United States
Environmental Protection
Agency

Office of Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-93-023
December 1993

EPA

Reregistration Eligibility Decision (RED)

Lithium Hypochlorite

Printed on Recycled Paper

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA-738-F-93-018
December 1993

EPA R.E.D. FACTS

Lithium Hypochlorite

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 lithium hypochlorite.

Use Profile

Lithium hypochlorite is an algicide, disinfectant, fungicide and food contact surface sanitizer. Its primary pesticidal use is to control algae, bacteria and mildew in swimming pool water systems, hot tubs and spas; approximately 2,000,000 pounds of the active ingredient were used for this purpose in 1989. It also is used to sanitize food and cheese processing plant equipment, dairies, and eating establishment equipment and utensils. Lithium hypochlorite is formulated as a ready-to-use liquid and a soluble solid concentrate. It is applied to swimming pool water using a skimmer basket, and to equipment or utensils by hand or through use of a dish washing machine. Lithium is an element that occurs naturally at low levels in food and drinking water.

Regulatory History

Lithium hypochlorite was first registered in the U.S. in 1963, and has been used chiefly as a sanitizer in swimming pools. The Food and Drug Administration (FDA) lists the chemical as a sanitizer on food contact surfaces (please see 21 CFR 178.1010). EPA's Office of Water regulates

discharges into water systems through the National Pollutant Discharge Elimination System (NPDES) permit program.

EPA issued a Data Call-In (DCI) Notice in September 1992 requiring product chemistry and ecological effects data for lithium hypochlorite. Currently, 40 pesticide products are registered which contain this active ingredient, and no new uses are pending.

Human Health Assessment

Toxicity

In laboratory animal studies, technical grade lithium hypochlorite has been shown to be highly corrosive, placing it in Toxicity Category I (indicating the highest degree of acute toxicity) for both eye and skin irritation. It is moderately acutely toxic in acute oral and dermal toxicity studies, placing it in Toxicity Category III for oral toxicity and Toxicity Category IV for dermal toxicity. No mutagenic effects were seen in a battery of studies.

Studies on human use of lithium-containing drugs, including chronic use, have not shown any reason for concern over continued human exposure to lithium following its use as a pesticide. The medicinal exposures are at a much higher level than that which results from the compound's pesticide uses. Studies of people who swam in pools or bathed in spas treated with lithium hypochlorite/ chloride show no significant absorption of lithium through human skin. Accidentally swallowing pool or spa water should not increase exposure to lithium beyond that which occurs ordinarily through ingesting food and drink.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of lithium hypochlorite since no food or feed uses are registered.

Occupational and Residential Exposure

During application of pesticide products that contain lithium hypochlorite, workers may experience dermal and inhalation exposure (for example, while hand-washing utensils). However, this exposure does not pose significant concerns except to the eye and skin of workers who handle concentrated or solid formulations. Appropriate label precautions requiring eye and skin protection will continue to mitigate these risks. Post-application exposure is considered minimal, as the exposure is to a diluted material.

Human Risk Assessment

Since lithium hypochlorite has no food or feed uses, dietary risk is not expected. The chemical causes severe irritation and is corrosive to eyes and skin, but exhibits only moderate acute oral and dermal toxicity. To protect

applicators' eyes and skin, appropriate label precautions regarding use of protective clothing (including safety glasses or goggles and chemical-resistant gloves) continue to be required. No human health risk of concern is expected.

Environmental Assessment

Environmental Fate

Lithium hypochlorite, like all the hypochlorite salts, forms hypochlorous acid when dissolved in water; it is hypochlorous acid that exhibits actual pesticidal activity. Its mode of action is its oxidizing (sanitizing) effect on organic and inorganic contaminants. This disinfection by chlorination is achieved by maintaining a "free residual chlorine" concentration.

The major environmental/ecological concern would be if discharged effluent treated with hypochlorites showed free residual chlorine concentrations that exceeded those stipulated under NPDES permits. Since there are many forms of cations used to form hypochlorite salts (e.g., calcium, sodium, and lithium), it would be difficult to trace the source of contamination in cases where free residual chlorine concentrations are too high.

EPA conducted a Tier Ic Estimated Environmental Concentration (EEC) model to assess the residue levels of lithium hypochlorite in the receiving stream from several use sites. This model provides a reasonable worst case estimate of the maximum concentrations that may occur immediately downstream from an industrial point source discharge site under typical and high exposure scenarios. Results are discussed below.

Ecological Effects

Lithium hypochlorite is considered slightly toxic to nontoxic to avian species, and it is not expected to be found in the environment at levels of concern. Therefore, risk to avian species is expected to be minimal. Toxicity to fish and aquatic invertebrates, however, is considered very high.

Ecological Effects Risk Assessment

The results of the Tier Ic EEC stream flow screening model described above show that levels of concern would be exceeded during both high exposure and typical exposure scenarios for fish and aquatic invertebrates. Therefore, aquatic organisms may be at risk from typical use/exposure as well as from high use/exposure.

The discharge of water containing residues of lithium hypochlorite is regulated by the NPDES permit program administered by EPA. Exposure and risk to freshwater aquatic organisms should be considered in determining acceptable levels for such permits so that toxic levels are avoided.

Endangered Species

Both the typical and the high exposure scenarios described above exceed the levels of concern for endangered aquatic organisms. Effluent containing lithium hypochlorite should not be discharged into streams or waterways that endangered aquatic organisms are known to frequent. EPA is working with the U.S. Fish and Wildlife Service to develop a program to avoid jeopardizing the continued existence of identified species by the use of pesticides. When this program goes into effect, endangered species labeling will be required.

Additional Data Required

The generic data base for lithium hypochlorite is substantially complete. The Agency is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

All end-use products containing lithium hypochlorite must comply with EPA's current pesticide product labeling requirements. In addition:

- **Effluent Discharge Statement** - All end-use (and manufacturing use) products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following statement:

  "This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

Regulatory Conclusion

The currently registered uses of lithium hypochlorite could pose risks to aquatic organisms under certain conditions as industrial effluent containing the parent chemical is released into receiving waters. However, the uses will not cause unreasonable adverse effects to humans or the environment, and are eligible for reregistration.

Products containing lithium hypochlorite as the sole active ingredient will be reregistered once the required product-specific data, CSF and revised labeling are received and accepted by EPA. Products also containing other active ingredients will be reregistered only after the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for lithium hypochlorite 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.

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

For more information about EPA's pesticide reregistration program, the lithium hypochlorite RED, or reregistration of individual products containing lithium hypochlorite, 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 6:00 pm Central Time, Monday through Friday.

REREGISTRATION ELIGIBILITY DECISION

Lithium Hypochlorite

LIST C

CASE 3084

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

TABLE OF CONTENTS

LITHIUM HYPOCHLORITE REREGISTRATION ELIGIBILITY DECISION TEAM i

GLOSSARY OF TERMS AND ABBREVIATIONS iii

EXECUTIVE SUMMARY v

I. INTRODUCTION 1

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

III. SCIENCE ASSESSMENT 4
- A. Physical Chemistry Assessment 4
- B. Human Health Assessment 5
  - 1. Toxicology Assessment 5
    - a. Acute Toxicity 5
    - b. Reproductive and Developmental Toxicity 6
    - c. Mutagenicity 7
    - d. Metabolism 7
    - e. Other Toxic Endpoints 7
  - 2. Exposure Assessment 8
    - a. Dietary Exposure 8
    - b. Occupational and Residential 8
  - 3. Risk Assessment 8
    - a. Dietary 9
    - b. Occupational and Residential 9
- C. Environmental Assessment 9
  - 1. Environmental Fate 9
    - a. Environmental Chemistry, Fate and Transport 9
    - b. Environmental Fate Assessment 11
  - 2. Ecological Effects 13
    - a. Ecological Effects Data 13
      - (1) Terrestrial Data 13
      - (2) Aquatic Data 13
    - b. Ecological Effects Risk Assessment 13
      - (1) Industrial Biocide Use Pattern 13
      - (2) Swimming Pool Use Pattern 14

