



Reregistration Eligibility Decision (RED) Chlorine Gas



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Chlorine Gas. The enclosed Reregistration Eligibility Decision (RED), which was approved on December 5, 1995 contains the Agency's evaluation of the data base of this chemical, its conclusions on the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional generic data on chlorinated disinfection byproducts to confirm the risk assessments.

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

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 (FQPA) became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA. Since there are no tolerances associated with chlorine gas, the changes in tolerance reassessment required with FQPA do not affect this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Antimicrobial Division representative Wanda Mitchell at (703) 308-6345. Address any questions on required generic data to the Special Review and Reregistration Division representative Patrick Dobak at (703) 308-8180.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**
 - a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

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

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

 - d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**.

You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

Document Processing Desk (**RED-AD-RMB**)
Office of Pesticide Programs (7510C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk (**RED-AD-RMB**)
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

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

REREGISTRATION ELIGIBILITY DECISION

Chlorine Gas

LIST D

CASE 4022

TABLE OF CONTENTS

CHLORINE GAS REREGISTRATION ELIGIBILITY DECISION TEAM	i
EXECUTIVE SUMMARY	v
I. INTRODUCTION	1
II. CASE OVERVIEW	1
A. Chemical Overview	1
B. Use Profile	2
C. Data Requirements	6
D. Regulatory History	6
III. SCIENCE ASSESSMENT	6
A. Physical Chemistry Assessment	6
B. Human Health Assessment	7
1. Toxicology Assessment	7
a. Human Toxicology	7
b. Human Toxicology	9
(1) Acute Toxicity	9
(2) Subchronic Toxicity	9
(3) Chronic Toxicity	10
(4) Carcinogenicity	11
(5) Developmental Toxicity	11
(6) Reproductive Toxicity	12
(7) Mutagenicity	12
(8) Metabolism	12
(9) Other Toxic Endpoints	13
2. Exposure Assessment	14
a. Dietary Exposure	14
b. Regulatory Levels for Chlorine	15
c. Occupational and Residential	18
3. Risk Assessment	19
a. Dietary	19
b. Occupational and Residential	21
C. Environmental Assessment	22
1. Environmental Fate	22
a. Environmental Chemistry, Fate and Transport	22
b. Environmental Fate Assessment	24
2. Ecological Effects	24
a. Ecological Effects Data	24

	(1)	Terrestrial Data	24
	(2)	Aquatic Data	25
	(3)	Non-Target Insects Data	25
	(4)	Non-Target Plants Data	25
	b.	Ecological Effects Risk Assessment	26
	(1)	Non-Endangered Species	26
	(2)	Endangered Species	26
	(3)	Non-Target Aquatic Species Risk	26
IV.		RISK MANAGEMENT AND REREGISTRATION DECISION	29
	A.	Determination of Eligibility	29
		1. Eligibility Decision	29
		2. Eligible and Ineligible Uses	30
	B.	Regulatory Position	30
		1. Tolerance Reassessment	30
		2. Restricted Use Classification	30
		3. General Use Classification	32
		4. Improved Product Labeling	33
		5. Endangered Species Statement	33
V.		ACTIONS REQUIRED BY REGISTRANTS	33
	A.	Additional Data Requirements	34
		1. Additional Generic Data Requirements	34
		2. Additional Product-Specific Data Requirements	34
	B.	Labeling Requirements	35
		1. Labeling Requirements for Manufacturing-Use Products	35
		2. Labeling Requirements for End-Use Products	35
		a. Use Directions	35
		b. Guidance for Specific Directions for Use	37
		c. Effluent Discharge Labeling Statements	37
	C.	Existing Stocks	51
VI.		APPENDICES	53
	A.	Table of Use Patterns Subject to Reregistration	54
	B.	Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	60
	C.	Citations Considered to be Part of the Data Base Supporting the Reregistration Decision	63
	D.	Generic Data Call-In	73
		1. Generic Data Call-In Chemical Status Sheet	91
		2. Generic DCI Response Forms Inserts (Insert A) plus Instructions ..	93
		3. Requirements Status and Registrants' Response Forms (Insert B) plus Instructions	97
	E.	Product Specific Data Call-In	105
		1. Product Specific Chemical Status Sheets	118

2.	Data Call-in Response Form for the Product Specific Data (Form A inserts) Plus Instructions	120
3.	Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions	122
4.	EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration	129
5.	List of All Registrants Sent This Data Call-In (insert) Notice	131
F.	List of Available Related Documents and Electronically Available Forms	134

CHLORINE GAS REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Assessment

Alan Goozner
Rafael Prieto
Phyllis Johnson
Michele Cottrill

Economic Analysis Branch
Biological Analysis Branch
Biological Analysis Branch
Biological Analysis Branch

Environmental Fate and Effects Assessment

Tom Bailey
Silvia Termes
Sharlene Matten

Ecological Effects Branch
Environmental Fate and Groundwater Branch
Science Analysis and Coordination Staff

Health Effects Assessment

John Redden
Irving Mauer
Winston Dang
Bonnie Cropp-Kohlligian

Chemical Coordination Branch
Toxicology Branch I
Occupational and Residential Exposure Branch
Reregistration Support Chemistry Branch

Registration Assessment

JoAnne Hayes
Wallace Powell

Registration Support Branch
Antimicrobial Division

Risk Management Assessment

Tom Myers
Patrick Dobak
Kathleen Depukat
Jay Ellenberger

Accelerated Reregistration Branch
Reregistration Branch I
Accelerated Reregistration Branch
Accelerated Reregistration Branch

Stakeholder Input, Communications

John MacDonald
Deborah Hartman
Ronald Jackson

Field Operations Division
Policy and Special Projects Staff
Field and External Affairs Division

Office of Enforcement and Compliance:

Rose Lew

Office of General Counsel:

Robert Perlis

Office of Drinking Water:

Mary Manibusan

Jennifer McLain

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal uses of chlorine gas. The Agency has determined that the pesticidal uses of chlorine gas will not pose unreasonable risks to humans or the environment when products are labeled and used as specified in this Reregistration Eligibility Decision document. Therefore, all chlorine gas pesticide products are eligible for reregistration. Furthermore, the risks associated with this acutely toxic gas are considered reasonable in light of the health benefits provided by its use.

However, to reduce the risks of poisonings to workers from this chemical's high acute toxicity, the Agency is requiring that use associated with industrial and agricultural food settings, non-residential swimming pools, recirculating cooling water towers, and pulp and paper mill water process systems be restricted to certified pesticide applicators or to those under their direct supervision. The Agency is not imposing this limitation for applications to drinking water, sewage, or wastewater because applicators for these uses already receive formal training on the handling of hazardous chemicals. Although the Agency has concerns for the use of chlorine gas in residential pools, there currently are few reported incidents that would support requiring restricted use. In addition, all product labels will be upgraded with improved use directions, precautions, and instructions for the use of personal protective equipment.

Chlorine gas is used in water treatment to disinfect drinking water, sewage and wastewater, swimming pools, and other types of water reservoirs. Chlorine gas is also used as a microbistat/microbicide, disinfectant, and algicide for food and water processing systems, and pulp and paper mill systems. During washing operations, chlorine gas is used to control microorganisms that cause decay of meat, produce, and seeds.

The Agency concludes from a review of available data that chlorine gas is a highly acute toxicant by all routes of exposure. Also, the Agency classifies chlorine as a Group D carcinogen (not classifiable as to human carcinogenicity) and concludes that available studies report no adverse reproductive or developmental effects in test animals. Dietary exposures from food contact surface sanitizer uses are regulated by FDA and, under a separate action the Agency has established a Maximum Residual Disinfectant Level of 4 mg/L for chlorine in drinking water. For occupational exposures to chlorine gas there are various reports of poisonings to workers and to others near treatment areas. Many of these incidents resulted from chlorine transfer and chlorinator system maintenance operations and equipment failure.

While the consumption of chlorinated drinking water is considered safe by the Agency, there is a need to more adequately characterize the toxicity of three chlorinated organic byproducts. Bromodichloromethane, dichloroacetic acid, and dibromoacetic acid have been identified as having health effects in laboratory studies. Because these compounds occur at relatively high concentrations and have been shown to cause adverse effects in laboratory animals, there is a need for additional testing on these compounds to improve the Agency's ability to assess chronic risks from drinking water exposure. Two two-generation reproduction and three developmental toxicity studies are being requested from registrants that support the drinking water use.

While chlorine is highly toxic to aquatic organisms, uses which result in effluent discharges are regulated under NPDES permits to reduce the impact on aquatic environments. For other chlorine gas uses, such as residential swimming pools, the Agency believes there are minimal environmental exposures due to the minimal and intermittent discharges. Further, chlorine byproducts are highly reactive with organic matter which reduces the availability of residual chlorine to aquatic organisms.

Before reregistering the products containing chlorine gas, 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 for every product containing chlorine gas as an active ingredient. These data include product chemistry testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with the requirements listed in this document and Section 3(c)(5) of FIFRA, the Agency will reregister products. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for 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 continues to meet the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of chlorine gas, hereafter also referred to as "chlorine". The document consists of six sections. Section I is the introduction. Section II describes chlorine, 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 chlorine. Section V discusses the reregistration requirements for chlorine. 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.

II. CASE OVERVIEW

A. Chemical Overview

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

!	Common Name:	Chlorine Gas
!	Chemical Name:	Chlorine Gas
!	Chemical Family:	Halogen
!	CAS Registry Number:	7782-50-5

! **OPP Chemical Code:** 020501

! **Empirical Formula:** Cl₂

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 the currently registered uses of chlorine is in Appendix A.

For Chlorine Gas:

Type of Pesticide: disinfectant, sanitizer (for food and nonfood contact sites), microbicide/microbistat (slime-forming algae, bacteria and fungi) and algicide

Use Sites: AQUATIC NON-FOOD INDUSTRIAL:
Pulp/Paper Mill Water Systems
Commercial/Industrial Recirculating Water Cooling Systems
Sewage Systems
Lakes/Ponds/Reservoirs (Without Human and Wildlife Use)

AQUATIC NON-FOOD RESIDENTIAL:

Swimming Pool Water Systems
Ornamental Ponds/Aquaria

INDOOR FOOD:

Human Drinking Water Systems
Food Processing Water Systems
Egg Handling Equipment (Commercial)
Food Processing Plant Equipment (Food Contact)
Meat Processing Plant Equipment (Food Contact)
Poultry Processing Plant Equipment (Food Contact)
Fish/Seafood Processing Plant Equipment (Food Contact)
Food Processing Plant Premises (Nonfood Contact)
Meat Processing Plant Premises (Nonfood Contact)
Poultry Processing Plant Premises (Nonfood Contact)
Fish/Seafood Processing Plant Premises (Nonfood Contact)

INDOOR NON-FOOD:

Pasteurizer/Warmer/Cannery Cooling Water Systems
Egg Plants/Hatcheries/Brooder Rooms/Shoe Baths
(Hatching)

Target Pests: slime-forming bacteria, fungi and algae; organisms causing decay of raw agricultural commodities

Formulation Types Registered: Type: end use and manufacturing use
Form: pressurized gas

Method and Rates of Application: Types of Treatment -gas diffusion through a chlorinator into the appropriate water system

- spray, dip, wash water treatment for raw agricultural commodities and meats (including poultry, meat, seafood, and egg shells). Spray is also the treatment type for food handling premises and equipment

Equipment - dip tank, sprayer, flume, dump tank, hydrocooler, tank, cooler, brush washer spray, rinser, drencher

- cylinder-mounted chlorinators which are designed to convey chlorine under vacuum from the vacuum regulator to the injector check-valve assembly into the appropriate water system.

Timing - post harvest for food commodities

- continuous for water systems; see also below under Rates and Application

Rates of Application: Some of the following rates of application are not on the labels. They were obtained from a variety of sources and are presented here for informational purposes on the usage of chlorine gas.

