the open literature.**

Data Supporting Guideline Requirements for the Reregistration of Isoproponal

| REQUIREMENT | USE PATTERN | CITATION(S) |
|----------------------------------|--|-----------------|
| <u>PRODUCT CHEMISTRY</u> | | |
| 61-1 | Chemical Identity | CGLMNO 42478901 |
| 61-2A | Start. Mat. & Mnfg. Process | CGLMNO 42478901 |
| 61-2B | Formation of Impurities | CGLMNO 42478901 |
| 62-2 | Certification of limits | CGLMNO * |
| 62-3 | Analytical Methods | CGLMNO 42478901 |
| 63-2 | Color | CGLMNO 42705603 |
| 63-3 | Physical State | CGLMNO 42705603 |
| 63-4 | Odor | CGLMNO 42705603 |
| 63-6 | Boiling Point | CGLMNO 42705603 |
| 63-7 | Density | CGLMNO 42705603 |
| 63-8 | Solubility | CGLMNO 42705603 |
| 63-9 | Vapor Pressure | CGLMNO 42705603 |
| 63-11 | Octanol/Water Partition | CGLMNO * |
| 63-12 | pH | CGLMNO * |
| 63-13 | Stability | CGLMNO 42478901 |
| <u>ECOLOGICAL EFFECTS</u> | | |
| 72-2A | Invertebrate Toxicity | CGLMNO * |
| 72-3A | Esturine/Marine Toxicity Fish | CGLMNO * |
| <u>TOXICOLOGY</u> | | |
| 81-1 | Acute Oral Toxicity - Rat | CGLMNO * |

Data Supporting Guideline Requirements for the Reregistration of Isoproponal

| REQUIREMENT | USE PATTERN | CITATION(S) |
|---|-------------|-------------|
| 81-2 Acute Dermal Toxicity - Rabbit/Rat | CGLMNO | 0050951 |
| 81-3 Acute Inhalation Toxicity - Rat | CGLMNO | 42478902 |
| 81-4 Primary Eye Irritation - Rabbit | CGLMNO | * |
| 81-5 Primary Dermal Irritation - Rabbit | CGLMNO | * |
| 83-1A Chronic Feeding Toxicity - Rodent | CGLMNO | 00031038 |
| 83-3A Developmental Toxicity - Rat | CGLMNO | 42873501 |
| 84-2A Gene Mutation (Ames Test) | CGLMNO | * |
| 84-2B Structural Chromosomal Aberration | CGLMNO | * |
| 84-4 Other Genotoxic Effects | CGLMNO | * |
| 85-1 General Metabolism | CGLMNO | * |

* These guidelines were satisfied by studies in the open literature.

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Aliphatic Alcohols

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 Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, 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.

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CITATION

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APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. Aliphatic Alcohols RED Fact Sheet
4. PR Notice 86-5 (included in this appendix)
5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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.

| <u>Element</u> | <u>When Required</u> | <u>Example</u> |
|---|--|----------------|
| 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 © | 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, identify 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.

/S/

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

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 §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).

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 _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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)

| | | | |
|---------------------------------|--------------|--|--------------|
| <u>CROSS REFERENCE NUMBER 1</u> | | This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references. | |
| DELETED WORDS OR PHRASE: | | Ethylene Glycol | |
| <u>PAGE REFERENCE</u> | <u>LINES</u> | <u>REASON FOR THE DELETION</u> | <u>FIFRA</u> |
| 6 | 14 | Identity of Inert Ingredient | §10(d)(C) |
| 28 | 25 | " | " |
| 100 | 19 | " | " |

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

| | | | |
|---|--------------|--|------------------------|
| <u>CROSS REFERENCE NUMBER 5</u> | | 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 | |) | |
| (| |) | |
| <u>PAGE</u> | <u>LINES</u> | <u>REASON FOR THE DELETION</u> | <u>FIFRA REFERENCE</u> |
| 20. | 2-17 | Description of the quality control process | §10(d)(1)(C) |

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

| | | | |
|---|--|--|------------------------|
| <u>CROSS REFERENCE NUMBER 7</u> | | This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references. | |
| DELETED PAGES(S): are attached immediately behind this page | | | |
| <u>PAGES</u> | <u>REASON FOR THE DELETION</u> | | <u>FIFRA REFERENCE</u> |
| 35-41. | Description of 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 _____

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 _____

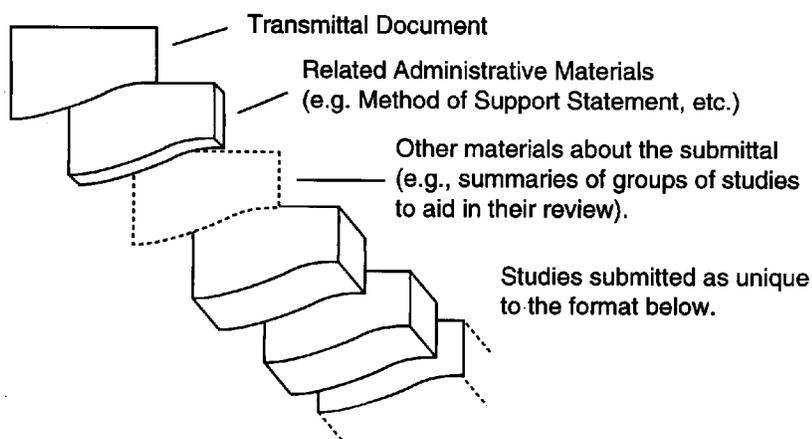
Example 3.