IV. RISK MANAGEMENT AND REREGISTRATION DECISION 16
A. Determination of Eligibility 16
1. Eligibility Decision 17
2. Eligible and Ineligible Uses 17

V. ACTIONS REQUIRED BY REGISTRANTS 17
A. Manufacturing-Use Products 17
1. Additional Generic Data Requirements 18
2. Labeling Requirements for Manufacturing-Use Products 18
B. End-Use Products 18
1. Additional Product-Specific Data Requirements 18
2. Labeling Requirements for End-Use Products 19
C. Existing Stocks 19

VI. APPENDICES 21
APPENDIX A. Table of Use Patterns Subject to Reregistration 23
APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision 27
APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Lithium Hypochlorite 33
APPENDIX D. List of Available Related Documents 41
APPENDIX E. 45
PR Notice 86-5 47
PR Notice 91-2 67
APPENDIX F. Product Specific Data Call-In 73
Attachment 1. Chemical Status Sheet 87
Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions 89
Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions 93
Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration 99
Attachment 5. EPA Acceptance Criteria 105
Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice 119
Attachment 7. Cost Share Data Compensation Form, and Confidential Statement of Formula Form 121

LITHIUM HYPOCHLORITE REREGISTRATION ELIGIBILITY DECISION TEAM
Office of Pesticide Programs:

Biological and Economic Analysis Division

Martin S. Lewis	Biological Analysis Branch
Rafael Prieto	Economic Analysis Branch

Environmental Fate and Effects Division

Sharlene Matten	Science Analysis and Coordination Staff
Silvia Termes	Environmental Fate and Groundwater Branch
R. David Jones	Environmental Fate and Groundwater Branch
Dana Lateulere	Ecological Effects Branch

Health Effects Division

Linda Kutney	Chemical Coordination Branch
Pat McLaughlin	Toxicology Branch II
William Hazel	Chemistry Branch-Reregistration Support
Winston Dang	Occupational and Residential Exposure Branch

Registration Division

Wallace Powell	Antimicrobial Program Branch
Shyam Mathur	Registration Support Branch
JoAnne Hayes	Registration Support Branch

Policy and Special Projects Staff

Deborah Hartman

Special Review and Reregistration Division

Ron Kendall	Accelerated Reregistration Branch
Teung Chin	Accelerated Reregistration Branch

Office of Compliance Monitoring:

Shruti Sanghavi	Pesticides Enforcement Policy Branch

Office of General Counsel:

Bret R. Williams

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe as designated by FDA
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_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin Of Exposure (PAD)
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
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TMRC	Theoretical Maximum Residue Contribution.

EXECUTIVE SUMMARY

Lithium hypochlorite is an algicide, disinfectant, fungicide and food contact sanitizer. It is produced by FMC Lithium Division and Olin Corporation and is registered for use in swimming pool water systems (including hot tubs and spas), and also on food processing plant equipment, dairies/cheese processing plant equipment, and in eating establishments for equipment/utensils. Lithium hypochlorite is listed by the FDA for use as a sanitizer on food contact surfaces in 21 CFR 178.1010. Lithium discharges into water systems are regulated through NPDES permits.

The Agency has determined that the uses of lithium hypochlorite as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency does have some concern about possible adverse effects to aquatic organisms from the discharge of effluent from industrial uses into the environment. However, such discharge is limited through the National Pollution Discharge Elimination System which the Agency defers to for regulation.

Before reregistering the products containing lithium hypochlorite, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing for each registration. 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 all the other active ingredients in those products 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 registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of lithium hypochlorite. The document consists of six sections. Section I is the introduction. Section II describes lithium hypochlorite, 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 lithium hypochlorite . Section V discusses the reregistration requirements for Lithium Hypochlorite . Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request[1].

[1]. EPA's review of data in the set of registered uses considered for EPA analysis may be obtained from the EPA Public Docket, Field Operations Division, 7506C, EPA, Washington D.C. 20461.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Lithium hypochlorite
- **Chemical Name:** Lithium hypochlorite
- **CAS Registry Number:** 13840-33-0
- **OPP Chemical Code:** 14702
- **Empirical Formula:** LiOCl
- **Trade and Other Names:** Lithio™ Lithium hypochlorite; Formula 2™
- **Basic Manufacturer:** Olin Corporation
  FMC Lithium Division

B. Use Profile

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

<u>Lithium Hypochlorite</u>:

Type of Pesticide: Algicide, Disinfectant, Fungicide and Food contact sanitizer.

Use Sites: Aquatic Non-Food Residential: swimming pool water systems (including hot tubs and spas).

Indoor Food: Food processing plant equipment, Dairies/cheese processing plant equipment, Eating establishments equipment/utensils.

Target Pests: Bacteria, Aquatic Algae and bacteria, Mildew.

Formulation Types Registered: Type--Manufacturing use, End use.Form--Liquid Ready-to-use, Soluble solid concentrate.

Method and Rates of Application:

Equipment- Aquatic non-food residential: skimmer basket.
Indoor Food: By Hand, Dish washing machine.

Method and Rate - Aquatic non-food residential: Water treatment, from 1 to 13 ppm available chlorine by weight.
Indoor food: Equipment treatment, from 43 ppm by weight to 181 ppm available chlorine by volume.

Timing - Aquatic non-food residential: Initial, Subsequent/maintenance, Shock/slug, Winterizing

Indoor-food: Not specified

Use Practices Limitations:

Minimum pH of 7.2 and maximum pH of 7.8 for aquatic non-food residential, Preclean claim for sanitizing.

C. Regulatory History

Pesticide products containing lithium hypochlorite as an active ingredient were first registered in the United States in 1963. Currently, there are 40 products registered by 17 companies. These products are chiefly used in swimming pools as a sanitizer. Most of the registered products are granular and ready-to-use. A few products are registered for use in indoor food areas.

As part of the reregistration process, a Data Call-In Notice was issued on September 24, 1992, for lithium hypochlorite requiring registrants to generate and submit product chemistry and ecological effects data to complete the target data base for reregistration. These data have been submitted to the Agency and are incorporated into this reregistration decision.

Lithium hypochlorite is listed by the FDA for use as a sanitizer on food contact surfaces in 21 CFR 178.1010. Discharges of effluent containing lithium into water systems are regulated through National Pollutant Discharge Elimination System (NPDES) permits. No new uses are pending as of the date of this RED.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The chemical lithium hypochlorite is manufactured by chlorinating a solution containing lithium hydroxide and sodium hydroxide in the presence of diluents such as sodium sulfate and potassium sulfate.

$$LiOH + NaOH + Cl_2 \text{-------}> LiOCl + NaCl + H_20$$

The solution of LiOCl thus produced is continuously cooled (to avoid thermal decomposition) and spray dried. The spray dried fines (maximum particle size 30 mu) are compacted, granulated, and screened to produce a granular product of about -10 to +70 mesh particle size. The Physical/Chemical Properties of lithium hypochlorite are summarized below:

Molecular Weight: 58.4

Physical State: Granular solid

Odor: Odorless or with slight odor of chlorine

Melting Point: 135°C with decomposition

Bulk Density: 58 lbs/ft^3

Solubility: Total solubility in water-43% by weight at 25°C

Vapor Pressure: Water (22 mm Hg) at 20°C

Dissociation Constant: 3.2×10^{-8} (of HOCl in aqueous solution)

pH: 9.9(available Cl_2 - 100 ppm); 10.3(available Cl_2 - 200 ppm); 10.7 (available Cl_2 - 300 ppm) in water at 25°C.

Stability: Stable and retains 90% of available chlorine when stored in fiber containers with aluminum overwrap at 75°F(23.88° C) and 75% relative humidity for 4 months.

Oxidizing/ Reducing: Lithium hypochlorite with 39% available chlorine has some oxidizing effect.