AQUATIC NON-FOOD INDUSTRIAL:

Pulp/Paper Mill Water Systems - A typical treatment is to feed 1 to 3 ppm available chlorine into the system in order to achieve a minimum of 0.2 ppm residual chlorine (microbicide/microbistat)*. (Source: Nalco Chemical Company, Naperville, Illinois)

Commercial/Industrial Water Cooling Systems - Recirculating water cooling systems are treated with a residual

chlorine level of 0.2 to 1.0 ppm for one hour. Once-through water cooling systems are treated with a residual chlorine level of 0.3 to 0.8 ppm for two hours (microbicide/microbistat)*. (Source: Betz Laboratories, Inc. 1980. Betz Handbook of Industrial Water Conditioning. 8th Edition. p. 187.

Sewage Systems - A typical treatment is to feed 1 to 5 ppm available chlorine into the system in order to achieve 1 ppm for 30 minutes (disinfectant/algaecide)*. (Source: Water Environment Federation)

Lakes/Ponds/Reservoirs (Without Human and Wildlife Use) - 3 to 5 ppm available chlorine (microbicide/microbistat).

AQUATIC NON-FOOD RESIDENTIAL:

Swimming Pool Water Systems - A level of 0.6 to 1.0 ppm residual chlorine (1 to 2 ppm residual chlorine for pools containing cyanuric acid) should be maintained (disinfectant/algaecide)*. (Source: American Water Works Association; Seymour S. Block, ed. 1991. Disinfection, Sterilization, and Preservation. 4th Edition. p. 146.

Ornamental Ponds/Aquaria - 3 to 5 ppm available chlorine (microbicide/microbistat).

INDOOR FOOD:

Human Drinking Water Systems - A typical treatment is to feed 5 to 6 ppm available chlorine into the system in order to achieve a 0.2 ppm residual chlorine level (disinfectant/algaecide)*. (Source: American Water Works Association)

Food Processing Water Systems - 1 to 400 ppm available chlorine (for control of organisms causing decay of raw agricultural commodities, poultry, meat, and seafood; for sanitizing egg shells).

Food Processing Plant Equipment (Food Contact) - 15 (porous surfaces) to 200 (hard surfaces) ppm available chlorine (sanitizer/microbicide/microbistat).

Food Processing Plant Premises (Nonfood Contact) - 50 to 200 ppm available chlorine (sanitizer).

INDOOR NON-FOOD:
Pasteurizer/Warmer/Cannery Cooling Water Systems - 10 to 15 ppm available chlorine (microbicide/microbistat).

Egg Plant Premises - 50 ppm available chlorine (sanitizer).

*Rates of application for this use site were not given on the product label and were obtained from the indicated source to include information concerning the usage of chlorine gas. These rates of application are not meant to be guidance regarding use directions and do not represent actual label usage information.

Current Use Practice Limitations:

Below, are use practice limitations that appear on various product labels for different uses. Through this document the Agency is revising these limitations for clarity, consistency, and to further reduce the risks of accidents and adverse effects. The revisions are described in Section V.

"For use by 'experienced personnel' only. For use by 'trained personnel' for dispensing from large stationary containers such as tank cars, tank trucks, 1-ton and 150-pound cylinders. For use by "trained and qualified servicemen," under the control and supervision of the registrant of this pesticide, and in accordance with state or municipal regulatory requirements. Only specifically designed dispensing equipment should be used in accordance with the manufacturer's instructions and with the Chlorine Institute recommendations. Only specifically designed dispensing equipment should be used in accordance with the manufacturer's instructions and according to state regulatory agency recommendations for dosages or residual chlorine levels which should be maintained for each specific site of application."

"Dosages of residual chlorine levels which should be maintained for each specific site of application must be consistent with recommended practice and state and municipal recommendations. Use only valves, gauges, regulators, fittings, piping, etc., recommended for chlorine service. Proper ventilation required. Keep away from intense heat or open sunlight. Corrosive to most metals in the presence of moisture. Do not heat cylinder. Segregate from other compressed gasses. Keep away from intense heat, open sunlight, and combustible materials. Reacts dangerously with many other chemicals. Do not vent chlorine containers, lines or valves. Do not use heat or hot water to increase discharge rate. Proper ventilation is required. There are NPDES license restrictions. Water is not to be contaminated by cleaning or disposal of wastes and, food or animal feed are not to be contaminated by product storage or disposal."

C. Data Requirements

In addition to data requirements imposed to obtain the original registration of this active ingredient, the Agency required generic data in the reregistration Phase IV Data Call-In issued on November 9, 1993. Appendix B includes all generic data requirements identified by the Agency for currently registered uses needed to support reregistration. These data include studies on chlorine's physical chemistry and toxicology. The Agency has also relied on available published information.

D. Regulatory History

Chlorine gas was registered as a pesticide in the United States as early as 1948. Six chlorine products were registered that year, to six companies. One of those products was a manufacturing-use product. The other five were all registered as disinfectants against algae and pathogenic bacteria in general, for use in swimming pools, human drinking water, cooling towers, and sewage systems. After 1949 there were no further chlorine product registrations until 1964. In 1976, chlorine gas was classified for general use based on the premise that the industrial users of this chemical were already adequately trained in its use.

Currently there are 94 products registered to 94 companies. In addition, there are three 24(C) State Registrations. Chlorine products are currently registered for use against pathogenic bacteria, in general, and against the algae, fungi, and bacteria that cause slime and decay. Current use sites include various water applications, sewage treatment, food processing applications, and wash water for about 40 fruits and vegetables and meats, poultry, and seafood. The labeling of registered chlorine products is generally in accordance with the standard labeling that was agreed upon by EPA and the Chlorine Institute. However, changes are necessary, which are described in Section V of this RED document.

Chlorine gas is exempt from the requirement of a tolerance when used pre-harvest or post-harvest in solution on all raw agricultural commodities. Both the Proposed Rule and the Final Rule for this exemption were announced in the Federal Register in 1991, and the exemption has since been promulgated in 40 CFR §180.1095.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Chlorine, at normal pressures and temperatures, exists as a diatomic gas. Chlorine hydrolyzes in water to form hypochlorous acid and hypochlorite ion. Hypochlorous acid is an oxidizing agent and thus, chemicals that generate hypochlorous acid in water (such as chlorine gas, hypochlorite salts and chlorinated isocyanurates) are used in water treatment to disinfect drinking water, sewage and wastewater, swimming pools and other types of water reservoirs.

The physical and chemical properties* of chlorine are given in Table 1.

Table 1: Physical and Chemical Properties of Chlorine Gas

Property	Description
Molecular Formula	Cl ₂
Molecular weight	70.906
Physical form (25°C)	gas
Boiling point	-34.05°C
Melting point:	-101°C
Density, as liquid (20°C/6.864 atm)	1.4085 g/mL
Density, as liquid (-35°C/0.9949 atm)	1.5649 g/mL
Specific gravity	2.482 (0°C)
Water solubility	7.3 g/L (20°C), 14.6 g/L (0°C)
Color	greenish-yellow
Odor threshold	0.002 mg/L water, 0.31 ppm air
Conversion factors	1 ppm=2.9 mg/m ³ 1 mg/m ³ =0.344 ppm
Residue level (water):	0.2-1.5 mg/L

* This information is from the U.S. EPA, 1994, Drinking Water Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion.

Chlorine exists as a greenish-yellow gas under standard conditions (25°C and 1 atmosphere) or as a high-density amber liquid when compressed. The chlorine TGAI is packaged as a liquefied gas in pressurized containers. Chlorine gas is stable under pressure, and has a characteristic pungent bleach odor. Chlorine is slightly soluble in water, 8.3 kg/m³ at 15.6°C and 1 atmosphere; however, in pure water, chlorine forms a mixture of hydrochloric and hypochlorous acids. Hypochlorous acid acts as an oxidant toward organic and inorganic contaminants.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for chlorine is adequate and will support reregistration eligibility. In addition to submitted studies, the Agency is also relying on information contained in the U.S. EPA, 1994, Drinking Water Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion as noted above.

a. Human Toxicology

The list of reported adverse health effects associated with chlorine gas exposure ranges from bronchitis, asthma and pulmonary edema to headaches, meningitis and heart disease (NRC, 1976; WHO, 1982). In addition, acute

exposure to chlorine gas has resulted in adverse health effects which include pulmonary congestion, respiratory failure, pulmonary edema and bronchopneumonia (WHO, 1982). Table 2 indicates the threshold levels of the effects produced by inhaling chlorine gas. The authors of the (WHO, 1982) report also stated that there were no indications of permanent respiratory damage in persons surviving acute exposures to chlorine gas. In cases of acute, low-level exposure to chlorine gas, complete and rapid recovery occurred with symptomatic treatment.

Table 2: Threshold Levels for Chlorine Gas Inhalation Effects*

Effect	Cl ₂ Threshold Levels - mg/m ³	Cl ₂ Threshold Levels - ppm
Odor perception/irritation	0.06-5.8	0.02-2.0
Perceivable sensory irritation	2.9	1.0
Intolerable sensory irritation	11.6	4.0
Chronaxie/visual adaptation changes	1.5	0.52
Pronounced dyspnea, anxiety, vomiting, cyanosis, pulmonary edema	87.0-116.0	30.0-40.0

*Source: WHO, 1982

Episodes of dermatitis have been linked to exposure to chlorine and hypochlorite ion (U.S. EPA, 1981). Sodium hypochlorite disinfectants, in particular, have been determined to be the causal agent in the development of occupational allergic reaction or irritation of the skin.

Individuals who are allergic to chlorine products or who are asthmatic may be at high risk for adverse reactions after inhalation or ingestion of even low levels of chlorine compounds. Asthmatic attacks have been reported after consumption of municipal drinking water that contained 0.2-0.4 ppm chlorine (Sheldon and Lovell, 1949). Studies by (Lubbers et al., 1983, 1984) have indicated that individuals with an A-variant form of G6-PD deficiency may also be at higher risk due to oxidant stress. Newborns, especially those with enzymatic deficiencies, are also a group which may be at increased risk from oxidant-stress agents (Jones and McCance, 1949; Ross, 1963).

Acute exposure to chlorine has also occurred through the ingestion of household bleach usually consisting of 3-6% solutions of sodium hypochlorite in water with pH values averaging ~11.0. The typical amount of bleach ingested by a child has been estimated to be ~4-5 ml. Intake of this small amount of bleach generally results in irritation of the oropharynx and esophagus, a burning sensation in the mouth and throat, spontaneous emesis, and in rare instances, permanent injury to the esophagus with perforation or stricture formation dependent upon the pH of the solution (Mack, 1983).

Ingestion of a few teaspoons of bleach proved fatal for an 18-month-old girl (Done, 1961). The bleach solution was apparently aspirated into the trachea where it caused acute tracheobronchitis. Strange et al., 1951, reported a case in which a 49-year-old male ingested a quart of liquid bleach containing roughly 5% free available chlorine in the form of sodium hypochlorite (~6557 mg/kg). Injury to the stomach eventually necessitated a total gastrectomy. The individual's esophagus appeared to be healthy. There is further discussion of reported effects from accidental exposure to chlorine's uses as a pesticide in Subsection 3.b., Occupational and Residential Risk Assessment, below.

b. Human Toxicology

(1) Acute Toxicity

Table 3: Acute Toxicity

Test	Results	Category
Oral LD ₅₀ - Rat	Waived	I
Dermal LD ₅₀ - Rabbit	Waived	I
Inhalation LC ₅₀ - Rat	Waived	I
Eye Irritation - Rabbit*	Waived	I
Dermal Irritation - Rabbit*	Waived	I
Dermal sensitization - Guinea Pig*	Waived	positive

*Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

Technical (99%) chlorine (gas and/or liquid) and its reactive byproducts, hypochlorous acid and hypochlorite ions, are highly toxic and corrosive substances, and are thus classified as Toxicity Category I for acute oral and dermal effects (GDLN 81-1, -2). Due to its corrosivity, the Agency has not required studies for acute inhalation (GDLN 81-3), primary eye irritation (GDLN 81-4), primary dermal irritation (GDLN 81-5), and dermal sensitization (GDLN 81-6). Accordingly, chlorine and its byproducts have also been assigned Toxicity Category I for these effects.