The submitter 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.

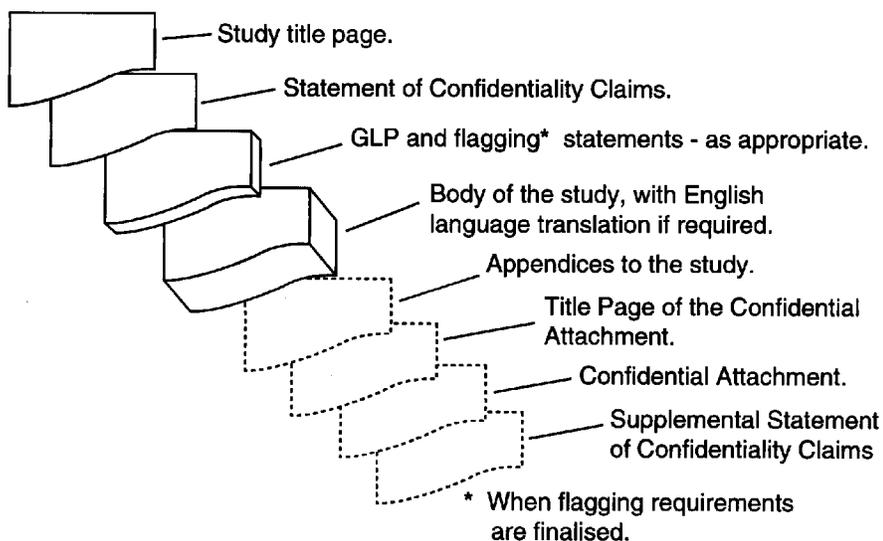
Submitter _____

ATTACHMENT 7.

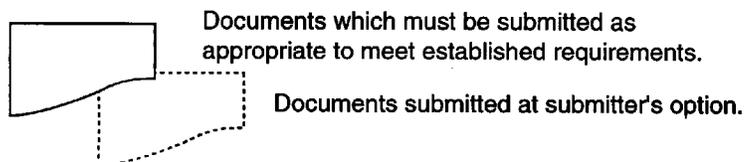
FORMAT OF THE SUBMITTAL PACKAGE



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 than 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.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Product Specific Data Call-In



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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 1 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 3, 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 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

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:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - EPA Acceptance Criteria
- 6 - List of Registrants Receiving This Notice
- 7 - 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 3, 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 3, 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 2 and Attachment 3. 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 2). 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 1.

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 7. 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 1. 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 1, 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 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. 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,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - EPA Acceptance Criteria
- 6 - List of Registrants Receiving This Notice
- 7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

ALIPHATIC ALCOHOLS DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 aliphatic alcohols. 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 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this aliphatic alcohols Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for aliphatic alcohols are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on aliphatic alcohols 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 aliphatic alcohols products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of aliphatic alcohols, please contact Leonard Ryan at (703) 308-8067.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Bruce Kapner at (703) 308-8013.

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

Bruce Kapner
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Aliphatic Alcohols

**Attachment 2. Product Specific Data Call-In Response
Forms (Form A inserts) 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 registration 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 company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

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

- Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5. The study title associated with the guideline reference number is identified.
- Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9. **Enter 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. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (**EPA Form 8570-29**) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
 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 **only** 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 may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (**EPA Form 8570-29**) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
 3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed

"Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
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)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data

requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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 canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

**Attachment 3. Product Specific Requirement Status and
Registrant's Response Forms (Form B inserts) and
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 patterns (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 may be subject to suspension.
 3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be

subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

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

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and 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 registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

Items 10-13. Self-explanatory.

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

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF ALIPHATIC ALCOHOL PRODUCTS FOR 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 aliphatic alcohols as the active ingredient, the Agency has batched products which can be considered similar 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.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar 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 referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred thirty eight products were found which contain aliphatic alcohols as the active ingredient. Seventy of these contain ethanol, sixty five contain isopropanol, and three contain both ethanol and isopropanol. The products containing ethanol have been placed into 10 batches, the products containing isopropanol have been placed in 6 batches, and the products containing both alcohols have been placed in a list under no batch in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each of the ethanol batches, table 2 does the same for the isopropanol batches. The last list in each table is for products that cannot be batched in any group.