Explodability: Formulations of 39% available chlorine or less are not classed as dangerous articles under Interstate Commerce Commission Regulations.

Storage Stability: During 60 days' storage at 43°C lithium hypochlorite loses 12% of available chlorine. The storage stability data for lithium hypochlorite containing 1% to 10% available chlorine show that it is identical or similar to that of sodium hypochlorite solution.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on lithium hypochlorite is adequate and will support reregistration eligibility. The primary toxicological consideration is the effect from exposure to the lithium ion that is produced from the reaction of lithium hypochlorite with water produces hypochlorous acid and lithium ions. Hypochlorous acid (which is an oxidizing agent and the chemical species showing actual pesticidal activity) acts by oxidizing organic and inorganic chemical contaminants. As hypochlorous acid exerts its oxidizing effect, the chlorine reduces to chloride ions. Thus the end - products of lithium hypochlorite are chloride and lithium ions, both ubiquitous in the environment, and adverse effects from the incremental lithium hypochlorite contribution are not expected.

a. Acute Toxicity

Data from an acute oral toxicity study in rats indicated LD_{50}s of 748 mg/kg for males and 555 mg/kg for females. This study, which used technical lithium hypochlorite, indicates category III toxicity (MRID 40803901). A second acute oral toxicity study (MRID 234351) in rats that was conducted only in male animals is useful for indicating the nature of the observed effects. The effects in the rats were primarily due to the corrosive nature of the substance and included inflamed gastric mucosa and lungs, distended stomach, congested kidneys, yellow purulent material in chest cavity, and labored respiration. The oral LD_{50} for males in this study was 286 mg/kg.

The dermal LD_{50} was approximately 8100 mg/kg for female and male rabbits, which is category IV toxicity (MRID# 234351). The effects were dermal necrosis, severe erythema, anorexia, depression, and lack of body fat.

The corrosive nature of lithium hypochlorite puts this compound in toxicity category I for both eye irritation and dermal irritation. A dermal sensitization study, which used solid lithium hypochlorite as a 10% solution in saline, did not demonstrate any dermal sensitization (MRID 252294).

Acute Toxicity Study Results-- Lithium Hypochlorite

TEST	RESULT (MG/KG)	CATEGORY
Oral LD_{50} - Rat	746 mg/kg for males 555 mg/kg for females	III
Dermal LD_{50} - Rabbit	8100 mg/kg both sexes	IV
Eye Effects - Rabbit	Severe irritation	I
Skin effects - Rabbit	Severe irritation	I
Dermal sensitization - Guinea pig	Not sensitizing	N.A.

b. Reproductive and Developmental Toxicity

In a developmental toxicity study four groups of 25 female rats were given, by gavage, lithium hypochlorite on gestation days six through fifteen (MRID 40648101) with one additional group of 25 rays as control. The dose levels were 0, 10, 50, 100, or 500 mg/kg/day using 30% test substance in water. The maternal and developmental NOELs were 100 mg/kg/day of lithium hypochlorite, which is equivalent to 4.1 mg/kg/day of lithium. The maternal LOEL was at 500 mg/kg/day, based on deaths, reduced weight gain, reduced food consumption, and inflamed and congested respiratory system. The developmental LOEL was also at 500 mg/kg/day, where the fetuses showed reduced fetal weight, dilated renal pelvis, bifid vertebrae, wavy ribs, and unossified foot bones.

A survey of animal studies in the published literature (MRID 41367401) generally found the no-effect levels at or above 4.5 mg/kg/day of lithium. None of the studies showed developmental effects at levels below those which showed maternal toxicity. Human studies related to pregnancy and

lithium drug consumption were of various types and had varied findings, but all dealt with much higher levels of lithium intake than are expected from pesticide use.

c. Mutagenicity

Technical lithium hypochlorite was negative, with and without metabolic activation, in an Ames test for mutagenicity using five strains of Salmonella (MRID 40545702). A study of unscheduled DNA synthesis in rat hepatocytes using technical lithium hypochlorite was also negative (MRID 40545704). Lithium hypochlorite was negative in the CHO/HGPRT mutation assay with and without activation (MRID 40545701). A test for chromosome aberration in CHO cells with technical lithium hypochlorite was positive (MRID 40545703). However, a test for chromosomal aberrations in rat bone marrow cells was negative with lithium hypochlorite (MRID 40907500).

d. Metabolism

The lithium ion is rapidly absorbed after ingestion and is distributed through the body. It is excreted by the kidney and most of the ion is excreted within 6-8 hours after ingestion (MRID 240927).

e. Other Toxic Endpoints

The average background level of lithium in human serum has been reported as 0.014 mg/L, which comes primarily from the natural content of lithium in food and drinking water (MRID 41367401). It has been estimated that the natural sources of lithium provide 2.3-4.9 mg/day of lithium.

Lithium carbonate has been used as a human drug since about 1970. The intake levels are 179 to 282 mg/day of lithium ion and they provide about 4.16 to 8.33 mg/L of lithium in the serum (MRID 41367401). For the therapeutic use, the reported maximum no-toxicity levels are 10.41 to 13.88 mg/L in serum. These levels are far higher than the background levels and higher than any expected from pesticide use of lithium hypochlorite. In addition, lithium orotate and lithium aspartate salts are sold as over-the-counter mineral supplements that provide about 5 mg of lithium per daily dose. Clinical and epidemiologic studies on human use of lithium-containing drugs, including chronic use, have not shown any reason for concern over continued human exposure to lithium in a pesticidal use scenario.

Information on the effects to humans exposed to lithium not by natural sources or by therapeutic treatment is also available. One study looked at the levels of lithium in the urine of people who had been swimming in pools treated with lithium hypochlorite. No indication was found that these exposures led to significant lithium absorption (MRID 240927).

A controlled study on dermal absorption was conducted with humans who bathed in spas containing lithium chloride in the water. The subjects were exposed to solutions containing 40 to 45 ppm lithium ion for 20 minutes/day, 4 days/week for two weeks. Lithium levels in the serum of the bathers were not increased above normal serum levels (MRID 40746701). This study demonstrates that there is no significant absorption of lithium through intact human skin. Without significant absorption, there would not be intake or accumulation of lithium in the body by this route and thus, no reason for particular concern about long term dermal exposure in spas and swimming pools. There is no indication that intake by accidental drinking of water while swimming would increase the serum level of lithium nor increase intake over that ingested in ordinary food and drink. Certainly any intake in pools is not significant compared to the levels ingested in drug use.

2. Exposure Assessment

a. Dietary Exposure

There are no direct food/feed uses for this chemical; consequently there are no dietary exposure concerns and a dietary exposure assessment was not performed. Residues of lithium hypochlorite from the use of products on food contact surfaces in food processing plants and eating establishments are limited under the FFDCA regulations, 21 CFR 178.1010, to solutions containing no more than 200 ppm of available chlorine and 30 ppm of lithium.

b. Occupational and Residential

Workers who handle lithium hypochlorite may be exposed to the formulated soluble concentrate or solid. The potential for dermal and inhalation exposures of workers exists (such as in hand washing of utensils). Post-application exposure is considerably less and is minimal, as the exposure is to a diluted material such as dermal exposure to swimmers.

There are no significant exposure concerns other than appropriate label precautions for eye and dermal hand protection for workers who handle

concentrated or solid lithium hypochlorite.

3. Risk Assessment

a. Dietary

As stated above there are no direct food/feed uses for this chemical; consequently there are no dietary exposure concerns and a dietary risk assessment was not performed. Regulations in 21 CFR 178.1010 state that solutions of lithium hypochlorite used on food handling surfaces can be considered safe provided they do not exceed the concentration limits referenced above.

b. Occupational and Residential

Lithium hypochlorite is a Toxicity Category I eye and dermal irritant. It is in Toxicity Category III for acute oral and Toxicity Category IV for dermal toxicity.