(2) Subchronic Toxicity

The Agency has not received any subchronic toxicity studies (GDLN 82-1 through 7) with chlorine or its byproducts from any of the registrants. Due to its acknowledged corrosivity (see above), the registrants have been granted a waiver for submission of data from a 90-day dermal study (GDLN 82-3). The data from a 90-day

inhalation study (GDLN 82-4) will be discussed together with the Final Report of a chronic rat inhalation study conducted at the Chemical Industries Institute of Toxicology (CIIT).

Daniel et al., 1991, reported that chlorinated drinking water over a three-month period was without adverse effects to rats at up to 250 mg/L available chlorine (intakes up to 16.7 mg/kg/day males; 24.9 mg/kg/day females), and occasioned only decreased water consumption in mice at comparable concentrations (intakes up to 34.4 mg/kg/day, males; up to 39.2 mg/kg/day, females) (Daniel et al., 1991).

(3) Chronic Toxicity

The Agency is relying on published studies for its assessment of chlorine's chronic toxicity. Because of the sufficiency of these studies, which are presented below, the Agency has not required registrants to generate and submit the standard chronic toxicology studies normally required for registration or reregistration (GDLN 83-1; oncogenicity, GDLN 83-2; developmental toxicity, GDLN 83-3 and reproduction, GDLN 83-4). Additionally, a 2-year inhalation study with chlorine was conducted at CIIT. Chlorine gas was administered at 0,0.4, 1.0 and 2.5 ppm to both mice and rats. Dose-dependent lesions in the upper respiratory tracts were present at all dose levels including the LDT (0.4 ppm, equivalent to 0.001 mg/L), however no neoplasms were present at any dose level. The HDT, 2.5 ppm (equivalent to 0.007 mg/L) was considered a MTD, since it caused a 10-12% reduction in body weight. The results of this study indicate that chlorine gas is negative for oncogenic potential and were consistent with the findings in the previous studies.

Diverse results have been reported for chronic exposure to chlorine in drinking water. National Toxicology Program (NTP) studies reported no treatment-related clinical adverse effects other than decreased water consumption in F-344 rats drinking water containing up to 275 ppm (13.3 mg/kg/day, males; 14.4 mg/kg/day, females) (NTP, 1990). In contrast, an earlier study recorded significant decreases in body and liver weights in both sexes, coincident with decreased brain and heart weights in male rats and salivary gland and kidney weights in female rats, administered 0.1 to 1.0% sodium hypochlorite in drinking water (5.5 to 21.9 mg/kg/day, males; 15.5 to 54.7 mg/kg/day, females) (Hasegawa et al., 1986).

(4) Carcinogenicity

The Agency has classified chlorine in Group D, that is, not classifiable as to human carcinogenicity. This classification stems from the findings of the NTP (1990) study indicating equivocal evidence in female rats (increased mononuclear cell leukemia) and no evidence in male rats or in male and female mice, discussed below. The International Agency for Research on Cancer (IARC, 1991) also evaluated chlorinated drinking water and hypochlorite for potential human carcinogenicity. IARC determined that there was inadequate evidence for carcinogenicity of drinking water and hypochlorite salts in humans and animals. IARC concluded that chlorinated drinking water and hypochlorite salts were not classifiable as to their carcinogenicity to humans and thus assigned these chemicals to IARC Group 3. This category is similar to the Agency's cancer classification Group D.

In the NTP study, Fischer 344/N rats and B6C3F1 mice (70/sex/group) were administered chlorinated drinking water containing 0, 70, 140 or 275 ppm available chlorine for up to 104 weeks (corresponding to intake levels of 4.2/4.2, 7.3/7.8 and 13.6/14.4 mg/kg/day for male/female rats; 7.4/7.6, 14.0/14.2 and 24.0/24.2 mg/kg/day for male/female mice). Due to lack of palatability, 275 ppm was considered the maximum dose animals would drink, as evidenced by significantly decreased water consumption.

Epidemiologic studies have also been inadequate to develop any conclusions as to the carcinogenicity of chlorine or its byproducts, hypochlorous acid and/or the hypochlorite ion (U.S. EPA, 1994, Drinking Water Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion).

(5) Developmental Toxicity

Published sources recorded no adverse clinical, reproductive or developmental effects in mouse dams or fetuses from chlorinated water administration during pregnancy (Chernoff et al., 1979 and Staples et al., 1979). These studies were not designed to assess the toxicity associated with chlorinated organic byproducts of water treatment.

(6) Reproductive Toxicity

In a single published study, no adverse clinical, reproductive or developmental effects were reported in BD-II rats receiving highly chlorinated water (100 mg/L residual chlorine equivalent to intake of 10 mg/kg/day) for seven consecutive generations (Druckrey, 1968). This study was also not designed to assess the toxicity associated with chlorinated organic byproducts of water treatment.

(7) Mutagenicity

Acceptable data (unpublished) from the primary battery of mutagenicity studies submitted under Guideline 84-2 recorded negative results for gene mutation in bacteria (*Salmonella*-Ames Test) and mammalian cells (L5178Y mouse lymphoma), as well as for chromosome aberrations *in vivo* (mouse micronucleus) at doses up to cytotoxic or maximum tolerated levels (MRIDs 42002801, 42002802, and 42002803).

Table 4: Mutagenicity

Study	Reported Results	MRID
Ames Test	Negative for reversions in <i>Salmonella</i> strains, exposed up to 0.5-0.7 ppm, non-toxic doses.	42002801
Mouse Micronucleus	Negative for micronuclei in bone marrow cells of mice exposed up to toxic doses (80 ppm).	42002802
Mammalian cell (L5178Y) gene mutation	Negative for forward mutation in mouse lymphoma cells exposed up to cytotoxic doses.	42002803

The results of other studies are confounded by the reactive nature of chlorine and its reaction products which generated positive results at low doses (50 µg/ml in bacterial assays (Rosenkranz et al., 1973; Sweeny et al., 1985; Walton et al., 1976; Wlodkowski, 1975), but only at severe cytotoxic levels in mammalian cell cultures (Mickey, 1971), with essentially negative results *in vivo* (Meier et al., 1985 and Cumming, 1978).

(8) Metabolism

Radiolabelled (³⁶Cl) chlorine-containing compounds orally administered to rats are rapidly absorbed into blood, peaking in 2-4 hours, with a half life of 2.2 hours (Abdel-Rahman et al., 1983; Suh et al., 1983). After 72-96 hours, the label was highest in plasma, followed by bone marrow, kidney, testes, lungs, skin and liver; lowest

concentrations remained in ileum and adipose tissue (Abdel-Rahman et al., 1983 and Abdel-Rahman et al., 1982). As the gas or base liquid (Cl_2) or as byproducts (OCl^- ; HOCl), chlorine is a potent oxidizing agent, readily reacting in biological systems with proteins and nucleotides to produce a wide variety of chlorinated organic compounds (Abdel-Rahman et al., 1983; Abdel-Rahman et al., 1982; Baker, 1947; Cumming, 1978; Dennis et al., 1978; Hoyano et al., 1973; Mink et al., 1983; Patton et al., 1972; Pereira, 1973). Chlorine is eliminated primarily in urine and feces, mainly (81% of ingested label) as the chloride ion (Abdel-Rahman et al., 1983 and Suh et al., 1983).

These published sources contribute limited understanding to the toxicokinetics of chlorine and its byproducts in biological systems, due to their high reactivity with other molecules, generating short-lived chlorinated products (Seegert et al., 1980). Because of its high reactivity, additional data to fulfill the Agency's standard metabolism requirement (GDLN 85-1) are not required at this time.

(9) Other Toxic Endpoints

Cardiovascular effects have been reported in some published subchronic studies. Increased hydroxyproline levels were found in heart tissue of New Zealand white rabbits drinking water containing 15 mg/L chlorine (1.6 mg/kg/day) (Revis, 1985). Sprague-Dawley rats administered 100 mg/L (14/mg/kg/day) chlorinated water registered transient but significant decreases in erythrocyte counts and hematocrit, as well as increased osmotic fragility early in a 12-month treatment schedule, all of which reversed by six months of the treatment (Abdel-Rahman et al., 1984).

(10) Toxicological Endpoints of Concern

The risk assessment for noncancer health effects is characterized by a Reference Dose (RfD). The RfD is an Agency-wide number used to estimate, with uncertainty spanning perhaps an order of magnitude, the daily exposure to the human population, including sensitive subgroups, that is likely to be without an appreciable risk of deleterious health effects during a lifetime. Other toxicological endpoints used for regulatory purposes for drinking water are discussed below in the dietary exposure subsection of the exposure assessment.

The RfD for chlorine in drinking water can be estimated as follows:

$$\begin{aligned} \text{RfD} &= \frac{14.4 \text{ mg/kg/day}}{100} \\ &= 0.144 \text{ mg/kg/day (rounded off to 0.1 mg/kg/day)} \end{aligned}$$

where: 14.4 mg/kg/day is the NOAEL based upon absence of adverse effects in female rats exposed to chlorinated water for two years (NTP, 1992);

and: 100 is the uncertainty factor (10 for interspecies and 10 for intraspecies variation).

No toxicological endpoint for cancer was selected because chlorine is classified as a Group D carcinogen (i.e., not classifiable based on lack of data or inadequate evidence of carcinogenicity from animal data). Further, no definitive carcinogenic effects have been detected for hypochlorous acid or hypochlorite ion. Therefore, no quantification of potential cancer effects is appropriate.

2. Exposure Assessment

a. Dietary Exposure

Chlorine gas is exempt from the requirement of a tolerance when used preharvest and postharvest in solution on all raw agricultural commodities [40 CFR §180.1095]. Although chlorine residues of concern may remain in/on raw agricultural commodities resulting from currently registered postharvest uses of chlorine gas, there is no reasonable expectation that finite residues or residues significantly above naturally occurring background levels would be incurred. Therefore, residue data are not required to support the reregistration of chlorine for use in food processing water systems to control decay in or on raw agricultural commodities.

The Agency has considered the possibility that livestock might ingest chlorine-treated water and has determined that in the unlikely event that livestock did ingest chlorine-treated water that there is no reasonable expectation that finite residues of chlorine or residues significantly above naturally occurring background levels would be incurred in meat, milk, or eggs as a result [40 §CFR 180.6(c)]. Therefore, animal metabolism, storage stability and magnitude of the residue data are not required to support the reregistration of chlorine for use in drinking water.

A full risk assessment for the use of aqueous chlorine gas solutions as a food contact surface sanitizer in or on food, meat, and/or poultry processing premises and/or equipment was not performed because these issues are under FDA purview. The Agency defers to FDA on this subject, and they have concluded that chlorine gas solutions may be safely used for these applications. For this RED, the Agency is relying on drinking water risk assessments performed under the Safe Drinking Water Act (SDWA). Current risk assessments continue to support the conclusion that chlorine gas can be safely used in public water systems. However, because most of the U.S. population is exposed to chlorinated drinking water, it is necessary to better characterize the chronic risks associated with exposure to chlorinated byproducts that may be present.

In summary, the regulation of chlorine gas when used in solution as a food contact surface sanitizer in or on food, meat, and/or poultry processing premises and/or equipment falls under FDA jurisdiction. The regulation of chlorine gas when used in potable water systems falls under the jurisdiction of the Agency's Office of Drinking Water. It has the responsibility to determine the nature and magnitude of the residues of chlorine gas in potable water resulting from the maximum permitted uses of chlorine gas. Regulatory endpoints for chlorine in potable water are described below.

b. Regulatory Levels for Chlorine

In addition to developing the previously discussed RfD, which is used for risk assessment, the Agency has developed several health-related thresholds for chlorine gas. The Drinking Water Equivalent Level (DWEL), Maximum Residual Disinfectant Level Goal (MRDLG) and Health Advisories (HA) represent the EPA Office of Water's efforts in assessing potential adverse effects. Each of these endpoints is described as follows.

Drinking Water Equivalent Level (DWEL)

The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, non-carcinogenic health effects are not anticipated to occur. The DWEL provides the non-carcinogenic health effects basis for establishing a drinking water standard. A DWEL can be calculated as follows:

$$DWEL = \frac{0.1 \text{ mg/kg/day} \times 70 \text{ kg}}{2 \text{ L/day}} = 3.5 \text{ mg/L} = 4 \text{ mg/L}$$

where: 0.1 mg/kg/day is the RfD;
70 kg = assumed human adult body weight;
2 Liter/day = assumed adult water consumption.