| Table 1 | | | |
|----------------|---------------------|--|-------------------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| 1 | 334-214 | ETOH 52.7, p-tert-amyl phenol 0.047 o-phenyl phenol 0.200 | pressurized liquid |
| | 334-312 | ETOH 53.959 p-tert-amyl phenol 0.050 o-phenyl phenol 0.176 | " " " |
| | 334-313 | ETOH 53.298 p-tert-amyl phenol 0.050 o-phenyl phenol 0.201 | " " " |
| | 334-317 | ETOH 53.460 p-tert-amyl phenol 0.044 o-phenyl phenol 0.176 | " " " |
| | 334-318 | ETOH 53.267 p-tert-amyl phenol 0.048 o-phenyl phenol 0.201 | " " " |
| | 334-385 | ETOH 53.268 p-tert-amyl phenol 0.048 o-phenyl phenol 0.201 | " " " |
| 2 | 1839-68 | ETOH 20.0 Alkyl dimethyl benzyl ammonium chloride (C14 50 %, C12 40 %, C16 10 %) 80 | liquid concentrate |
| | 1839-71 | ETOH 20.0 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %, C12 5 %) 80 | technical liquid |
| | 47371-22 | ETOH 20.0 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %, C12 5 %) 80 | formulation inter- mediate |
| 3 | 1839-31 | ETOH 10.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%, C16 15%) 80.0 | Inter- mediate Liquid |
| | 6836-186 | ETOH 10.60 Alkyldimethyl benzyl ammonium chloride (C14 50%,C12 40%, C16 10%) 80.0 | " " " |
| 4 | 6836-183 | ETOH 10.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%,C16 15%) 50.0 | " " " |
| | 47371-16 | ETOH 10.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C16 30%,C18 5%, C12 5 %)50.0 | " " " |
| 5 | 9157-10 | ETOH 3.20 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%,C16 15%) 16.0 | pool algicide concentrate |
| | 47000-29 | ETOH 2.50 Alkyldimethyl benzyl ammonium chloride (C14 60%,C16 30%,C18 5%, C12 5 %) 10.0 | pool algicide ready to use |
| | 36341-1 | ETOH 2.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C16 30%,C18 5%, C12 5 %) 10.0 | soluble concentrate |
| | 34282-6 | " " " " " | solution |

| Table 1 | | | |
|----------------|---------------------|---|------------------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| 6 | 1839-70 | ETOH 20.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%, C16 15%) 40.0 Alkyldimethyl ethylbenzyl Ammonium chloride (C12 50%, C14 30%, C16 17%,C18 3%)40.0 | Liquid concentrate |
| | 1839-69 | " " " " " | formulation inter-mediate |
| | 10807-100 | ETOH 20.0 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%, C16 15%) 40.0 Alkyldimethyl ethylbenzyl Ammonium chloride (C12 68%, C14 32%) 40.0 | Soluble concentrate |
| | 47371-13 | ETOH 12.5 Alkyldimethyl benzyl ammonium chloride (C14 60%,C12 25%, C16 15%) 40.0 Alkyldimethyl ethylbenzyl Ammonium chloride (C12 50%, C14 30%, C16 17%,C18 3%)40.0 | Liquid concentrate |
| | 1839-34 | " " " " " | " " " |
| | 1839-54 | " " " " " | Formulation inter-mediate |
| 7 | 11525-30 | ETOH 50.088 Alkyldimethyl benzyl ammonium chloride (C14 60%,C16 30%,C18 5%, C12 5 %) 0.072 Alkyldimethyl ethylbenzyl Ammonium chloride (C12 68%, C14 32%) 0.072 | Pressurized Liquid |
| | 11525-31 | " " " " " | pressurized Liquid |
| 8 | 777-74 | ETOH 79.646 o-phenyl phenol0.078 | " " " |
| | 777-53 | EtOH 79.0 O-phenyl phenol 0.100 | " " " |
| | 675-25 | ETOH 78.5 O-phenyl phenol 0.1360 | " " " |
| 9 | 211-32 | ETOH 73.49 O-phenyl phenol 0.214 | " " " |
| | 56392-4 | ETOH 69.1 O-phenyl phenol 0.12 | " " " |
| | 56392-2 | ETOH 69.1 O-phenyl phenol 0.13 | " " " |
| | 56392-6 | ETOH 66.6 O-phenyl phenol 0.12 | " " " |
| 10 | 67346-1 | ETOH 92.46 | Ethylene fluid |
| | 58502-1 | " " " " " | Solution |

| Table 2 | | | |
|----------------|---------------------|--|-------------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| No batch | 7405-51 | ETOH 53.72 p-tert amyl phenol 0.03 o-phenyl phenol 0.10 | pressurized liquid |
| No batch | 3862-99 | ETOH 53.78 p-tert amyl phenol 0.02 o-phenyl phenol 0.08 | " " " |
| | 1270-237 | ETOH 67.6 p-tert amyl phenol 0.055 o-phenyl phenol 0.221 | " " " |
| | 706-69 | ETOH 52.580 p-tert amyl phenol 0.055 o-phenyl phenol 0.1801 | " " " |
| | 5197-50 | ETOH 56.99 p-tert amyl Phenol 0.050 o-phenyl phenol 0.10 | " " " |
| | 334-417 | ETOH 66.5860 p-tert amyl phenol 0.060 o-phenyl phenol 0.251 | Liquid |
| No batch | 64039-1 | ETOH 76.0 Alkyl dimethyl benzyl ammonium chloride (C14 50 %, C12 40 %, C16 10 %) 0.16 | pump spray |
| | 42964-17 | ETOH 62.74 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.15 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 32 %) 0.15 | Pressurized spray |
| | 1270-192 | ETOH 53.00 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.100 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 32 %) 0.100 | " " " |
| | 15035-1 | ETOH 3.5, Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 7.00 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 32 %) 7.00 | liquid concentrate |
| | 4822-55 | ETOH 62.56, Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.065 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 60 %, C16 4 30%, C18 5 %, C12 5 %) 0.065 | pressurized liquid |
| No batch | 4822-94 | ETOH 37.00, Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.05 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 60 %, C16 4 30%, C18 5 %, C12 5 %) 0.05 | " " " |