Because of the potential for eye and dermal exposure, appropriate label precautions are required. The current requirements for protective clothing, including safety glasses or goggles and chemical-resistant gloves while using MP or end-use products must be continued to reduce exposure potential. Post-application exposure to the compound in swimming pools is expected to be minimal. Because these exposures are expected to be low no human health risk of concern is expected.

C. Environmental Assessment

1. Environmental Fate

The Agency is relying on data available in the scientific literature to assess the environmental fate and transport of lithium hypochlorite used as a pesticidal compound.

a. Environmental Chemistry, Fate and Transport

Lithium hypochlorite, like all of the other hypochlorite salts (sodium, potassium, calcium) form hypochlorous acid when dissolved in water.[1, 2, 3] Thus, lithium hypochlorite can be considered as a precursor to hypochlorous acid. Hypochlorous acid is the chemical species exhibiting actual pesticidal activity. The pesticidal mode of action of hypochlorous acid is linked to its oxidizing effect on organic and inorganic

contaminant sources.[3] The environmental fate of lithium hypochlorite is essentially that of hypochlorous acid. The advantage of lithium hypochlorite over calcium hypochlorite is that lithium hypochlorite can be used in hard waters (that is, waters in which the concentrations of calcium and magnesium ions are above 3 milliequivalents per liter [5]), where the use of a calcium salt would be contraindicated.[1]

Hypochlorous acid is a weak acid; the pK_a of hypochlorous acid at 25^0 C is 7.4.[4] In acidic pH, the predominant species is undissociated hypochlorous acid; in the neutral range small amounts of hypochlorite anions are present together with hypochlorous acid. The acid is completely dissociated into hypochlorite anions and hydronium ions only at very high pH. The maximum decomposition rate of hypochlorous acid occurs at pH 6.89.[4] For swimming pool sanitation it is recommended that the pH be maintained between 7.2 and 7.6, where hypochlorous acid predominates together with hypochlorite anions.

The mechanisms and rates of decomposition of hypochlorous acid and hypochlorite anions are not only dependent on pH, but also on concentration and temperature.[1, 2, 4] Sunlight affects the decomposition of hypochlorous acid/ hypochlorite as these species absorb in the 292 to 380 nm region.[4] The concentration and nature of organic and inorganic matter present in the aqueous media have an effect on the decomposition of hypochlorous acid; redox reactions are involved in this case. The oxidation state of chlorine in hypochlorous acid and hypochlorite is +1.

The oxidizing effect (and hence the sanitation properties) can be either associated with hypochlorous acid or with the hypochlorite anion, but rarely to both species simultaneously.[1] In disinfection by chlorination operations it is customary to use the expression "free residual chlorine" to define the sum of the concentrations of hypochlorous acid and hypochlorite anions; "free residual chlorine" is often used as a measure of the effectiveness of chlorination, which is also a measurement of the available chlorine in solution.[5]

The aim in disinfection is to add sufficient chlorinating agent to achieve "free residual chlorine." The most common redox reactions are [1] the oxidation of iron(II), sulfide and organic matter, in which chlorine (+1) is reduced to chlorine (-1) (that is, to chloride). This is followed by formation of chloroamines and chloroorganic compounds, which are then further oxidized by addition of sufficient disinfectant to achieve a "free residual chlorine". The recommended rates of application (in terms of available chlorine by weight) for aquatic non-food (residential) uses of lithium hypochlorite varies from 1 to 13 ppm; for indoor food handling

establishment uses it varies from 43 ppm by weight to 181 ppm by volume.

b. Environmental Fate Assessment

Water sanitation with hypochlorite salts is widely used. Products containing lithium hypochlorite carry NPDES permit restrictions. The major environmental/ecological concern would be if discharged effluent treated with hypochlorites show free residual chlorine concentrations that exceed those stipulated under the NPDES permits. Note that free residual chlorine can be independent of the source of chlorination (lithium, sodium, calcium, potassium hypochlorites; chlorinated isocyanurates; chlorine gas) since all of these materials form hypochlorous acid in water. Thus, in cases where free residual chlorine levels may be found above recommended levels, it may be difficult to trace the source of contamination considering that the counter cations (lithium, sodium, calcium and potassium) are ubiquitous in nature.

A fate model was used to determine the Tier lc[2] estimated environmental concentration (EEC) for lithium hypochlorite from effluent discharge after lithium hypochlorite products are used in food processing plants and eating establishments. A single EEC was calculated to represent the milking equipment, food processing plants, and eating establishment uses (Table 1). The EEC has been presented in several different representations for easy comparisons to hazard data. Although the primary use of lithium hypochlorite is for swimming pools, no EEC was calculated for this use as discharge data are not available for swimming pools. However, it would be expected that the exposure from the swimming pool use pattern is small as discharges may occur only once or twice a year should pools be drained.

A Tier lc EEC provides the maximum concentration that occurs immediately downstream from an industrial (point source) discharge site. The EECs calculated are those for a high exposure site with a return frequency of 1 in 10 years. The high exposure site represents a site that would be expected to produce larger EECs than 90% of all sites with the specified use pattern. A one in 10 year EEC has a 10% probability of being equalled or exceeded in any single year at a given site, or, would be equalled or exceeded once every ten years at that site on a long term average. This is similar to the site and frequency assumptions that are

[2] A tier 1c EEC is a preliminary or lower exposure assessment for industrial biocides.

generally being used for agricultural pesticides. EECs for a 50% (typical site) at mean stream flow were also calculated. These values are listed in Table 1 on a lithium hypochlorite basis.

Table 1. Tier 1c EECs for Lithium Hypochlorite at Food Processing Facilities

Chemical Representation	High Exposure Case	Typical Exposure Case
LiOCl	88 $mg \bullet L_{-1}$	0.300 $\mu g \bullet L^{-1}$
as Cl, Cl^{-1}, or "available chlorine"	53 $mg \bullet L^{-1}$	0.179 $\mu g \bullet L^{-1}$
as $O^{-1}CL$	77 $mg \bullet L^{-1}$	0.260 $\mu g \bullet L^{-1}$

Following is a description of the Agency's method for estimating the environmental concentrations. Two products, E-Z Chlor Litho Industrial Sanitizer (EPA Reg. # 8791-51), manufactured by E-Z Chlor Systems, Inc, and Lithco Lithium Hypochlorite (EPA Reg. # 7675-4), manufactured by FMC Lithium Division, have uses for sterilizing milking equipment, in food processing plants, and in eating establishments. All these uses are represented as Publicly Owned Treatment Works (POTW) (SIC Code 4952) as recommended by the Agency's, Office of Pollution Prevention and Toxics (OPPT). The concentration in the waste stream is assumed to be the same as the application rate, 210 ppm; this assumes that no degradation of the hypochlorite occurs in the processing stream. The concentration in the waste stream is then used to calculate the concentration in the receiving stream immediately downstream from the discharge site. Dilution factors are taken from a compilation of dilution factors compiled for the Agency [6]. All sites in the classification are then ranked from best to worst based on the mean flow in water body receiving the waste stream. The typical EEC is then calculated by dividing the waste stream concentration by the tabulated dilution factor for the mean flow condition at the median site. The high exposure EEC is calculated by using the dilution factor tabulated for the 90% site (90% of the sites had greater mean stream flows) for the low flow condition at the site, which is the seven day mean low flow that would be expected to occur once in 10 years.

Because Tier lc EECs make many very conservative assumptions and do not address the environmental fate of the pesticide, they may significantly

overestimate the true exposure to the chemical. A higher tier EEC calculation which more accurately reflects the fate and transport properties of hypochlorite would likely show that the risk is less than that reported in the Ecological Effects section below. There is some evidence that hypochlorite degrades within hours in aquatic environments [7] which would significantly reduce the exposure. Waste water treatment prior to discharge, restriction on discharge during low flow periods and other methods which may be available through the NPDES permitting process may reduce EECs below the level of concern at each site using the pesticide.