Maximum Residual Disinfectant Level Goal (MRDLG)

The Agency regulates contaminants in drinking water under the Safe Drinking Water Act (SDWA). In general, the Agency regulates contaminants that may have an adverse health effect and are known or anticipated to occur in public water systems. In addition to the standards that are designed to protect against certain microorganisms (54 FR 27486), the Agency has recently established a MRDLG of 4 mg/L for chlorine. MRDLGs are like the Maximum Contaminant Level Goal and are established at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin or safety. MRDLGs are nonenforceable health goals based on health effects.

Health Advisories (HAs)

In addition to the RfD and the DWEL, Health Advisories for exposures of shorter duration (1-day, 10-day and longer-term) are determined. The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur. HAs can be calculated for 1 or 10 days or longer periods of time and for a child or adult. Below are the equations for these calculations. The NOAEL and LOAEL are identified from acute or subchronic studies.

$$HA = \frac{(NOAEL/LOAEL) \times bw}{UF \times L/day} = mg/L$$

1-day HA: In the absence of suitable data to derive a 1-day HA, the Agency recommends that the 10-day HA of 2.5 mg/l be used as a conservative estimate of the 1-day HA.

10-day HA: The 10-day HA for a 10 kg child is calculated as follows:

$$10\text{-day HA} = \frac{25\text{mg/kg/day} \times 10\text{kg}}{1\text{L/day} \times 100} = 2.5\text{mg/L}$$

where:

25 mg/kg/day = NOAEL based on the absence of adverse gross or histologic effects in a mouse drinking water study (Blabaum and Nichols, 1956)

10 kg = assumed weight of a child

1 Liter/day = assumed water consumption by a child

100 = uncertainty factor chosen in accordance with U.S. EPA (1988) guidelines for use of a NOAEL from an animal study.

Longer-term HA for a child: The longer-term HA for a 10 kg child is calculated as follows:

$$HA(child) = \frac{16.7mg/kg/day \times 10kg}{1L/day \times 100} = 1.67mg/L \approx 2mg/L$$

where:

16.7 mg/kg/day = NOAEL based on the absence of adverse gross effects in male rats exposed to chlorinated drinking water for 90 days (Daniel et al., 1990) (Blabum and Nichols, 1956)

10 kg = assumed weight of a child

1 liter/day = assumed water consumption by a child

100 = uncertainty factor chosen in accordance with U.S. EPA (1988) guidelines for use of a NOAEL from an animal study.

Longer-term HA for an adult: The longer-term HA for a 70 kg adult is calculated as follows:

$$HA(child) = \frac{16.7mg/kg/day \times 10kg}{1L/day \times 100} = 1.67mg/L \approx 2mg/L$$

where:

16.7 mg/kg/day = NOAEL based on the absence of adverse gross effects in male rats exposed to chlorinated drinking water for 90 days (Daniel et al., 1990) (Blabum and Nichols, 1956)

70 kg = assumed weight of an adult

2 Liter/day = assumed water consumption by a adult

100 = uncertainty factor chosen in accordance with U.S. EPA (1988) guidelines for use of a NOAEL from an animal study.

c. Occupational and Residential Exposure

Chlorine gas is metered into water through closed systems in manufacturing processes or from large stationary containers such as tank cars, tank trucks, 20 and 150-pound and 1-ton cylinders. Given the current use patterns of chlorine gas, there is potential for dermal and inhalation exposure to the applicators and to other people who are exposed to the chlorinated water, including swimmers, bystanders, and workers in food processing plants and in water/sewage treatment plants.

The Agency believes post-application exposure to chlorine during swimming in treated water is not significant provided if proper application methods are followed. No post-application exposure studies are required.

There are a number of occupational exposure guidelines that are established from different sources, including ACGIH, the U.S. Occupational Safety and Health Administration (OSHA), and foreign government agencies. These guideline values are listed in Table 5.

Table 5: Existing Guidelines on Human Exposure to Chlorine^a

Source	Type of Guideline	Exposure Level (ppm)
American Conference of Government Industrial Hygienists	TLV-air TWA STEL-air	1 3
OSHA	Standard in air	1
U.S. Mine Safety and Health Administration	Standard-air TWA	1
ACGIH Criteria Document	Occupational exposure to chlorine in air	0.5 for 15 minutes
West Germany, Switzerland, former Yugoslavia	TLV	0.5
(former USSR, most eastern European countries)	TLV	0.3
most other countries	TLV	1

TLV= Threshold limit value STEL= short-term exposure limit TWA= Time Weighted Average
 *Source: ACGIH, 1986

California is the only State with a system designed specifically to track pesticide illnesses. Case reports received by the California Pesticide Illness Surveillance Program in which health effects were attributed to the use of chlorine gas as a pesticide in 1991 demonstrated that there were approximately 62 events involving about 100 people. A majority of the accidents occurred at swimming pools and food processing plants. Many of the incidents at food processing plants involved workers who reported dermal, ocular, and/or respiratory irritation from exposure to chlorinated wash water. Pool incidents involve applicator error in switching cylinders that resulted in the release of chlorine gas.

The 1992-1993 California Case Reports included 64 incidents specifically involving chlorine gas as a source. Of these incidents, 22 occurred at food processing facilities. There were 10 incidents each at commercial swimming pools and water/wastewater treatment plants. There were 3 incidents involving repackaging to small cylinders, and 2 involving residential swimming pool treatment. Some of these use incidents were not attributable to specific use patterns. In general, the majority of these incidents involved tank changing, maintenance operations or equipment failure of in-place gas chlorinator systems. A significant number of these incidents involved untrained personnel or resulted from precautions not taken.

Between 1982 and 1986, 81 cases of chlorine gas poisoning were reported by the California Department of Food and Agricultural averaging 16 per year. About 50% of the cases (41) involved agricultural uses, 25% (20) involved sewage treatment facilities, and 20% (16) involved swimming pools.

The 1986 report of the American Association of Poison Control Centers reported 3,174 cases of chlorine exposure. Of these cases 1,231 were treated in a health care facility. The number of cases related to chlorine gas could not be distinguished from other sources of chlorine such as sodium and calcium hypochlorite and chlorinated isocyanurates.

The Chlorine Institute, an industry association, reported approximately 200 accidents involving non-residential swimming pools over the 5-year period prior to 1988. Annually, on average, one person was admitted to a hospital and seven persons were treated. A significant number of accidents which involved leaks in chlorine cylinders were reportedly the result of application error.

In the past few years there have been four deaths related to the use of chlorine gas in Florida. In all of these cases it appears that applicator error was the cause of death. In two cases, the applicators apparently were asthmatics which may have contributed to their death. These cases both occurred at water treatment plants.

3. Risk Assessment

a. Dietary

Adverse risk to the general population from consumption of food or potable water treated with chlorine as a pesticide is not expected. Chlorine residues may remain in or on raw agricultural commodities resulting from currently registered postharvest uses of chlorine gas. However, because of

a lack of toxicological concerns, the current exemption from the requirements for a tolerance is adequate for chlorine residues resulting from preharvest or postharvest uses on all raw agricultural commodities [40 CFR §180.1095].

The Agency has considered the possibility that livestock might ingest chlorine-treated water and has determined that in the unlikely event that livestock did ingest chlorine-treated water that there is no reasonable expectation that finite residues or residues significantly above naturally occurring background levels would be incurred in meat, milk, or eggs as a result [40 CFR §180.6(c)].

The regulation of chlorine gas when used in solution as a food contact surface sanitizer in or on food, meat, and/or poultry processing premises and/or equipment falls under FDA jurisdiction.

The Agency regulates contaminants in drinking water under the Safe Drinking Water Act (SDWA). Through this authority, the Agency regulates contaminants that may have adverse health effects and are known or anticipated to occur in public water systems. The Office of Drinking Water has recently established a Maximum Residual Disinfectant Level (MRDL) of 4 mg/L for chlorine. This is an enforceable Federal standard.

Because FIFRA has the authority to require the submission of testing relevant to the use pattern of each pesticide, the adequacy of the database for all uses, especially those under the Agency's authority was considered. While the proper use of chlorine gas for drinking water treatment continues to be considered safe, advances in the understanding of the significance of chlorinated hydrocarbons as drinking water byproducts have resulted in a greater level of uncertainty regarding the long-term health effects of drinking water exposure. The Office of Ground Water and Drinking Water identified three byproducts which occur at relatively high concentrations where additional testing would reduce the uncertainty in the understanding of the health effects from these three byproducts. The most commonly occurring byproduct, chloroform, is already adequately characterized.

Bromodichloromethane is a key brominated trihalomethane. This byproduct has been associated with early term miscarriages in a recent epidemiologic study conducted in California (Waller et al., 1998). Thus, it is important to better characterize its developmental risk. BDCM has been shown to alter male reproductive function in F344 rats (Klinefelter et al., 1995). A dose-response increase in sternebra aberrations (50, 100, and 200 mg/kg bw/day) were observed in a developmental study in Sprague-Dawley rats (Ruddick et al., 1983), and a recent study in F344 rats found that BDCM induced full litter resorptions at 50 and 75 mg/kg/bw/day (Narotssky et al., 1997).

Dichloroacetic acid (DCA) is a major byproduct in the haloacetic acid family. It is generally the highest occurring of the haloacetic acids. Damage and atrophy to sexual organs has been reported in male rats and dogs exposed to level from 50 mg/kg BW/day to 2000 mg/kg BW/day for up to 3 months. DCA has been shown cause to heart defects in fetal rats at a dose of 140 mg/kg BW/day during 9-11 day of gestation (Smith, et al., 1992). Exposure of rats during days 12-15 of gestation to 1900 mg/kg BW/day produces the same heart defects (Epstein et al., 1992). Developmental toxicity testing is considered adequate in the rat.

Dibromoacetic acid (DBA) is another haloacetic acid that will occur in higher levels in waters high in bromine. DBA has been shown to cause histopathologic changes in the tests and alter spermatogenesis (e.g., marked effects on epididymal sperm counts and morphology) in rats (Linder et al., 1994; 1996; 1997). DBA has been shown to cause developmental defects in a mouse developmental assay (Narotsky et al, 1996; Teratogly abstract). The developmental toxicity data on DBA has been adequately characterized since it has been tested in both rats and mice already.

b. Occupational and Residential

As stated above, chlorine gas is highly acutely toxic by inhalation. Under the Agency's scheme of categorizing acute toxicity, it is the highest category, Category I. A level of 3.5 ppm it produces a detectable odor, 15 ppm causes immediate irritation of the throat, 50 ppm is life threatening for even short exposures, and 1,000 ppm may be fatal. The occupational permissible exposure limit (PEL) for chlorine in air has been set at 0.5 ppm/15 minutes.

The Agency has significant concerns with applicator and post-application exposure because chlorine gas is highly toxic for all routes of exposure. The greatest risk is from uses that could expose many people in the vicinity of chlorine's storage and use. This includes applicators and bystanders in the vicinity of accidental releases of chlorine gas in swimming pools and to applicators and workers in the industrial food use settings. While there are reported chlorine gas releases from its use in drinking water and sewage treatment plants, these facilities are subject to operator certification requirements and have standard operating procedures to minimize accidents.

Applicators and other people in the vicinity of the chlorine gas tanks can be exposed to gas released when metering equipment fails or there is human error in working with the tank and equipment. Exposure can be to the

skin, eyes, and respiratory tract. Secondary exposure can also occur to workers in food processing plants and swimmers who are exposed to the chlorinated water. Routes of exposure are the same as for the gas.

The Agency has summarized the reported poisoning incidents above in the Occupational and Residential Exposure discussion. While pesticide incidents are typically under-reported, the Agency believes the available reports are sufficient to strongly suggest that the use of chlorine gas in certain situations presents a significant risk of acute toxicity to applicators, other workers, and bystanders. Reported hazards include fatalities, hospitalizations, and acute transient irritations to the skin, eyes, and respiratory tract.