| Table 2 | | | |
|----------------|---------------------|---|-------------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| | 4822-158 | ETOH 19.736 #Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.0875 #Alkyl dimethyl ethyl benzyl ammonium chloride (C12 60 %, C164 30%, C18 5 %, C12 5 %) #Combined# 0.0875 | Liquid |
| No Batch | 1270-47 | ETOH 0.05 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 0.025 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 60 %, C163030%, C18 5 %, C12 5 %)0.025 | solution |
| | 5813-26 | ETOH 3.00 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C12 5 %, C18 5 %) 1.5 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 60 %, C163030%, C18 5 %, C12 5 %)1.5 | solution |
| | 777-55 | ETOH 82.965 o-phenyl ohenol 0.108 | liquid |
| | 11694-99 | ETOH 68.00 o-phenyl ohenol 0.192 | pressurized liquid |
| | 11694-98 | ETOH 68.00 o-phenyl ohenol 0.190 | liquid |
| | 43222-6 | ETOH 14.91 o-phenyl ohenol 0.071 | pressurized liquid |
| | 3743-1 | ETOH 86 | liquid |
| | 10801-1 | ETOH 75.101 | Pump spray |
| | 66288-1 | ETOH 58.60 | liquid |
| | 4822-329 | ETOH 56.0 | Pressurized liquid |
| | 2230-43 | ETOH 0.11 Hydrogen Chloride 10 Alkyl dimethyl benzyl ammonium chloride (C14 50 %, C12 40 %, C16 10 % 0.42 | soluble concentrate |
| | 10648-1 | ETOH 82.19 Formaldehyde 0.043 | solution |
| | 5741-22 | ETOH 64.0 2-benzyl chlorophenol 0.275 o-phenyl phenol 0.051 | Pressurized liquid |
| | 1270-243 | ETOH 53.46 2-benzyl chlorophenol 0.08 o-phenyl phenol 0.10 | " " " |
| | 7405-34 | ETOH 32.10 diisobutylphenoxy ethoxy dimethyl benzyl ammonium chloride 0.10 (hyamine 1622) Triethylene glycol 4.5 | Pressurized liquid |
| | 6836-162 | ETOH 80 Alkyl dimethyl ammonium chloride (C14 58 %, C16 28 %, C12 14 %) 20 | Concentrate liquid |
| | 777-72 | ETOH 79.646 Alkyl dimethyl ammonium chloride (C14 50 %, C12 40 %, C16 10 %) 1.06 | Pressurized liquid |

| Table 2 | | | |
|----------------|---------------------|---|-------------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| | 1043-19 | ETOH 53.09 o-benzyl chlorophenol 0.077 p-tert-amyl phenol 0.072 o-phenyl phenol 0.041 BTC 2125 0.085 | " " " |
| | 33176-5 | ETOH 44.26 o-phenyl phenol 0.255 n-alkyl dimethyl benzyl ammonium chloride 0.33 | " " " |
| | 257-295 | ETOH 37.00 alkyldimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %, C12 5 %)0.05 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 38 %) 0.05 3,4',5-dibromosalicylanalide 0.0067 Triethylene glycol 8.00 | " " " |
| | 4822-88 | ETOH 37.00 Alkyl dimethyl benzyl ammonium chloride (C14 60%, C16 30 %, C18 5%, C12 5 %)0.05 alkyl dimethyl ethylbenzyl ammonium chloride (C12 50 %, C14 30 %, C 16 17 %, C 18 3 %) 0.05 Triethylene glycol 8.00 | " " " |
| | 11715-116 | ETOH 30.148 Alkyl dimethyl benzyl ammonium chloride (C12 61 %, C14 23 %, C16 11 %, C18 5 %) 0.192 Propanol, oxy bis 3.84 Essential oils 0.96 | pressurized liquid |
| | 323-28 | ETOH 16.92 1,2 propanediol 2.5 alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %, C12 5%) 0.05 | " " " |