2. Ecological Effects

a. Ecological Effects Data

(1) Terrestrial Data

The acute toxicity of lithium hypochlorite to mallard ducks is classified as slightly toxic with an LD_{50} of 567.0 mg/kg active ingredient(MRID# 94673). The dietary toxicity to bobwhite quail is classified as almost nontoxic with an LC_{50} of greater than 5,000 ppm(MRID# 104674).

(2) Aquatic Data

The 96-hour acute toxicity to rainbow trout was reported as an LC_{50} of 0.20 mg a.i./L.; thus, classifying lithium hypochlorite as highly toxic to cold water fish(MRID# 94672). The 48-hour acute toxicity to Daphnia magna was reported as an EC_{50} of 23.0 μg a.i./L; thus, classifying lithium hypochlorite as very highly toxic to aquatic invertebrates(MRID# 94674).

b. Ecological Effects Risk Assessment

(1) Industrial Biocide Use Pattern

Lithium hypochlorite is considered slightly toxic to nontoxic to avian species. Due to hypochlorite's reactivity, any level of exposure would be expected to dissipate rapidly as contact is made with organic matter in the environment. In addition, it is not expected to be found in the environment at levels that are hazardous. Therefore, risk to avian species is expected to be minimal. Toxicity to fish and aquatic

invertebrates is considered very high. The Agency determined a single Tier Ic EECs, as documented above, (estimated environmental concentration) to represent the aquatic residues occurring immediately downstream from the milking equipment, food processing plants, and eating establishment use discharges.

Toxicity to fish and aquatic invertebrates is considered extremely high. A stream flow screening model was utilized by the Agency to determine a "high exposure case" and a "typical exposure case" EEC - these numbers depict the highest value that could occur in these situations. The Agency determined a single Tier Ic EEC (estimated environmental concentration), as documented above, to represent the aquatic residues occurring immediately downstream from the milking equipment, food processing plants, and eating establishment use discharges. Even though the freshwater LOCs have been triggered for the high exposure scenario, there is significant experience in the use and NPDES permitting of industrial microbicidal uses of lithium hypochlorite to mitigate the aquatic risk. The permitting system that is in place is the appropriate mechanism to set the appropriate discharge limits based on the receiving body of water.

When the EEC is greater than or equal to 1/2 the LC_{50}, the level of concern (LOC) for acute effects is exceeded. As the high level of exposure EEC of 88 ppm is greater than and the typical exposure EEC of 0.300 ppb is less than 1/2 the LC_{50} values for rainbow trout and Daphnia magna (100 ppb and 11.5 ppb, respectively), LOC's for acute aquatic risk are exceeded only for the high exposure scenario. Therefore, aquatic organisms may be at high risk from only the high use exposure, but not from the typical use exposure. However, the Agency cannot state with any degree of certainty whether there will be a significant risk under the high exposure scenario due to the use of lithium hypochlorite as an industrial biocide.

(2) Swimming Pool Use Pattern

The Agency could not calculate a Tier Ic EEC for swimming pools because there is no discharge and site data available on the receiving water. At best, The Agency can only make an intuitive risk assessment of the swimming pool use pattern. That is, there is no data to support any risk assessment conclusion for the swimming pool use pattern. However, there are mitigating factors in which the Agency may conclude that the aquatic organism exposure resulting from swimming pool drainage is minimized. First, it is not customary to routinely empty and refill pools. Swimming pools may be emptied at the end of the swimming season or for maintenance. It is not expected that these drainings would be very

frequent, at most, twice per year. Second, one would be unlikely to treat a swimming pool with lithium hypochlorite and then immediately discharge the water into a lake or stream. Third, direct discharge of swimming pool water into a lake or stream is probably not typical. Pools are most often drained either directly into the area immediately surrounding the pool or into municipal sewage systems. In either case, the reactivity of hypochlorite ions with organic matter and the pathway to a natural body of water, as well as the organic matter in the receiving body of water, greatly reduces the levels of hypochlorite available to aquatic organisms.

The Ambient Water Quality Criteria for Chlorine - 1984 (Office of Water, EPA 440/5-84-030, 1985) is used to regulate the discharge of chlorine forming chemicals into receiving waters. The document states:

"..except possibly where a locally important species is very sensitive, freshwater aquatic organisms and their uses should not be affected unacceptably if the four-day average concentration of total residual chlorine does not exceed 11 µg/1 (ppb) more than once every three years on the average and if the one-hour average concentration does not exceed 19 µg/L (ppb) more than once every three years on the average.

....except possibly where a locally important species is very sensitive, saltwater aquatic organisms and their uses should not be affected unacceptably if the four-day average concentration of total residual chlorine produced oxidants does not exceed 7.5 µg/L (ppb) more than once every three years on the average and if the one-hour average concentration does not exceed 13 µg/L (ppb) more than once every three years on the average.

The recommended exceedence frequency of three years is the Agency's best scientific judgment of the average amount of time it will take an unstressed system to recover from a pollution event in which exposure to chlorine exceeds the criterion. Stressed systems, for example, one in which several outfalls occur in a limited area, would be expected to require more time for recover. The resilience of ecosystems and their ability to recover differ greatly, however, and site-specific criteria may be established if adequate justification is provided."

The EECs as determined by the Agency, exceed the Agency's Office of Water Criteria for 'unacceptable exceedence' for freshwater organisms. The uses for lithium hypochlorite are covered under NPDES permit regulation; the exposure and subsequent risk to freshwater organisms should be included in the determination of acceptable regulatory levels for

this permit.

Endangered Species

When the EEC is greater than or equal to 1/20 the LC_{50}, the LOC for endangered species is exceeded. As the high exposure EEC of 88 ppm is greater than and the typical exposure EEC of 0.300 ppb is less than 1/20 the LC_{50} values for rainbow trout and the Daphnia magna (10 ppb and 1.15 ppb), LOC's for acute risk are exceeded only for the high exposure scenario. Therefore, endangered aquatic organisms may be at high risk from only the high use exposure but not from the typical use exposure.

Based on the registered uses, lithium hypochlorite is expected to be discharged at a number of different sites; endangered species may be present in these aquatic sites. Based on these EEC screening values effluent containing lithium hypochlorite should not be discharged into streams and other waterways where endangered aquatic organisms are known to frequent.

At the present time, the Agency is working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species by the use of pesticides. When the Endangered Species Protection Program is implemented and subsequent guidance is given, endangered species labeling amendments may be required on affected end-use products. Labeling statements for end-use products will likely refer users to county specific bulletins specifying detailed limitations on use to protect endangered species.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing lithium hypochlorite. 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 lithium hypochlorite. 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. Appendix B

identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of lithium hypochlorite, 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 lithium hypochlorite and to determine that lithium hypochlorite can be used without resulting in unreasonable adverse effects to humans. Conversely, the Agency has some concerns about possible adverse risks to aquatic species from discharge of effluent containing lithium hypochlorite. Since this discharge is regulated through the NPDES permitting program for specific sites the Agency defers to that program to regulate the use of lithium hypochlorite products at specific sites. Likewise, the Agency will incorporate in the future appropriate risk mitigation measures to minimize impacts on endangered species. The Agency therefore finds that all products containing lithium hypochlorite as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

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

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients lithium hypochlorite, the Agency has sufficient information on the health effects of lithium hypochlorite and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing lithium hypochlorite for all uses are eligible for reregistration. The Agency is requiring precautionary labeling on all registered products because lithium hypochlorite is highly toxic to fish and aquatic invertebrates.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of lithium hypochlorite are eligible for reregistration.

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 lithium hypochlorite for the above eligible uses has been reviewed and determined to be complete. No additional generic data are required at this time.

2. Labeling Requirements for Manufacturing-Use Products

Effluent Discharge Labeling Statements

All manufacturing-use or end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

"This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

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.

2. Labeling Requirements for End-Use Products

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

Effluent Discharge Labeling Statements

Refer to subsection A above for labeling requirements for effluent discharge.