C. Environmental Assessment

1. Environmental Fate

The Agency is relying on data available in the scientific literature to assess the environmental chemistry, fate, and transport of chlorine used as a pesticidal compound. The environmental fate of chlorine in aqueous media is essentially that of hypochlorous acid. Hypochlorous acid is also formed when hypochlorite salts (sodium, potassium, lithium and calcium) and chlorinated isocyanurates react with water.

a. Environmental Chemistry, Fate and Transport

Chlorine (Cl_2), a greenish yellow gas at room temperature, is usually transported as a liquefied gas in pressurized containers. Chlorine reacts readily with water to form solvated chlorine, Cl_2 (aqueous). The solvated chlorine molecule disproportionates very rapidly (in the order of milliseconds) to hypochlorous acid and hydrochloric acid (Greenwood et al., 1984; Cotton et al., 1988; Tchobanoglous et al., 1985; Snoeyink et al., 1980). Chlorine (aqueous) is not a predominant species at pHs above 2.

Hydrochloric acid (a strong acid) is completely dissociated (to chloride anions and hydronium ions) under usual dilute aqueous solution conditions (Snoeyink et al., 1980). The formation of hydrochloric acid by addition of chlorine gas to water causes a lowering of pH in the aqueous medium, which affects the subsequent chemical properties of the water (Snoeyink et al., 1980).

Molecular chlorine can be considered primarily as a precursor to hypochlorous acid, which is known and registered for its pesticidal activity. The pesticidal activity of hypochlorous acid arises from its oxidizing effect on organic and inorganic contaminant sources (Wojtowicz, 1978). Hypochlorous acid is a weak acid, with a pK_a of 7.4 at 25°C (Adam et al., 1992). In the

acidic pH media, the predominant species is undissociated hypochlorous acid; in the neutral range, small amounts of hypochlorite ions are present together with hypochlorous acid. Only at very alkaline pHs does the acid completely dissociate into hypochlorite anions and hydronium ions.

The mechanisms and rates of decomposition of hypochlorous acid and hypochlorite anions are dependent on a number of factors including pH, chemical concentration, sunlight, and temperature (Greenwood et al., 1984; Cotton et al., 1988; Adam et al., 1992). Sunlight increases the rate of decomposition of hypochlorous acid/hypochlorite anions; these species absorb energy in the 292 to 380 nm region (Adam et al., 1992). The concentration and nature of organic and inorganic matter present in the aqueous medium (waters receiving treatment; natural waters) have an important effect in the decomposition of hypochlorous acid. The decomposition of hypochlorous acid/hypochlorite anions by organic and inorganic matter involves redox reactions that are pH-dependent (Greenwood et al., 1984; Cotton et al., 1988; Tchobanoglous et al., 1985; Snoeyink et al., 1980). The maximum decomposition rate of hypochlorous acid occurs at pH 6.89 (Adam et al., 1992).

The sanitizing properties or oxidizing effects of chlorinating agents such as chlorine, can be either associated with hypochlorous acid or with the hypochlorite anion. However, it is rare that both species are involved simultaneously in the same reaction (Greenwood et al., 1984). The most common redox reactions are: (a) oxidation of reduced inorganic matter, such as iron(II), manganese(II), nitrite, and sulfide; (b) reactions with ammonia and organic nitrogen (formation of chloroamines); (c) reactions with phenols; (d) reactions with an acetyl group to form chloroform; (e) addition to double bonds (Snoeyink et al., 1980).

In disinfection by chlorination operations, the use of the expression free residual chlorine is used 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 in turn is also a measurement of the available chlorine in solution (Wojtowicz, 1978). There are many chlorine by-products that are formed as a result of chlorination of organic compounds. Chloroamines, for example, are formed as a result of chlorination of amines in the effluent stream or receiving body of water. Each of the chloroamines (monochloroamine, dichloroamine and trichloroamine) contribute to the total (or combined) chlorine residual in water.

The amount of chlorine that must be added to water receiving treatment before a stable free chlorine residual can be obtained is known as

the "breakpoint dosage". When sufficient chlorine is added to completely oxidize and destroy chloroamines, the residual remaining consists almost entirely of free residual chlorine. Possible end products of the oxidation of ammonia are hydrazine, hydroxylamine, nitrogen, oxides of nitrogen, nitrite and nitrate, depending on the dosage of chlorine used.

Chlorine can react with organic chemicals containing an acetyl group (of which a major source appears to be the humic substances). This reaction can lead to the formation of chloroform. Formation of chloroform during water treatment is undesirable and of concern because chloroform is a suspected carcinogen (Snoeyink et al., 1980).

b. Environmental Fate Assessment

Treated effluents (which contain a free residual chlorine) released into receiving waters appear to dissipate rapidly, reducing the residence time at the point of discharge. Processes involved in the dissipation of free residual chlorine are dilution, phototransformation, volatilization and redox chemical reactions (Jolley, 1983; Heinimman et al., 1983; Osborne, 1985; Abel-Gawad et al., 1988). Temperature of the aqueous media influences the rate of dissipation (Heinimman et al., 1983). A half-life of free residual chlorine in natural freshwater systems has been estimated as 1.3 to 5 hours (Jolley, 1983).

There is no evidence at this point that active chlorine accumulates in sediments. This is attributed to the presence of reducing inorganic materials and of organic material capable of reacting with chlorine (Haas, 1990).

The ultimate fate of chlorine containing effluents released into receiving waters is site-specific and depends on such factors as the chemical constituents of the receiving waters, their temperature, dilution ratio and the intensity of sunlight.

2. Ecological Effects

Studies for lithium hypochlorite, used as an industrial biocide, were deemed appropriate for satisfying all ecological effects data requirements for chlorine when it is used as an industrial microbicide. Both lithium hypochlorite and chlorine form hypochlorous acid when dissolved in water.

a. Ecological Effects Data

(1) Terrestrial Data

Lithium hypochlorite (data acceptable for chlorine) was practically non-toxic to birds on a sub-acute dietary basis. An LD₅₀

of 567 mg/kg was determined for lithium hypochlorite (data acceptable for chlorine) in an acute avian oral toxicity test with the Bobwhite quail and was shown to be slightly toxic on an oral basis (Piccavillo, 1977; MRID 94673). The LD₅₀s for both the mallard duck (Piccavillo, 1977) and the Bobwhite quail (Piccavillo, 1977, MRID 104674) were >5000 ppm which indicated that lithium hypochlorite was practically non-toxic on a sub-acute dietary basis.

(2) Aquatic Data

Chlorine is very highly toxic to fish. In acute freshwater fish toxicity tests, an LC₅₀ of 0.20 mg/L (Buccafusco, 1978, MRID 94672) was determined for the rainbow trout (cold water) and an LC₅₀ of 0.28 mg/L (Buccafusco, 1978) was determined for the bluegill (warm water). Lithium hypochlorite was highly toxic to freshwater fish. EPA (Ambient Water Quality Criteria for Chlorine, 1984, EPA 440/5-84-030) reported that the toxicity of chlorine to 21 species (16 genera) of fish ranged from 0.045 mg/L (channel catfish) to 0.710 mg/L (Stickleback).

Chlorine was very highly to highly toxic to freshwater invertebrates. LeBlanc (MRID 94674) reported in 1978 that lithium hypochlorite (data acceptable for chlorine) was very highly toxic to freshwater invertebrates with an LC₅₀ of 0.037 mg/L for *Daphnia magna*. Additionally, data was reported for chlorine by EPA (Ambient Water Quality Criteria for Chlorine, 1984, EPA 440/5-84-030) on 12 species of freshwater invertebrates in 12 genera with LC₅₀s ranging from 0.017 mg/L (*D. magna*) to 0.673 mg/L (crayfish). EPA (Ambient Water Quality Criteria for Chlorine 1984, EPA 440/5-84-030) reported data on 24 species of saltwater organisms in 21 genera. Fish and invertebrates had similar sensitivities to chlorine and LC₅₀s ranged from 0.026 mg/L (eastern oyster) to 1.42 mg/L (shore crab).

(3) Non-Target Insects Data

There are no non-target insect data requirements for industrial microbicide pesticides.

(4) Non-Target Plants Data

There are no non-target plant data requirements for industrial microbicide pesticides.

b. Ecological Effects Risk Assessment

(1) Non-Endangered Species

The acute risk for the use of this pesticide is based on the residue levels in water receiving effluent from a facility using the pesticide. If residues should exceed one-half of the EC₅₀ to aquatic invertebrates [*D. magna* ½ EC₅₀ (0.017 ppm) = 0.009 ppm] and/or freshwater fish [channel catfish ½ LC₅₀ (0.045 ppm) = 0.023 ppm] these organisms are potentially at risk. If residues should exceed one-half of the EC₅₀ to estuarine invertebrates [eastern oyster ½ LC₅₀ (0.026 ppm) = 0.013 ppm] estuarine organisms are at risk. If these acute levels of concern are exceeded, a significant risk to aquatic organisms can be anticipated.

(2) Endangered Species

The acute risk to endangered species for the use of this pesticide is based on the residue levels in the receiving stream from a facility using the pesticide. If residues should exceed one-twentieth of the EC₅₀ to aquatic invertebrates [*D. magna* 1/20 EC₅₀ (0.017 ppm) = 0.85 ppb] and/or freshwater fish [channel catfish 1/20 LC₅₀ (0.045 ppm) = 2.3 ppb] these organisms are potentially at risk. If residues should exceed one-twentieth of the EC₅₀ to estuarine invertebrates [eastern oyster 1/20 LC₅₀ (0.026 ppm) = 1.3 ppb] estuarine organisms are at risk. If these acute levels of concern are exceeded, a significant risk to endangered aquatic organisms can be anticipated.

(3) Non-Target Aquatic Species Risk

Initial maximum exposure levels required for efficacious use were based on label information and are expressed in terms of residual chlorine ppm and are as follows: sewage systems (0.02 ppm effluent), pulp and paper mills (0.2 ppm), water cooling systems (0.3-0.8 ppm), swimming pool water (0.6-2 ppm), lakes/pond/reservoirs/aquaria (no human, fish, wildlife use) (3-5 ppm), human drinking water systems (0.2 ppm), food water processing systems (50-200 ppm), food/meat/poultry processing (food contact/non-contact) (3-5 ppm/10-25 ppm). These values are assumed to be equal to the estimated environmental concentration discharged because there is a lack of actual data and no degradation of residual chlorine.

The chlorine uses may be categorized into two divisions, NPDES regulated and non-NPDES regulated.

Non-NPDES Regulated Uses

For reregistration purposes, all aquatic non-food residential and indoor uses are considered to be non-NPDES regulated e.g., swimming pool, aquaria, and the indoor use patterns consisting of agricultural (fruit and vegetable rinse) and food processing. The concentration of any discharges from these uses should be minimal and intermittent resulting in minimal environmental exposures.

There are no acceptable exposure data to support any risk assessment conclusions for these use patterns. However, there are mitigating factors that support the conclusion that the aquatic organism exposure resulting from swimming pool, ornamental pool or other indoor use drainage is minimal. First, pools are not routinely emptied and refilled. For example, swimming pools may be emptied at the end of the swimming season or for maintenance. These drainings should be very infrequent, at most, twice per year. Second, owners/operators would be unlikely to treat a swimming pool with chlorine 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 onto the area immediately surrounding the pool, including onto a nearby street, or into municipal sewage systems. In either case, the high reactivity of hypochlorous and hypochlorite ions with organic matter greatly reduces the levels of residual chlorine available to aquatic organisms.

NPDES Regulated Uses

Aquatic non-food industrial use patterns are included under the NPDES permitting system administered by the Office of Water e.g., water-cooling towers, sewage treatments plants, and pulp and paper mills.

Processes involved in the dissipation of free residual chlorine are dilution, phototransformation, temperature, volatilization and redox chemical reactions. A half-life of free residual chlorine in natural freshwater systems has been estimated as 1.3 to 5 hours.