| Table 3 | | | |
|----------------|--------------|--|---------------------|
| Batch | EPA Reg. No. | % Active Ingredient | Formulation Type |
| 1 | 8133-17 | Isopropanol 4.0 didecyl dimethyl ammonium chloride 10.0 | Solution |
| | 4482-15 | Isopropanol 3.0 didecyl dimethyl ammonium chloride 7.50 | Soluble concentrate |
| | 48815-1 | Isopropanol 3.0 didecyl dimethyl ammonium chloride 7.5 | Liquid dip |
| 2 | 1769-187 | Isopropanol 30.66 1,2 propanediol 4.62 methyl dodecylbenzyl trimethyl ammonium chloride 0.042 Triethylene glycol 4.94 | Solution |
| | 1769-47 | Isopropanol 27.30 1,2 propanediol 4.40 methyl dodecylbenzyl trimethyl ammonium chloride 0.16 Triethylene glycol 4.70 | Solution |
| 3 | 8047-34 | Isopropanol 4.750 pine oil 3.95 Alkyl dimethyl benzyl ammonium chloride (C14 58 %, C16 28 %, C12 14 %) 1.97 | Soluble concentrate |
| | 1182-21 | " " " " " | " " " |
| | 5680-14 | " " " " " | " " " |
| 4 | 6658-39 | isopropanol 53.0 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %, C12 5%) 0.1 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 32 %) 0.10 | Pressurized liquid |
| | 10806-21 | " " " " " | " " " |
| | 11623-24 | " " " " " | " " " |
| | 33176-24 | " " " " " | " " " |
| | 9852-54 | " " " " " | " " " |
| 5 | 5197-30 | Isopropanol 60.0 4-tert-amylphenol 0.05 o-phenyl phenol 0.10 | solution |
| | 5197-40 | Isopropanol 63.79 4-tert amyl phenol 0.053 0-phenyl phenol 0.105 | " " " |
| 6 | 6836-176 | Isopropanol 43.22 Alkyl dimethyl benzyl ammonium chloride (C14 50%, C16 28 %, C12 14%) 0.25 | Pressurized liquid |
| | 11715-114 | Isopropanol 43.22 Alkyl dimethyl benzyl ammonium chloride (C14 50%, C16 28 %, C12 14%) 0.25 | " " " |

| Table 4 | | | |
|----------|--------------|---|----------------------------------|
| Batch | EPA Reg. No. | %active ingredient | Formulation Type |
| No Batch | 68329-5 | Isopropanol 20.0 didecyl dimethyl ammonium chloride 50.0 | solution |
| | 8540-13 | Isopropanol 10.0 didecyl dimethyl ammonium chloride 25.0 | soluble concentrate |
| | 60142-1 | Isopropanol 70.0 | solution |
| | 3150-1 | Isopropanol 13.0 Alkyl dimethyl benzyl ammonium chloride (C12 50 %,C14 30 %, C16 17 %, C18 3%)6.5 cetyl dimethyl ammonium bromide 6.5 | solution |
| No Batch | 3150-3 | Isopropanol 13.0 Alkyl dimethyl benzyl ammonium chloride (C12 50 %,C14 30 %, C16 17 %, C18 3%)6.5 cetyl dimethyl ammonium bromide 6.5 | Pressurized liquid |
| | 11715-128 | Isopropanol 15.7 Triethylene glycol5.0 | " " " |
| | 4758-143 | Isopropanol 89.5 d-limonene 10.0 pyrethrins 0.25 piperonyl butoxide 0.25 | solution |
| | 6768-8 | Isopropanol 25.0 diisobutyl phenoxyethoxy ethyldimethyl ammonium chloride 0.69 o-phenylphenol 0.21 bromine 0.04 pyrethrins 0.1 | solution |
| | 283-3 | Isopropanol 60 Alkyl dimethyl benzyl ammonium chloride (C12 61%, C14 23%,C16 11% C18 5%) 0.13 | solution |
| | 6836-191 | Isopropanol 6.049 Alkyl dimethyl benzyl ammonium chloride (C12 67 %, C14 25 %, C18 1 %, C10 1 % C8 1 %)51.74 | Formulation inter- mediate |
| | 9601-5 | Isopropanol 2.00 Alkyl dimethyl benzyl ammonium chloride (C14 60 %, C16 30 %, C18 5 %,C12 5 %) 0.65 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68 %, C14 28 %) 0.65 Tetrasodium ethylenetriamine triacetate 5.0 | Liquid concentrate |
| | 8047-22 | Isopropanol 1.00 Alkyl dimethyl benzyl ammonium chloride (C14 58 %, C16 28 %, C12 14%) 2.00 Essential oils 0.25 | Soluble concentrate |
| | 421-16 | Isopropanol 24.23 Essential oils 0.50 2-benzyl chlorophenol 4.92 0-phenyl phenol 0.75 Methyl salicylate 1.222 Soap 15.38 | " " " |
| | 402-113 | Isopropanol 23.23 Essential oils 2.00 2-benzylchlorophenol 3.16 0-phenylphenol 2.02 tert-amyl phenol 2.03 | Emulsify-able concentrate |
| | 1270-24 | Isopropanol 21.3 2-benzyl chlorophenol 6.7 | Soluble concentrate |