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; State of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

APPENDIX A - Case 3084, [Lithium Hypochlorite] Chemical 014702 [Lithium Hypochlorite]

Application Timing	Application Equipment	Application Type	Surface Type	Form	Minimum Application Rate (ppm a.i.)	Maximum Application Rate (ppm a.i.)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval	Geographic Limitations		Use Limitations
											Allowed	Disallowed	
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
Site: Dairies/Cheese Processing Plant Equipment (Food Contact)			**(Use Group: INDOOR FOOD)**										
			equipment treatment, NOL, NOL, hard	SC/S	210 W	210 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim
Site: Eating Establishments Equipment/Utensils (Food Contact)			**(Use Group: INDOOR FOOD)**										
			equipment treatment, NOL, by hand, hard	SC/S	210 W	210 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim
			equipment treatment, NOL, dishwashing machine, hard	SC/S	52 W	52 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim
			equipment treatment, NOL, NOL, hard	SC/S	210 W	210 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim
Site: Food Processing Plant Equipment (Food Contact)			**(Use Group: INDOOR FOOD)**										
			equipment treatment, NOL, NOL, hard	SC/S	210 W	210 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim
NON-FOOD/NON-FEED USES													
Site: Swimming Pool Water Systems			**(Use Group: AQUATIC NON-FOOD RESIDENTIAL)**										
			water treatment, initial, NOL, NA	SC/S	3 W	8 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim; 7.2 - 7.4 minimum pH; 7.6 - 7.8 maximum pH
			water treatment, shock/slug, NOL, NA	SC/S	2 W	16 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim; 7.2 - 7.4 minimum pH; 7.6 - 7.8 maximum pH
			water treatment, subsequent/maintenance, NOL, NA	SC/S	1 W	4 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; 7.2 - 7.4 minimum pH; 7.6 - 7.8 maximum pH
			water treatment, winterizing, NOL, NA	SC/S	7 W	8 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim; 7.4 minimum pH; 7.6 maximum pH
			water treatment, sock/slug, skimmer basket, NA	SC/S	6 W	6 W	NS	NS	NS	NS	NA	NA	NPDES license restriction; Preclean claim; 7.2 minimum pH; 7.6 maximum pH

breviations used

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

rm: SC/S - Soluble Concentrate/Solid
te: W - calculated by weight
general: NOL - not on the label; NA - not applicable; NS - not specified

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Lithium Hypochlorite covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Lithium Hypochlorite 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 Lithium Hypochlorite

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	GL	93138001
61-2A	Start. Mat. & Mnfg. Process	GL	42940801
61-2B	Formation of Impurities	GL	42940802
62-1	Preliminary Analysis	GL	93138002
62-2	Certification of limits	GL	42991801
62-3	Analytical Method	GL	7257
63-2	Color	GL	93138001
63-3	Physical State	GL	93138001
63-4	Odor	GL	93138001
63-5	Melting Point	GL	93138001
63-7	Density	GL	93138001
63-8	Solubility	GL	42967001
63-9	Vapor Pressure	GL	42967002
63-10	Dissociation Constant	GL	42967003
63-12	pH	GL	93138001
63-13	Stability	GL	7258
63-17	Storage Stability	GL	94669

Data Supporting Guideline Requirements for the Reregistration of Lithium Hypochlorite

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	G	94673
71-2A	Avian Dietary - Quail	G	104674
72-1C	Fish Toxicity Rainbow Trout	G	94672
72-2A	Invertebrate Toxicity	G	94674
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	GL	Waived
81-2	Acute Dermal Toxicity - Rabbit/Rat	GL	Waived
81-3	Acute Inhalation Toxicity - Rat	GL	Waived
81-4	Primary Eye Irritation - Rabbit	GL	Waived
81-5	Primary Dermal Irritation - Rabbit	GL	Waived
81-6	Dermal Sensitization - Guinea Pig	GL	Waived
84-2A	Gene Mutation (Ames Test)	GL	Waived
84-2B	Structural Chromosomal Aberration	GL	Waived
84-4	Other Genotoxic Effects	GL	Waived

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Lithium Hypochlorite

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.

BIBLIOGRAPHY

MRID	CITATION
00234351	a. Acute Oral Toxicity Study in Rats. (1977) Unpublished study prepared by Hazleton and submitted by Lithium Corp. of America. Study No. 668-103. b. Acute Dermal Toxicity Study in Rabbits. (1977) Unpublished study prepared by Hazleton and submitted by Lithium Corp. of America. Study No. 668-104. c. Primary Skin Irritation Study in Rabbits. (1977) Unpublished study prepared by Hazleton and submitted by Lithium Corp. of America. Study No. 668-105. d. Acute Eye Irritation Potential Study in Rabbits. (1977) Unpublished study prepared by Hazleton and submitted by Lithium Corp. of America. Study No. 668-106.
240927	Nelli, J. R. The Build-up of Lithium Ion in Swimming Pool Waters and Its Effect on Swimmers. (1964) Unpublished study submitted by Lithium Corp of America.
252294	Guinea Pig Maximization Test with Lithcoa Lithium Hypochlorite (1984) Unpublished study prepared by Hazleton. Study No. 668/115.
00007257	Lithium Corporation of America (1969) Analysis of Lithium hypochlorite. Includes R & D method no. 210 dated Nov 1969. (Unpublished study received Dec 29, 1972 under 7675-1; CDL: 008072-A)
00007258	Lithium Corporation of America (19??) Product Information: LCA Lithium hypochlorite: Data Sheet 111-463. (Unpublished study received Aug 28, 1964 under 7675-2; CDL:008073-A)
00094669	Lithium Corporation of American (1977) Storage Stability Data for Lithcoa Lithium Hypochlorite. (Unpublished study received Aug 24, 1979 under 7675-4; CDL:246731-B)
00094672	Buccafusco, R.J. (1978) Acute Toxicity of Lithcoa Lithium Hypochlorite to Rainbow Trout (¬ ~Salmo gairdneri~¬): Report #BW-782-031. (Unpublished study received Apr 25, 1978 under 7675-4; prepared by EG & G Bionomics, submitted by Lithium Corp. of America, Gastonia, N.C.; CDL:246732-C)
00094673	Piccirillo, V.J. (1977) Final Report: Acute Oral LDæ50¬ Study in Mallard Ducks: Project No. 668-107. (Unpublished study received Apr 25, 1978

MRID	CITATION
	under 7675-4; prepared by Hazleton Laboratories America, Inc. and Truslow Farms, Inc., submitted by Lithium Corp. of America, Gastonia, N.C.; CDL:246732-D)
00094674	LeBlanc, G.A. (1978) Acute Toxicity of Lithcoa Lithium Hypochlorite to the Water Flea (¬ ~Daphnia magna~¬): Report #BW-78-2-032. (Unpublished study received Apr 25, 1978 under 7675-4; prepared by EG & G Bionomics, submitted by Lithium Corp. of America, Gastonia, N.C.; CDL:246732-E)
00104674	Piccirillo, V.J. (1977) Final Report: Subacute Dietary LCæ50¬ Study in Bobwhite Quail: Project No. 668-109. (Unpublished study received Apr 25, 1978 under 7675-4; prepared by Hazleton Laboratories America, Inc. and Truslow Farms, Inc., submitted by Lithium Corp. of America, Gastonia, N.C.; CDL:246732-B)
40545701	Yang, L. (1988) CHO/HGPRT Mutation Assay: I1945 ¢Lithium Hypochlorite | : Study No. T5674.332005. Unpublished study prepared by Microbiological Associates Inc. 30 p.
40545702	Batt, K. (1987) Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test): Study No. I87-0975. Unpublished study prepared by FMC Corp., Genetic Toxicology Laboratory. 33 p.
40545703	Putman, D. (1988) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: I1945 ¢Lithium Hypochlorite | : Study No. T5674. 337020. Unpublished study prepared by Microbiological Associates, Inc. 29 p.
40545704	Curren, R. (1988) Unscheduled DNA Synthesis in Rat Primary Hepatocytes: I1945 ¢Lithium Hypochlorite | : Final Report: T5674.380017. Unpublished study prepared by Microbiological Associates, Inc. 28 p.
40648101	Lochry, E. (1988) Developmental Toxicity (Embro/Fetal Toxicity and Teratogenic Potential) Study of Lithium Hypochlorite Administered Orally via Gavage to Crl:CD(SD)BR Presumed Pregnant Rats: Sponsor's Study No. I87-0978. Unpublished study prepared by Argus Research Laboratories, Inc. 236 p.
40746701	McCarty, J.; Carter, S.; Fletcher, M.; et al. (1988) Study of Lithium Absorption by Users of Spas Treated with Lithium Ion: Study No. I87-0981.