There is no available evidence that active chlorine accumulates in sediments. The lack of accumulation is attributed to the presence of reducing inorganic materials and of organic material capable of reacting with chlorine. The type and relative amounts of organic

chemicals already present in the effluent and receiving water into which the chlorine is being discharged will determine the formation of chlorinated organic compounds.

Acceptable chlorine levels on a national level (at the end of mixing) have been described in the Water Quality Criteria document for Chlorine (50 FR 30788). These values are as follows: fresh water acute (19 ppb), estuarine acute (13 ppb), fresh water chronic (11 ppb), and estuarine chronic (7.5 ppb). Effluent discharges containing chlorine are regulated under NPDES permits to reduce the impact on water bodies. The maximum concentration of chlorine in the effluent stream established by the NPDES permit is done on a site-specific and use-specific basis in order to achieve the lowest possible concentrations of chlorine in the receiving stream. The chlorine concentration at the site of discharge is dependent on the location of the site (lake, river or ocean), the flow of the current, the duration of the discharge, the frequency of the discharge, and the length of time before discharge occurs.

The acute aquatic risk level of concern for non-endangered aquatic species calculated by the Agency's Office of Pesticide Programs is $\frac{1}{2}$ the LC_{50} . Based on this approach, the levels of concern for chlorine are as follows: freshwater fish (23 ppb); miscellaneous invertebrates including *Daphnia* (9 ppb); and miscellaneous estuarine/marine invertebrates (13 ppb). The calculated acute aquatic risk level of concern for endangered aquatic species is $\frac{1}{20}$ LC_{50} : freshwater fish (2.3 ppb), miscellaneous invertebrates including *Daphnia* (0.85 ppb), and estuarine/marine invertebrates (1.3 ppb).

The values cited in the Water Quality Criteria document for Chlorine are not directly comparable to the levels of concern calculated by the Office Of Pesticide Programs because the methodologies used to calculate these values are significantly different. However, because chlorine discharge is regulated by the Agency (Office of Water) and the Water Quality Criteria are adequate, no significant adverse effects to aquatic organisms are anticipated from the discharge of chlorine under the NPDES permitting system.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing chlorine as the active ingredient. 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 chlorine as the sole active ingredient. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorine, 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 chlorine and to determine that chlorine can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing chlorine 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, published scientific literature, available incident information, and the data identified in Appendix B. Although the Agency has found that all uses of chlorine 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 chlorine, 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 ingredient chlorine, the Agency has sufficient information on the health effects of chlorine and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that chlorine products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment if products are labeled and applied according to the requirements specified in Section V. Therefore, the Agency concludes that products containing chlorine for all uses are eligible for reregistration. 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.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of chlorine, labeled and used as specified in the RED, are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Chlorine gas is exempt from the requirements for a tolerance when used preharvest or postharvest in solution on all raw agricultural commodities [40 CFR §180.1095]. Because of the exemption, plant metabolism, storage stability, and magnitude of the residue data are not required. The Agency believes this exemption is appropriate and no change is needed.

2. Restricted Use Classification

Because of its high toxicity and occurrence of poisoning incidents, the Agency is requiring restricted use status for the non-residential swimming pool use, the industrial food use settings, cooling water towers, and for pulp and paper mill process water systems. Under the provisions of restricted use, only certified applicators or other persons under direct supervision of a certified applicator (40 CFR §171.6) would be able to apply chlorine gas and only for these uses covered by the Certified Applicators certification. This level of restricted use is appropriate because of the rapid, acute action of released chlorine. For automated systems which monitor water and add chlorine as needed, direct supervision is required only when the chlorine tanks are changed and allowed to operate without supervision between tank changes.

The Agency is using the authority of FIFRA section 3(d)(2) to reclassify these uses of chlorine gas from "General Use" to "Restricted Use". Chlorine gas meets the criteria for restricted use by certified applicators for human hazard as stated in CFR 152.170 because of acute inhalation toxicity, dermal toxicity and corrosivity to the eyes and to the skin, and because of the occurrence of poisoning incidents.

The Agency has determined that the chlorine gas uses consisting of non-residential swimming pools, pulp and paper mill processes, and industrial food processing plants should be reclassified from General Use to Restricted Use. In 1976 the Agency classified all pesticidal uses of chlorine gas as General Use. It assumed

that training programs and oversight by various State and Federal agencies would provide sufficient guidance and assurance that risks from the use of chlorine gas would be held to a minimum. The reports of incidents suggest this assumption was not correct. Based chiefly on California incident reports, the Agency believes that many applicators of chlorine gas for these uses lack adequate training. This has significantly contributed to the potential for accidents. This regulatory action is required to improve the application practices and to reduce the risks of accidents and injury to applicators and other people in the vicinity of applications.

The Agency believes the Restricted-Use classification is appropriate for the uses of chlorine gas in food processing, public/ commercial pools, and commercial and industrial water treatment systems. These uses involve in-place chlorinator systems, and the majority of reported chlorine gas incidents involve chlorinator system maintenance operations, particularly changing tanks. These are sites at which many people can be in the vicinity of a chlorine gas release and exposed to toxic levels. Incidents involving lifeguards and other untrained maintenance workers are common among those reported. Because of the high acute toxicity of chlorine gas and the potential for exposures to untrained workers, these uses will be limited to certified applicators. Labeling changes alone could not be expected to adequately address risks to untrained workers.

When the Agency classifies a use of a pesticide as Restricted, the pesticide can only be used by or under the direct supervision of an applicator who is certified in the appropriate category for that use. State Lead Agencies for pesticide programs carry out their certification programs under cooperative agreement with the Agency. The Agency has approved the certification program plan for each state that conducts such a program. Within those plans, the states identify categories of certification that must be met to become certified in each category and standards of competency. The Agency will work with industry groups and any interested parties in the development of training materials for use by State Lead Agencies and Extension Service. These processes are likely to take 12 to 18 months to accomplish.

As required under FIFRA § 3(d)(2), the Agency will publish a notice of this proposed change in classification from General to Restricted Use in the Federal Register. Registrants will need to amend their registrations and product labels to incorporate the Restricted Use Statement, and the other required language in this RED, to coincide with the certification program.

The Agency must coordinate the timing of the distribution and sale of products with restricted use labeling with the 12 to 18 months it will take states to develop and implement new certification training programs. To accomplish this, the Agency will follow the normal course for label amendments for product reregistration. That is, eight months for registrants to submit revised labels and another six months for Agency review. Additionally, the Agency is requiring that restricted use labeling

cannot be on products sold or distributed by registrants prior to October 1, 2000 (approximately 20 months after the issuance date of this document), and that by April 1, 2001 (approximately 26 months after the issuance date), all products subject to the restricted use labeling must have that labeling for distribution or sale to any person.

3. General Use Classification

Chlorine gas was previously classified as a general use pesticide. In order to harmonize chlorine labeling with Label Review Manual directions, the remaining non-restricted uses of chlorine will be considered unclassified.

The Agency does not, at this time, support the need to restrict the use of chlorine gas for the industrial uses of drinking water, sewage, and wastewater treatment. These uses are year round, so there are no seasonal applicators/ workers that are not familiar with application techniques of chlorine gas. Fewer workers are likely to be in the vicinity of chlorine tanks and dispensing equipment. Pesticide handler's training would be of marginal benefit since it is geared toward agricultural uses, and would add a regulatory burden without providing additional protection to workers. Additionally, these applicators/ workers receive formal training on proper use of chlorine gas through State Operator Certification Programs. Improvements in labeling are considered to be more an effective approach to reducing chlorine gas exposure risks to water/wastewater treatment workers. Since access to these facilities is controlled, bystander risks are not significant.

For the residential swimming pool use, the Agency also does not support the need to restrict the use of chlorine gas to trained applicators at this time. Currently, the incident information on residential pool use is not sufficient to support adding this additional regulatory burden; however the Agency recognizes that incidents at these sites may fall outside the normal incident reporting mechanisms. Treatment of residential swimming pools does not rely on the in-place chlorinator systems, so the risks associated with the in-place systems are not applicable. Improvements in labeling will facilitate the states' ability to enforce proper application procedure. Currently, most of the states where residential pool use is common place have implemented programs that require training of applicators which may meet the purpose and intent of certification. Even though there is little documented evidence of accidents associated with the treatment of smaller residential swimming pools, the applicator and residents with residential swimming pools can be at risk to the same type of injuries as other chlorine gas uses. While the Agency is not, at present, reclassifying the residential swimming pool use site as restricted use, this change could be made in the future, as an independent action, if new information becomes available to the Agency. The Agency will attempt to gather information on incidents related to residential use and evaluate the effectiveness of existing training programs to ensure the same level of protection to applicators and bystanders at residential swimming pools.

Pursuant to FIFRA §6(a)(2), the Agency has the authority to reclassify or otherwise regulate the use of pesticides based on the review of toxicological, environmental fate, incident reports, or in general any information indicating adverse effects. This issue is particularly important with regard to residential pool use because of the Agency's regulatory position and because of the likelihood of unreported incidents. PR Notice 92-1 specifically includes incident reports as part of the §6(a)(2) reporting requirements, and informs the public of the Agency's intention to aggressively enforce the failure to report such information.

4. Improved Product Labeling

To promote more consistent and appropriate use of chlorine gas products, the Agency through this document is requiring significant revisions to product labeling. Currently, product labels refer users to consult printed materials published by the Chlorine Institute for additional directions for use. However, labels and this supplemental information do not contain sufficient specific use information. This major deficiency is being corrected through this RED. Also, any supplemental printed information will be brought under FIFRA labeling requirements and will be made part of the official accepted labeling of products. Use directions and precautions will be provided for all uses and clearly presented.

Labeling improvements are necessary since the current label language is not specific enough to support enforcement actions. States and EPA Regions have had difficulty citing specific procedural failures because of these ambiguities. These changes are intended to bring chlorine gas labeling up to parity with that associated with other acutely hazardous substances.

5. Endangered Species Statement

When the Endangered Species Protection Program becomes final, limitations in the use of chlorine gas may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

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. Additional Data Requirements

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of chlorine for the above eligible uses has been reviewed and determined to be substantially complete to characterize acute risks. For the majority of exposure scenarios, enough data exists to adequately characterize chronic risks, also. Regarding the drinking water treatment use, although the quality of data is sufficient to reregister this public health use, there is some uncertainty regarding the health effects of halogenated byproducts.

The Agency has concluded that there is a need to better characterize the reproductive and developmental risks associated with drinking water consumption in order to assure that children, infants and fetuses do not face unreasonable risk from chronic exposure to drinking water byproducts. Because of the high levels of exposure, both in terms of population (greater than 200,000,000) and individual consumption of chlorinated drinking water, it is necessary to assess the associated risks with greater certainty.

Three disinfection byproducts in particular have been identified for which the health effects need to be better characterized. Bromodichloromethane, dichloroacetic acid, and dibromoacetic acid have been identified as having health effects in laboratory studies. Because these compounds occur at relatively high concentrations and have been shown to cause adverse effects in laboratory animals, there is a need for additional testing on these compounds to improve the Agency's ability to assess chronic risks from drinking water exposure.

The following confirmatory tests on particular halogenated hydrocarbons will be required:

Bromodichloromethane (BDCM): Rodent and non-rodent developmental test (40 CFR §870.3700); and a two-generation reproductive test (40 CFR §870.3800).

Dichloroacetic acid (DCA): Non-rodent developmental test (40 CFR §870.3700)

Dibromoacetic acid (DBA): Two-generation reproductive test (40 CFR §870.3800)

2. 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 E, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix E; Attachment 3) 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.

B. Labeling Requirements

1. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the statements specified in Table 6.

Because of space limitations on labels and the complexity of the precautions necessary to use chlorine gas safely, the Agency is requiring registrants to submit an applicator's manual which provides the necessary details for the safe use of chlorine gas. The manual should provide, but need not be limited to, information on chemical and physical properties, equipment operation, care and use of personal protective equipment, first aid and medical management of exposures, leak detection, emergency response, storage and handling of containers, and instructions to comply with all local regulations and ordinances. The manual is to be submitted concurrently with submittal of the product label. The label should contain a statement referring the user to the manual for instructions on the required product use and safety procedures.