| Table 4 | | | |
|---------|--------------|---|---------------------|
| Batch | EPA Reg. No. | %active ingredient | Formulation Type |
| | 402-96 | Isopropanol 13.13 pine oil 10.0 soap 15.79 nonyl phenoxypolyethoxy ethanol 5.47 | " " " |
| | 5747-2 | Isopropanol 5.00 Pine oil 75.0 soap 10.0 | " " " |
| | 10807-95 | Isopropanol 0.050 Pine oil 80.0 | Soluble Concentrate |
| | 1275-28 | Isopropanol 7.560 Pine oil 7.04 Alkyl dimethyl 3,4-dichlorobenzyl ammonium chloride 3.00 | " " " |
| | 10807-111 | Isopropanol 4.75 pine oil 3.95 alkyl dimethyl benzyl ammonium chloride (C 14 58 %, C16 28 %, C12 14%) 1.97 | " " " |
| | 1130-6 | Isopropanol 8.08 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 0.14 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 0.14 | Impregnated cloth |
| | 12192-2 | Isopropanol 5.0 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 6.00 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 6.00 | solution |
| | 11715-30 | Isopropanol 53.0 Essential oils 0.500 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 0.10 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 0.10 | Pressurized Liquid |
| | 1839-82 | Isopropanol 75.14 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 0.14 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 0.14 | Liquid |
| | 1839-85 | isopropanol 53.0 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 0.10 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 0.10 | Pressurized liquid |
| | 44446-20 | Isopropanol 50.70 alkyl dimethyl benzyl ammonium chloride (C 14 60 %, C16 30 %, C185 %, C12 5 %) 0.10 alkyldimethyl ethylbenzyl ammonium chloride (C12 68%, C14 32%) 0.10 | " " " |
| | 4000-42 | isopropanol 86.6 o-phenyl phenol 0.20 | " " " |

| Table 4 | | | |
|---------|--------------|---|-------------------------------------|
| Batch | EPA Reg. No. | %active ingredient | Formulation Type |
| | 421-21 | Isopropanol 28.46 triethylene glycol 10.80 propylene glycol 3.0 p-diisobutyl phenoxy ethoxyethylbenzyl dimethyl ammonium chloride 0.24 propylene glycol 3.00 | solution |
| | 1769-25 | Isopropanol 38.5 1,2 prparendiol 8.12 Triethylene glycol 12.17 | Pressurized liquid |
| | 1769-201 | Isopropanol 57.0 tert-amyl phenol 0.02 o-phenyl phenol 0.080 | " " " |
| | 954-10 | Isopropanol 11.0 0-phenylphenol 0.25 | " " " |
| | 8370-8 | Isopropanol 35.0 Alkyl dimethyl benzyl ammonium chloride (C14 50%,C12 40%, C16 10%) 3.00 | Soluble concentrate |
| | 8047-25 | Isopropanol 1.50 Alkyl dimethyl benzyl ammonium chloride (C14 50%,C12 40%, C16 10%) 2.0 essential oils 0.80 | Soluble concentrate |
| | 48920-1 | Isopropanol 40.41 Alkyl dimethyl benzyl ammonium chloride (C14 58%,, C16 28%, C12 14%) 4.0 | solution |
| | 8654-1 | Isopropanol 50.0 alkyl dimethyl benzyl ammonium chloride (C14 58%,C16 28%,C12 14%) 0.183 | " " " |
| | 8047-31 | Isopropanol 4.00 alkyl dimethyl benzyl ammonium chloride (C14 58%,C16 28%,C12 14%) 4.00 | Emulsi-fyable concentrate |
| | 397-13 | Isopropanol 60.9 sumithrin 0.22 Alkyl dimethylbenzyl ammonium chloride (C14 50%,C12 40%,C16 10%) with didecyl dimethyl ammonium chloride 0.199 | solution |
| | 58369-2 | Isopropanol 37.5 Eucaliptus oil 12.5 | " " " |
| | 58369-3 | Isopropanol 18.75 Eucliptus oil 6.25 Quarternium-15 0.3 | " " " |
| | 38526-1 | Isopropanol 15.3 diisobutylphenoxyethoxy ethyl dimethylbenzyl ammonium chloride 0.25 | " " " |
| | 10770-10 | Isopropanol 15.3 diisobutylphenoxyethoxy ethyl dimethylbenzyl ammonium chloride 0.25 | " " " |
| | 10770-8 | Isopropanol 14.85 diisobutylphenoxyethoxy ethyl dimethylbenzyl ammonium chloride 0.25 | Pressurized liquid |
| | 875-137 | Isobutanol 10.0 Phosphoric acid 72.0 Dodecyl benzene sulfonic acid 4.5 | soluble concentrate |
| | 45447-10 | Isopropanol 8.5 Phosphoric acid 57.0 Dodecyl benzene sulfonic acid 15.5 | " " " |
| | 6836-188 | Isopropanol 3.00 Alkyl diethylbenzyl ammonium Chloride 50.0 (C14 58%,C16 28%, C12 14%) Benzyl chloride 16.363 | Formulation inter-mediate liquid |