BIBLIOGRAPHY

MRID	CITATION
	Unpublished study prepared by FMC Toxicology Dept. 225 p.
40803901	Freeman, C. (1988) Lithium Hypochlorite: Acute Oral Toxicity Study in Rats: Study No. I87-0982. Unpublished study prepared by FMC Toxicology Laboratory. 47 p.
40907500	Lithium Corporation of America (1988) Submission of Toxicity Data in Support of Lithium Hypochlorite Products. Transmittal of 1 study.
41367401	Todhunter, J.; Mandava, N. (1990) Supplemental Data and Documentation in Support of Data Waiver Requests filed by Lithium Corporation of America dated November 24, 1989: FMC Study No. I90-1108. Unpublished study prepared by SRS International. 1424 p.
42940801	Hatch, H. (1993) Beginning Materials and Manufacturing Process: FIFRA Reregistration of Lithium Hypochlorite: Product Class-C: Data Gaps in Phase III Submission. Unpublished study. 18 p.
42967001	Hatch, H. (1993) FIFRA Reregistration of Lithium Hypochlorite, Product Class-C: (Response to) Data Gaps in Phase III Submission: Solubility. Unpublished study prepared by FMC Corp. 7 p.
42967002	Hatch, H. (1993) FIFRA Reregistration of Lithium Hypochlorite, Product Class-C: (Response to) Data Gaps in Phase III Submission: Vapor Pressure. Unpublished study prepared by FMC Corp. 4 p.
42967003	Hatch, H. (1993) FIFRA Reregistration of Lithium Hypochlorite, Product Class-C: (Response to) Data Gaps in Phase III Submission: Dissociation Constant. Unpublished study prepared by FMC Corp. 10 p.
42991801	Eschbach, J. (1993) Method Validation and Determination of Lithco Lithium Hypochlorite for Swimming Pool/Spa Sanitation and Algea (sic) Control. Final Report: Lab Project Number: 93/9078: P93/0035. Unpublished study prepared by Pharmaco-LSR. 55 p.
93138001	Cinq-Mars, R. (1990) Lithium Corporation of America Phase 3 Summary of MRID 00051222 and Related MRIDs 00007258, 00031511, 00094670, 00007261, 00094669, 00094670. Chemical and Physical Properties of Lithium Hypochlorite. 34 p.

BIBLIOGRAPHY

MRID **CITATION**

REFERENCES

1. Greenwood, N.N. and Earnshaw, A. The Chemistry of the Elements, 1984, Pergamon Press, Oxford, UK. pp. 988-1013.

2. Cotton, A.F. and Wilkinson, G. Advanced Inorganic Chemistry, Fifth Edition, 1988, John Wiley and Sons, New York, pp. 560-570.

3. Wojtowicz, J.A., "Chlorine Monoxide, Hypochlorous Acid and the Hypochlorites" in Kirk-Othmer Encyclopedia of Chemical Technology, Third Edition, Vol. 5, Wiley-Interscience, New York, pp. 580-611.

4. Adam, L.C., Fabian, I., Suzuki, K. and Gordon, G. "Hypochlorous Acid Decomposition in the pH 5-8 Region", Inorganic Chemistry, 1992, vol.31, pp. 3534-3541.

5. Tchobanoglous, G. and Schroeder, E.D. Water Quality-Characteristics: Modeling: Modification, 1985, Addison-Wesley Publishing Company, Reading, MA, pp. 92; 560-571.

6. Office of Prevention and Toxic Substances. 1992. Summary of Stream Dilution Factor Program (SDFP) Outputs for 40 Industrial Categories (Updated January, 1991, 1Q10 & 3Q5 Added October, 1992.

7. Jolley, R. L. 1983. A review of the chemistry and environmental fate of reactive oxidant species in chlorinated water. in Water Chlorination: Environmental Impact and Health Effects vol. 4. pp. 3-47.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Lithium Hypochlorite. 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 Lithium Hypochlorite 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. Lithium HypochloriteRED 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.

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

D.1. Title Page

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

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

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

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

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

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

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

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

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

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

D.3. Confidential Attachment

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

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

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

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

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

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

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

D.5. Good Laboratory Practice Compliance Statement

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

E. Reference to Previously Submitted Data

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

F. Physical Format Requirements

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

Please be particularly attentive to the following points:

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

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

G. Special Requirements for Submitting Data to the Docket

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

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

V. For Further Information

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

James W. Akerman
Acting Director,
Registration Division

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

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

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

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

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

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

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

3. Transmittal date

4. List of submitted studies

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

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

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

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

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

Company Official: _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

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

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

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

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

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

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

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

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

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

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

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

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

DELETED WORDS OR PHRASE: Ethylene Glycol

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

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

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

DELETED PARAGRAPH(S):

(Reproduce the deleted paragraph(s) here)

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

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

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

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

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

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

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

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

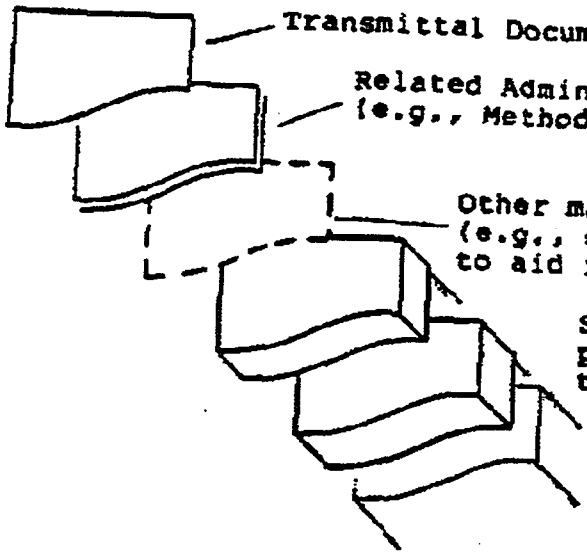
Example 3.

The 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.