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. Additionally, the Agency intends to work with the Chlorine Institute to bring its published materials on the use of chlorine gas for pesticidal uses under FIFRA labeling requirements. These materials will be considered supplemental labeling. All EUP labeling must bear the statements specified in Table 6.

a. Use Directions

The end-use label must indicate the specific intended uses. Each use must have specific directions. Products must be labeled for only restricted-use sites or unclassified use sites, not both, as stipulated in Section 156.10(j). This may require label revision and application for new product registrations if a registrant wishes to have products intended for both types of uses.

In this document, several revisions are being made to the standard label text required for chlorine products:

1. The standard Precautionary Statements and the First Aid Statement/ Statement of Practical Treatment have been re-worded based on current policy and recent data review.
2. In accordance with Agency policy, a product may not be labeled for both end-use and manufacturing-use under the same EPA Registration Number.
3. For end-use products, specific directions must be provided for each use, either on the main label or in collateral labeling referenced by the main label. Any supplemental labeling thus referenced must be submitted as part of the product labeling for EPA acceptance.

A product registration may include either restricted or non-restricted (unclassified) uses, but not both. Therefore, if a product is currently registered for any of the uses now being classified as restricted and the registrant wishes to retain that use for its product registration, all non-restricted uses must be deleted from that registration. The non-restricted uses may then be registered separately under a new registration number.

In this RED document, all the uses of chlorine gas except for treatment of drinking water and sewage and wastewater and commercial applications to residential swimming pools serviced by professional applicators are being declared Restricted. The uses now classified as restricted are treatment of non-residential swimming pool water, treatment of wash-water for raw agricultural commodities and certain other food commodities, treatment of food-contact and non-food contact surfaces in the food processing plants, and treatment of cooling tower water and cooling water for pulp and paper mill process water systems.

For products being reregistered under this RED document with a use being declared restricted, a restricted use legend must appear at the top of the front panel of the label, as shown in the standard labeling below. No other wording or symbols may appear above the legend. It must begin with the heading "RESTRICTED USE PESTICIDE," followed by a brief statement of the reason for the restricted use classification (i.e., "DUE TO HIGH ACUTE TOXICITY"). Following this, the terms of the restriction must be stated as, "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

Until recently, one of two standard labels would be selected based on whether stationary storage containers were to be used, or smaller portable cylinders. Now, however, because of the similarity of the two standard labels and for the sake of complete labeling, they are being merged into one standard label, with the provision that the appropriate general usage paragraph (above the ingredients statement) should be selected based on the type of container and use.

Following the standard labeling depicted below, various comments and examples are provided as guidance in developing specific directions for use.

Because of space limitations on labels and the complexity of the precautions necessary to use chlorine gas safely, the Agency is requiring registrants to submit an applicator's manual which provides the necessary details for the safe use of chlorine gas. The manual should provide, but need not be limited to, information on chemical and physical properties, equipment operation, care and use of personal protective equipment, first aid and medical management of exposures, leak detection, emergency response, storage and handling of containers, and instructions to comply with all local regulations and ordinances. The manual is to be submitted concurrently with submittal of the product label. The label should contain a statement referring the user to the manual for instructions on the required product use and safety procedures.

b. Guidance for Specific Directions for Use

The labels of all chlorine products must bear directions for each recommended use. The directions for use should include statements similar to the following sample directions. Those statements which are actually required are indicated as such. Additional instructions may be necessary for some product uses to ensure safe and effective use of a product. Such additional instructions may be recommended by the applicant, or required by the Agency, as determined on a case by case basis.

c. Effluent Discharge Labeling Statements

Refer to subsection V.A.2 or V.B.2.b., above for labeling requirements for effluent discharge.

Table 6: Summary of Required Labeling Changes for Chlorine Gas

Description	Required Labeling	Placement on Label
Manufacturing Use Products (MUPs)		
<p>Front Panel Labeling (all MUPs)</p>	<p style="text-align: center;">[Place brand name here if desired] “CHLORINE LIQUEFIED GAS UNDER PRESSURE</p> <p style="text-align: center;">ACTIVE INGREDIENT: Chlorine....____% INERT INGREDIENTS:.....____%</p> <p style="text-align: center;">KEEP OUT OF REACH OF CHILDREN</p> <p style="text-align: center;">DANGER</p> <p style="text-align: center;">POISON”</p> <p>[Place skull-and-crossbones close to the word POISON.]</p> <p style="text-align: center;">[“POISON” must be in red, on a background of distinctly contrasting color.]</p> <p style="text-align: center;">“FATAL IF INHALED. LIQUID CAUSES SEVERE BURNS</p> <p style="text-align: center;">EPA Reg. No. _____ EPA Est. No.”</p> <p style="text-align: center;">[Company name and address:] _____ _____ _____</p> <p style="text-align: center;">“NET CONTENTS: _____”</p>	<p>Front panel</p>
<p>Heading: Precautionary Statement (all MUPs)</p>	<p style="text-align: center;">“PRECAUTIONARY STATEMENTS”</p>	<p>Place directly below “Net Contents:____” Note: If some precautionary statements appear on other panels, the heading :Precautionary Statements” must also be placed above those statements.</p>

Description	Required Labeling	Placement on Label
<p>First Aid or Statement of Practical Treatment or (either heading is acceptable) (all MUPs)</p>	<p>“ FIRST AID:” or “ STATEMENT OF PRACTICAL TREATMENT”</p> <p>“IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. IF ON SKIN: Wash with plenty of soap and water while removing contaminated clothing and shoes. Get medical attention.”</p> <p>[If remaining precautionary statements (Hazards to Humans & Domestic Animals, Personal Protective Equipment, Environmental Hazards, and Chemical & Physical Hazards) are not placed on front panel, the following statement is also required.]</p> <p>“See back panel for additional precautions.”</p>	<p>Front Panel below the heading “Precautionary Statements”</p>
<p>Hazards to Humans and Domestic Animals (all MUPs)</p>	<p>“HAZARDS TO HUMANS AND DOMESTIC ANIMALS: DANGER. Fatal if inhaled or absorbed through skin. Corrosive. Causes irreversible eye damage and skin burns. Do not breathe vapors or get in eyes, on skin or clothing. Wear goggles, protective clothing and rubber gloves as discussed below. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.”</p>	<p>Front panel directly below the First Aid Statements or on other panels of the label.</p>
<p>PPE Requirements (all MUPs)</p>	<p>“PERSONAL PROTECTIVE EQUIPMENT: Handlers must wear long-sleeved shirts, long pants, shoes, and socks. In Case of Spill or Leakage: Under normal use-conditions, no protective eyewear, respirator, or gloves are required. However, in case of a spill or leak, handlers must wear chemical-resistant gloves (such as nitrile or butyl) and a full-face canister-style (gas mask) respirator with a canister approved for chlorine (MSHA/NIOSH approval number prefix TC-14G) OR a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F). Since there is always the possibility of a spill or leak, gloves and a respirator of a type specified above must be available and are required for anyone entering into an affected area in the event of a leak or spill.”</p>	<p>Directly below the Hazards to Humans and Domestic Animals Statement</p>
<p>Environmental Hazards (all MUPs)</p>	<p>“ENVIRONMENTAL HAZARDS: This pesticide is toxic or highly toxic to fish and aquatic invertebrates. 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.</p>	<p>Directly below/after the Personal Protective Equipment Statement</p>
<p>Physical and Chemical Hazards (all MUPs)</p>	<p>“PHYSICAL & CHEMICAL HAZARDS: Chlorine is a non-flammable gas, liquefied, under pressure. Do not drop container. Do not heat container. Keep away from intense heat or open sunlight. Corrosive to most metals in the presence of moisture.”</p>	<p>Directly below/after the Environmental Hazard Statement</p>

Description	Required Labeling	Placement on Label
<p>Directions for use (all MUPs)</p>	<p style="text-align: center;">“DIRECTIONS FOR USE</p> <p>It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Refer to [state the name of the manual being used] for instructions on the required product use and safety procedures. Before working with this product, handlers must be trained how to appropriately use respirators that conform to OSHA requirements (described in 29 CFR Part 1910.134) and how to appropriately handle and use chlorine. This product, including dispensing equipment, must be handled and used in accordance with the practices specified by all applicable product labeling and the [state the name of the manual being used]." Use only in well ventilated areas.</p> <p>Only for formulation into an” [fill blank with Sanitizer, Disinfectant, or the applicable term which describes the type of pesticide uses(s)] “for the following uses(s):” [fill blank only with those uses that are being supported by MP registrant].</p> <p>[Additional optional statement may be placed here as specified above under "Labeling Requirements for Manufacturing-Use Products."]</p> <p>[Note that directions for specific uses are not permitted on MP labels. A product must be labeled as EP or MP, not both.]</p>	<p>Directly below the PRECAUTIONARY STATEMENTS section.</p>
<p>Storage & Disposal (all MUPs)</p>	<p>“STORAGE & DISPOSAL</p> <p>STORAGE: Store cylinders and ton containers in a dry area away from sources of heat and protected from direct sunlight and precipitation. Do not store in excessive heat. Segregate chlorine containers from other compressed gases, and never store near hydrocarbons, finely divided metals, turpentine, ether, anhydrous ammonia, or other flammable materials. All storage containers and cylinders must have a weather resistant label and must not be accessible to the general public. Do not drop container. If container is damaged or leaking, refer to procedures in the [state the name of the manual being used] and/or notify supplier immediately. Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law.”</p>	

Description	Required Labeling	Placement on Label
Storage & Disposal (Continued) (all MUPs)	<p>“LEAK PROCEDURES: Make daily inspections for leaks. Stop a leak at once, since it will become worse with time.</p> <p>In case of a leak, evacuate everyone from the immediate area. For entry into the affected area to correct problem, wear personal protective equipment (including prescribed respirators) specified in the Hazards to Humans section of this labeling. When possible, move leaking or damaged cylinders outdoors or to an isolated location. Observe strict safety precautions. Work upwind, if possible. Allow any liquid chlorine to evaporate. Only correctly trained and Personal Protective Equipment (PPE)-equipped handlers are permitted to perform such cleanup. Do not permit entry into the leak area by any other person until the chlorine has completely dispersed.</p> <p>DISPOSAL OF CONTAINER: Container is returnable and must be properly identified with return tag and returned as promptly as possible to supplier according to prescribed instructions and practices in the” [state the name of the manual being used]. “All valves must be closed tight and closures or caps secured. It is illegal to ship a leaking chlorine container.”</p>	Place in Storage & Disposal box with Storage statement
End Use Products Intended for Occupational/Commercial Use		
Restricted Use Pesticide (RUP) Statement [required on all RUP products (products used on non-residential swimming pools, industrial food use settings, cooling water towers, and pulp and paper mill process water systems)]	<hr/> <p style="text-align: center;">“RESTRICTED USE PESTICIDE DUE TO HIGH ACUTE TOXICITY</p> <p>For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.”</p> <hr/>	Top of Front Panel and Beginning of Directions for Use
User Statement [required for non-RUP products only (water and sewage treatment, and residential swimming pools)]	“For Use Only By Trained Commercial Applicators”	Top of Front Panel
Brand Name and Chlorine Identification Statement (required for all End Use Products)	<p style="text-align: center;">[Place brand name here if desired] “CHLORINE LIQUEFIED GAS UNDER PRESSURE”</p>	Below/after the RUP or Trained Applicator Statement
Usage Statement (required for all bulk containers such as tank cars, tank trucks, and 1-ton and 150-pound cylinders)	“For use as a” [indicate whichever kind(s) of antimicrobial activity and specific uses(s) your product is registered for, e.g., disinfectant in swimming pools, or as a sanitizer for wash water treatment of food handling premises and equipment (fruit, vegetable, meat, poultry or seafood), or as an algicide and slimicide for use in recirculating cooling towers and pulp and papermill process water systems.] “The registrant is solely responsible for the safety of the servicing equipment used with this pesticide, and for the repackaging of this gas from larger containers into portable cylinders. Each repackager must obtain his own EPA Registration Number for this pesticide for this use, and his own EPA Establishment Number from the EPA. Repackers may only dispense this product to portable containers that are appropriately labeled.”	Directly below/after the “Chlorine Identification Statement”

Description	Required Labeling	Placement on Label
Usage Statement for portable containers used by service companies in treating swimming pools or wash water for raw agricultural commodities	“For use as a” [indicate whichever use(s) your product is registered for: disinfectant and algicide] “in” [indicate use, either “servicing swimming pools” or “wash water for raw agricultural commodities”].	Directly below/after the “Chlorine Identification Statement”
Front Panel Labeling (required on <u>all</u> End Use Products)	<p style="text-align: center;">“ACTIVE INGREDIENT: Chlorine.... ____% INERT INGREDIENTS:..... ____% KEEP OUT OF REACH OF CHILDREN DANGER</p> <p style="text-align: center;">[Place skull-and-crossbones close to the word POISON.] POISON” [“POISON” must be in red, on a background of distinctly contrasting color.]</p> <p style="text-align: center;">“FATAL IF INHALED. LIQUID CAUSES SEVERE BURNS</p> <p style="text-align: center;">EPA Reg. No. _____ EPA Est. No. _____”</p> <p style="text-align: center;">[Company name and address:] _____ _____ _____</p> <p style="text-align: center;">“NET CONTENTS: _____”</p>	Front Panel directly below/after Usage Statement
Precautionary Statements Heading required on all End Use Products	“PRECAUTIONARY STATEMENTS”	Front Panel directly below “Net Contents: _” Place directly below “Net Contents: ___” Note: If some precautionary statements appear on other panels, the heading :Precautionary Statements” must also be placed above those statements.