| Table 4 | | | |
|----------|--------------|--|----------------------|
| Batch | EPA Reg. No. | %active ingredient | Formulation Type |
| | 6836-189 | Isopropanol 5.0 Alkyl dimethyl benzyl ammonium chloride 33.75 (C14 58%, C16 28%, C12 14%) Benzyl chloride 18.36 | " " " |
| | 10492-4 | Isopropanol 63.25 Alkyl dimethyl benzyl ammonium chloride (C14 60%, C16 30 %, C18 5%, C12 5%) 0.120 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 68%, C14 32 %) 0.1200 | Towelette |
| No Batch | 4822-120 | Isopropanol 24.238 ETOH 24.238 Alkyl dimethyl benzyl ammonium chloride (C14 60%, C16 30 %, C18 5%, C12 5%) 0.065 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 50%, C14 30 %, C16 17%, C18 3 %) 0.065 | Pressurized liquid |
| | 1839-42 | Isopropanol 6.0 ETOH 5.0 Alkyl dimethyl benzyl ammonium chloride (C14 60%, C16 30 %, C18 5%, C12 5%) 13.0 Alkyl dimethyl ethyl benzyl ammonium chloride (C12 50%, C14 30 %, C16 17%, C18 3 %) 13.0 | Flowable Concentrate |
| No Batch | 9807-4 | Isopropanol 3.00 ETOH 1.00 Alkyl dimethyl ethyl benzyl ammonium chloride (C14 50%, C12 40 %, C16 10 %) 5.00 | soluble concentrate |

Attachment 5. 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 $> 0.1\%$ 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 $> 0.1\%$ or was found at $\geq 0.1\%$ by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $> 0.1\%$.
2. ___ Degree of accountability or closure $> ca 98\%$.
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 $> 0.1\%$ 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 or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft³ 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

| <u>Guideline</u> | <u>Study Title</u> |
|------------------|--|
| 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 (+ 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 cm².
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 6. List of All Registrants Sent This Data Call-In (insert) Notice

**Attachment 7. Cost Share, Data Compensation Forms, Confidential
Statement of Formula Form and Instructions**



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

Confidential Statement of Formula

A. Basic Formulation
 Alternate Formulation

B. Page of

See Instructions on Back

| | | | |
|---|--|--|---|
| 1. Name and Address of Applicant/Registrant (Include ZIP Code) | | 2. Name and Address of Producer (Include ZIP Code) | |
| 3. Product Name | | 4. Registration No./File Symbol | 5. EPA Product Mgr./Team No. |
| | | 7. Pounds/Gal or Bulk Density | 8. pH |
| 10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.) | | 11. Supplier Name & Address | 12. EPA Reg. No. |
| EPA USE ONLY | | 13. Each Component in Formulation a. Amount | 14. Certified Limits % by Weight a. Upper Limit b. Lower Limit |
| | | | 15. Purpose in Formulation |
| | | | 6. Country Where Formulated |
| | | | 9. Flash Point/Flame Extension |
| 16. Typed Name of Approving Official | | 17. Total Weight | 100% |
| 18. Signature of Approving Official | | 19. Title | |
| | | 20. Phone No. (Include Area Code) | |
| | | 21. Date | |

Instructions for Completing the Confidential Statement of Formula

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

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.



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
2070-0057

Approval Expires 3-31-96

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 |
| Product Name | EPA Reg. No. |

I Certify that:

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

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

| | |
|-----------------|---------------|
| Name of Firm(s) | Date of Offer |
|-----------------|---------------|

Certification:

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

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



**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

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-233, 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 |
| Product Name | EPA Reg. No. |

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) 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)

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)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

| | |
|-----------|------|
| Signature | Date |
|-----------|------|

Name and Title (Please Type or Print)

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

| | |
|-----------|------|
| Signature | Date |
|-----------|------|

Name and Title (Please Type or Print)

APPENDIX G. FACT SHEET



R.E.D. FACTS

Aliphatic Alcohols

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4003, aliphatic alcohols, which contains the active ingredients ethanol and isopropanol.

Use Profile

Aliphatic alcohols are registered for uses which include hard surface treatment disinfectants, sanitizers, a sterilant, virucides, fungicides, and mildewcides. Ethanol also is registered for use as a plant growth regulator (a ripener), and is used with quaternary ammonium compounds in swimming pool water systems. Isopropanol also is used in combination with other pesticide active ingredients to kill fleas, ticks, and other household insects. Both ethanol and isopropanol are well known substances and have a wide range of human uses. For example, ethanol is contained in some beverages, and isopropanol is the major ingredient in rubbing alcohol.

Aliphatic alcohols are applied as surface wipes, sprays, mop-on, sponge-on, wipe-on or pour-on treatments, by immersion, and through closed systems (for commercial/industrial water cooling systems).

Use practice limitations for ethanol include cautions not to use the product on polished wood furniture or rayon fabrics, and not to get the product on foods, drinks, feeds, or surfaces they may contact. Isopropanol is not recommended for use on aluminum, should not be used on polished wood furniture or rayon fabrics, and should not be sprayed on lacquered or

shellacked surfaces. Used solution should not be poured back into the bottle.