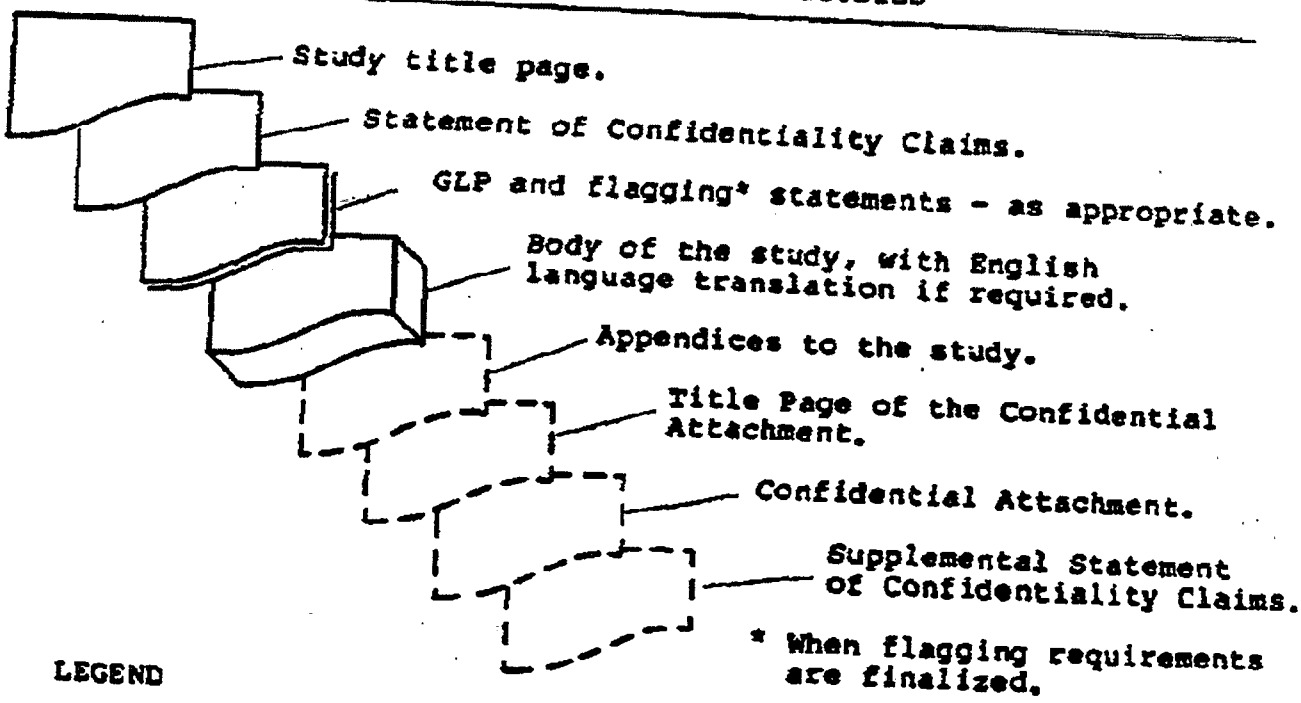
Submitter_____

ATTACHMENT 7.

FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND

Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40

CFR 158.175(c)(3).

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

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

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

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anna E. Lindsay

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

APPENDIX F. Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

This Notice is divided into six sections and seven Attachments. The Notice itself contains

information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

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

The Attachments to this Notice are:

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 Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
7 - List of Registrants Receiving This Notice
8 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data

requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the

six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending

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

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

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

Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

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 Grouping of End-Use Products for Meeting Acute Toxicology Dat 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

LITHIUM HYPOCHLORITE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Lithium Hypochlorite. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) EPA's Grouping of End[-]Use Products for Meeting Acute Toxicology Data Requirement (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), (6) a list of registrants receiving this DCI (Attachment F) and (7) the Cost Share and Data Compensation Forms in replying to this Lithium Hypochlorite Product Specific Data Call[-]In (Attachment G). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Lithium Hypochlorite, please contact Ron Kendall at (703) 308-8068.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Veronica Dutch (703) 308-8585. All responses to this Notice for the Product Specific data requirements should be submitted to:

ARB, Product Manager Team 52
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Lithium Hypochlorite**

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 reregistration numbers of your source (s); you would not complete the requirements status and registrant's response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share).

I understand that this option is available only for acute toxicity or certain efficac data and only if EPA indicates in an attachment to this Data Call-In Notice that m product is similar enough to another product to qualify for this option. I ar submitting evidence that I have made an offer to another registrant (who has a obligation to submit data) to share in the cost of that data. I am also submitting 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 tha offer. I am identifying the party which is committing to submit or provide th require data; if the required study is not submitted on time, my product may b subject to suspension. I understand that other terms under Option 3 in the Dat 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 bee submitted previously to the Agency by anyone (submitting an Existing Study). certify that this study will meet all the requirements for submittal of existing dat outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet th attached acceptance criteria (for acute toxicity and product chemistry data). I wi attach the needed supporting information along with this response. I also certify tha I have determined that this study will fill the data requirement for which I hav indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a stud 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 b upgraded and what information is required to do so. I will provide the MRID o Accession number of the study at the due date. I understand that the conditions fo 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 ha classified as acceptable or an existing study that has been submitted but not reviewe 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 efficac data and only if the cited study was conducted on my product, an identical produc or a product which EPA has "grouped" with one or more other products fo purposes of depending on the same data. I may also choose this option if I am citin 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 similar format. If I cite another registratrant's data, I will submit a complete "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my produc (Waiver Request). I am attaching a complete justification for this request, includin technical reasons, data and references to relevant EPA regulations, guidelines o policies. [Note: any supplemental data must be submitted in the format required b P.R. Notice 86-5]. I understand that this is my only opportunity to state the reason or provide information in support of my request. If the Agency approves my waive

request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

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

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

EPA'S DECISION ON BATCHING PRODUCTS CONTAINING LITHIUM HYPOCHLORITE FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient lithium hypochlorite, the Agency considered batching products. This process involves grouping similar products for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). 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 above. Acute toxicity data on individual products has frequently been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual 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 rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is cited, the registrant must clearly identify the material tested by its EPA registration number. 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.

Table I lists 3 batches of lithium hypochlorite products.

Table I.

Batch	EPA Reg. No.	% of Lithium hypochlorite	Formulation Type
1	3525-33	29.0	granules
	3525-96	"	"
	7152-15	"	"
	7152-19	"	"
	7368-68	"	"
	7675-1	"	"
	7675-4	"	"
	8791-51	"	"
	5185-384	"	"
	5185-385	"	"
	7368-75	"	"
	7675-5	"	"
	7675-7	"	"
	7675-8	"	"
	7675-9	"	"
	12014-31	"	"
	24310-1	"	"
	45309-13	"	"

Table I (cont.)

2	3432-56	29.0	granular
	3432-57	"	"
	6809-6	"	"
3	5185-323	29.0	granular
	5185-336	"	"
	5185-340	"	"
	5185-419	"	"
	5185-431	"	"
	6284-50	"	"
	7124-84	"	"
	7124-88	29.0	granular
	7675-6	"	"
	8791-34	"	"
	42177-14	"	"
	42177-15	"	"
	42177-49	"	"
	42177-54	"	"
	42177-55	"	"
	45309-5	"	"
	45309-58	"	"
	57787-14	"	"

Table II lists the products which could not be batched. For the purposes of acute toxicity batching, these products were not considered similar, or their similarity could not be determined using the information available. The registrants of these products are responsible for meeting the acute toxicity data requirements specified in the data matrix for end-use products.

Table II.

EPA Reg. No.	% of Lithium Hypochlorite	Formulation Type
1258-1194	65.0	granules
5185-369	27.0	granules
10079-4	29.0	granules

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 $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.

____ EPA Registration Number if registered; for other beginning materials, the following:

____ Name and address of manufacturer or supplier.
____ Brand name, trade name or commercial designation.
____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.

____ Statement of whether batch or continuous process.
____ Relative amounts of beginning materials and order in which they are added.
____ Description of equipment.
____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
____ Statement of whether process involves intended chemical reactions.
____ Flow chart with chemical equations for each intended chemical reaction.
____ Duration of each step of process.
____ Description of purification procedures.
____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

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 $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

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

63-3 Physical State

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

63-4 Odor

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

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

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

63-7 Density, Bulk Density, Specific Gravity

____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml <u>or</u> the specific gravity of liquids reported with reference to water at 20° C. [Note: <u>Bulk</u> density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

____ Measured at about 20-25° C

____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)

____ Data supporting reported value provided

63-12 pH

____ Measured at about 20-25° C

____ Measured following dilution or dispersion in distilled water

63-13 Stability

____ Sensitivity to metal ions and metal determined

____ Stability at normal and elevated temperatures

____ Sensitivity to sunlight determined

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.___ One of the following methods is utilized:
   _____ Freund's complete adjuvant test
   _____ Guinea pig maximization test
   _____ Split adjuvant technique
   _____ Buehler test
   _____ Open epicutaneous test
   _____ Mauer optimization test
   _____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*___ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

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

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

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

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

Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

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

21. Date

EPA Form 8570-4 (Rev. 12-90) Previous editions are obsolete. If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

structions 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.

1. 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 ail 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.

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

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
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:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-95)