Regulatory History

Aliphatic alcohols were first registered as indoor disinfectants in the U.S. as early as 1948. Currently, 73 ethanol and 67 isopropanol pesticide products are registered. Ethanol and isopropanol are considered inert ingredients in some pesticide formulations; a determination is made on a case-by-case basis.

Historically, aliphatic alcohols have been regulated both as pesticides under EPA's jurisdiction and as devices under the Food and Drug Administration (FDA)'s purview. This regulatory burden has been reduced by a 1993/94 Memorandum of Understanding (MOU) which divides liquid chemical germicides into two categories: sterilants (which FDA will regulate) and general purpose disinfectants (which EPA will regulate). Both Agencies will continue to have jurisdiction over all liquid chemical germicides until rulemaking has been completed, but product performance and efficacy data need only be reviewed by the Agency with primary jurisdiction.

The case aliphatic alcohols contains three other active ingredients--methanol, propyl alcohol, and tert-butyl alcohol--which are not being supported for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, aliphatic alcohols have been shown to be of low acute toxicity. Ethanol has been placed in Toxicity Category IV (indicating the lowest degree of acute toxicity) for all effects tested including acute oral and inhalation toxicity, and primary eye and skin irritation. Isopropanol also has been placed in Toxicity Category IV for all effects except acute oral toxicity, for which it is placed in Toxicity Category III. In an acute neurotoxicity study using rats, isopropanol vapors caused decreased motor activity and effects on nervous system functions at the higher dose levels.

In a subchronic toxicity study using rats, ethanol caused decreased body weights and fatty degeneration in the livers of treated animals. In a study using human volunteers, ethanol-saturated patches caused skin irritation at 19-21 days of exposure. An inhalation study using rats, guinea pigs, rabbits, monkeys, and dogs resulted in no signs of toxicity.

In a subchronic inhalation study using rats and mice, isopropanol caused some clinical signs including ataxia, narcosis, hypoactivity, and lack of startle response, as well as kidney lesions. In a subchronic inhalation study using rats, no treatment-related changes were noted but motor activity was increased at the highest dose level.

In a chronic toxicity study using rats, ethanol caused decreased mean body weights, decreased activity, and impaired maze learning ability. In a

chronic dermal toxicity study, no treatment-related effects were noted. Two similar studies with isopropanol caused similar results.

EPA's review of the scientific literature indicates that carcinogenic effects are not expected from the uses of ethanol. In a carcinogenicity study using rats, isopropanol caused an increased incidence of granular kidneys, thickened stomachs, and kidney lesions. A second study using mice also caused increased incidence of stomach and kidney lesions, which were determined not to be of biological significance.

Ethanol is generally recognized as a human developmental neurotoxicant, causing Fetal Alcohol Syndrome in the offspring of mothers who chronically consume high amounts of ethyl alcohol. However, the risk in an industrial environment appears to be minimal.

Developmental toxicity studies using rats and rabbits show that isopropanol causes reduced fetal body weights, decreased maternal body weights, and increases in liver or kidney weights.

Ethanol was negative for mutagenicity effects in six out of seven studies, while isopropanol was negative in all three studies available.

Dietary Exposure

Dietary exposure is not expected to result from the approved uses of ethanol and isopropanol, including the plant regulator (ripeners) use.

Occupational and Residential Exposure

Use of aliphatic alcohols may result in high dermal and inhalation exposure of mixers, loaders and applicators, especially when power sprays are used. However, the risk from exposure to these active ingredients is considered to be incidental, considering the frequent intentional human exposures to these substances.

Human Risk Assessment

Aliphatic alcohols are of low acute toxicity. No dietary exposure is expected from their use as pesticides. EPA does not expect developmental or reproductive effects to occur from the potential dermal and inhalation exposures that may result from the registered pesticidal uses of ethanol and isopropanol.

Environmental Assessment

Environmental Fate

Aliphatic alcohols are organic chemical compounds. They are flammable liquids and are highly soluble in water and many organic solvents. Highly volatile liquids, they are stable in water under typical use conditions. EPA does not anticipate significant exposure to the environment from their uses.

Ecological Effects

Ethanol and isopropanol are practically non-toxic to mammals, fish, and aquatic invertebrates.

Ecological Effects Risk Assessment

Aliphatic alcohols are practically non-toxic to all species tested. They are used primarily indoors. Both are highly volatile. Exposure to terrestrial organisms would be extremely minimal.

Additional Data Required

EPA is requiring product-specific data including product chemistry, acute toxicity, and efficacy studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All aliphatic alcohol end-use products must comply with EPA's current pesticide product labeling requirements. In addition, the following statement must be added to the label of each product, except sterilant products, that is registered for treatment of any medical device or medical equipment surface:

"This product is not to be used as a terminal sterilant/high level disinfectant 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. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

Regulatory Conclusion

The use of currently registered products containing aliphatic alcohols (ethanol and isopropanol) 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.

Aliphatic alcohol products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for aliphatic alcohols 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 document 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), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the aliphatic alcohols RED document also 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 EPA's pesticide reregistration program, the aliphatic alcohols RED, or reregistration of individual products containing aliphatic alcohols, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

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