Description	Required Labeling	Placement on Label
First Aid Heading and Statements (required on all End Use Products)	<p style="text-align: center;">“FIRST AID:”</p> <p>“IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention. IF ON SKIN: Wash with plenty of soap and water while removing contaminated clothing and shoes. Get medical attention.”</p> <p>[If remaining precautionary statements (Hazard to Humans & Domestic Animals, Personal Protective Equipment, Environmental Hazards, and Chemical & Physical Hazards) are not placed on front panel, the following statement is also required.]</p> <p style="text-align: center;">“See back panel for additional precautions.”</p>	Place directly below the heading “PRECAUTIONARY STATEMENTS” on Front Panel.
Precautionary Statements (required on all End Use Products)	<p style="text-align: center;">“Precautionary Statement” [and signal word] “Danger”</p> <p>“HAZARDS TO HUMANS AND DOMESTIC ANIMALS: DANGER. Fatal if inhaled or absorbed through skin. Corrosive. Causes irreversible eye damage and skin burns. Do not breathe vapors or get in eyes, on skin or clothing. Wear goggles, protective clothing and rubber gloves as discussed below. Wash hands thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.”</p>	May appear on front panel (below the First Aid Statements) or other panels of the label.
PPE Requirements (required on all End Use Products)	<p>“Personal Protective Equipment: Applicators and other handlers must wear long-sleeved shirts, long pants, shoes, and socks”.</p>	Directly below the Hazards to Humans and Domestic Animals Statement.
Leakage Personal Protective Equipment (required for bulk containers)	<p>“IN CASE OF LEAKAGE</p> <p>Under normal use-conditions, no protective eyewear, respirator, or gloves are required. However, in case of a leak, handlers must wear chemical-resistant gloves (such as nitrile or butyl) and a full-face canister-style (gas mask) respirator with a canister approved for chlorine (MSHA/NIOSH approval number prefix TC-14G) OR a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TC-13F). Since there is always the possibility of a leak, gloves and a respirator of a type specified above must be available. Gloves and a respirator are required for anyone entering into an affected area in the event of a leak.”</p>	Directly below the PERSONAL PROTECTIVE EQUIPMENT Statement.

Description	Required Labeling	Placement on Label
Leakage Personal Protective Equipment (required for portable cylinders or containers)	<p>“In Case of Leakage:</p> <p>Under normal use-conditions, no protective eyewear, respirator, or gloves are required. However, in case of a leak, handlers must wear chemical-resistant gloves (such as any waterproof material) and a full-face canister-style (gas mask) respirator with a canister approved for chlorine (MSHA/NIOSH approval number prefix TC-14G). Since there is always the possibility of a leak, gloves and a respirator of a type specified above must be available. Gloves and a respirator are required for anyone entering into an affected area in the event of a leak.”</p>	Directly below/following Personal Protective Equipment Statement.
Environmental Hazards	<p>“ENVIRONMENTAL HAZARDS: This pesticide is toxic or highly toxic to fish and aquatic invertebrates. 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.”</p>	Directly below/following Spillage Personal Protective Equipment Statement.
Physical & Chemical Hazards	<p>“PHYSICAL & CHEMICAL HAZARDS: Chlorine is a non-flammable gas, liquefied, under pressure. Do not drop container. Do not heat container. Keep away from intense heat or open sunlight. Corrosive to most metals in the presence of moisture.”</p>	Directly below/following Environmental Hazards statement.
General Directions for Use (required for all End Use Products)	<p style="text-align: center;">"DIRECTIONS FOR USE</p> <p>It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Refer to [state the name of the manual being used] for instructions on the required product use and safety procedures. Before using this product, handlers must be trained how to appropriately use respirators that conform to OSHA requirements (described in 29 CFR Part 1910.134) and how to appropriately handle and use chlorine. This product, including dispensing equipment, must be handled and used in accordance with the practices specified by all applicable product labeling and the [state the name of the manual being used]." Use only in well ventilated areas.”</p>	Directly below/following the PRECAUTIONARY STATEMENTS section.
Specific Directions for Use (required for all End Use Products)	<p>Specific Directions for Use. The following information must appear on the label or be referred to in supplemental labeling.</p> <ul style="list-style-type: none"> ! An instruction to test the chlorinated water with a test kit to ensure adequate concentration (ppm) of available chlorine or chlorine residual. ! Identification of the type of water, object, or surface to be treated, and the type of area or establishment in which the product is to be used. ! For surface treatments, an instruction for thorough pre-cleaning should be included. ! The recommended concentration (ppm) available chlorine or chlorine residual, and how to prepare it. 	Directly below/following the General Directions for Use statement or attached as supplemental labeling

Description	Required Labeling	Placement on Label
Specific Directions for Use (required for all End Use Products) (continued)	<p>! The method of application (e.g., wipe, rinse, immerse, spray), if not already understood (as in water treatment applications). For surface treatments, the reader must understand that all surfaces must be thoroughly wetted.</p> <p>! The contact time necessary for effectiveness. For surfaces, also indicate any necessary information on a final rinse, and if and how the product should be removed from the surface after the recommended contact time.</p> <p>! For some water treatment applications, a follow-up dosage(s) should be indicated.</p> <p>! For surface treatments, an instruction regarding limitations on re-use of the solution (e.g., whether it may be re-used if it has not become diluted or soiled, and for how many batches or how many days).</p> <p>! Additional instructions or information may be appropriate, or required on a case-by-case basis.</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Specific Directions for Use (required for all products registered for swimming pool water treatment)	<p>(a) The proper range in the concentration (ppm) of chlorine or residual (e.g., available chlorine) and pH to be maintained at all times. The directions should advise users to test the water with test kits to maintain pH and the proper concentration of principle active ingredient or residual.</p> <p>(b) The frequency of treatment required for the maintenance of the desired concentration of chlorine is dependent on bather load, and the concentration should be checked frequently with a test kit.</p> <p>(c) How the product is to be added to the pool (e.g., automatic metering device).</p> <p>(d) The maximum concentration of chlorine or residual allowable in the pool water, following application of the product, before swimmers are allowed to re-enter the pool.</p> <p>(e) Any water quality conditions essential to effective use of the product as a disinfectant (e.g., alkalinity).</p> <p>(f) Treatment procedure(s) for newly filled pools.</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Specific Directions for Use (required for all products registered for Industrial Water Treatment Systems)	<p>(a) <u>General</u>. This section provides labeling guidance for chlorine products intended for control of algal, bacterial, and/or fungal slime in industrial cooling water systems, pulp and paper mills and similar water treatment systems.</p> <p>(b) <u>Label Claims</u>. Broad label claims such as "microbicide", "microbistat", "slimicide" and "microorganism control" should not be used unless they are modified by:</p> <p>! The names of the types of organisms (algae, bacteria, fungi) for which control is intended. Terms such as "biocide" or "biostat" are generally not acceptable when only microorganism control is intended.</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling

Description	Required Labeling	Placement on Label
<p>Specific Directions for Use (required for all products registered for Industrial Water Treatment Systems) (continued)</p>	<p>! An identification of the industrial or commercial recirculating water cooling systems (e.g., industrial and/or commercial recirculating cooling water towers, air washers, and/or evaporative condensers) in which the product is intended for use.</p> <p>! An accurate description of the level of activity claimed for each use stated on the label. An acceptable statement for a microbicide would be: "Microbicide for use in industrial recirculating cooling water towers to reduce the number of living algae, bacteria and fungi." An acceptable statement for a "microbistat" would be: "A microbistat (microorganism control) for use in industrial recirculating cooling towers to control the growth of algae, bacteria, and fungi."</p> <p>(c) <u>Special Directions for Use</u>. Directions for general microbial control must include, but are not limited to, the following:</p> <p>! <u>Site of Use</u>. Directions should state where in the system the product is to be applied (e.g., at a point in the system where the product will be uniformly mixed).</p> <p>! <u>Time of Use</u>. Directions should specify when the product should be applied (e.g., when the system is in danger of becoming impaired or after cleaning a system whose efficiency is already impaired).</p> <p>! <u>Dosage</u>. The dosage rate or amount should be specified as volume or weight of chlorine per unit volume of water. The product weight per gallon must be shown on the label, whether the dosage is given as volume or weight.</p> <p>! <u>Method of Application</u>. The method of application or pattern of use must appear on the label and should conform to the instructions provided below for the intermittent or "slug method", the modified intermittent method, or the continuous feed method.</p> <ul style="list-style-type: none"> • <u>Intermittent or Slug Method</u>. The directions should state an initial dosage range of relatively high product concentration to obtain control of obvious microbial contamination. When microbial control is evident, a subsequent dosage regimen of relatively lower product concentration should be stated. The label should state the usual time interval between doses, or include the phrase "as needed to maintain control", or both. The label should not claim maintenance of any particular pesticide concentration. The following is an example of acceptable directions or use: <u>Initial Dose</u>. When the system is noticeably fouled, apply ___ to ___ (volume or unit weight) of (product name or active ingredient) per ___ (unit volume) of water in the system. Repeat until control is achieved. Badly fouled systems must be cleaned before initial treatment. 	<p>Directly below/following the General Directions for Use statement or attached as supplemental labeling</p>

Description	Required Labeling	Placement on Label
<p>Specific Directions for Use (required for all products registered for Industrial Water Treatment Systems) (continued)</p>	<p><u>Subsequent Dose.</u> When microbial control is evident, add ___ to ___ (volume or unit weight) of ___ (product name or active ingredient) per ___ (unit volume) of water in the system every ___ days (weekly), or as needed to maintain control.</p> <ul style="list-style-type: none"> <p><u>Modified Intermittent Method.</u> This method is similar to the intermittent, or slug method, except that the interval between treatments is based on the time for a stated fraction of the system water to be lost by blowdown. This method of application may be accompanied by label claims for the maintenance of the pesticide concentration within a stated maximal and minimal limit. The following is an example of acceptable directions for use:</p> <p><u>Initial Dose.</u> When the system is noticeably fouled, apply ___ to ___ (volume or unit weight) of ___ (product name or active ingredient) per ___ (unit volume) of water in the system. Apply half (or 1/3, 1/4, or 1/5) of this initial dose when half (or 1/3, 1/4, or 1/5) of the water in the system has been lost by blowdown. Badly fouled systems must be cleaned before initial treatment.</p> <p><u>Subsequent Dose.</u> When control of microbial growth is evident, apply ___ to ___ (volume or unit weight) of ___ (product name or active ingredient) per ___ (unit volume) of water in the system. Apply half (or 1/3, 1/4, 1/5) of this initial dose when half (or 1/3, 1/4, 1/5) of the water in the system has been lost by blowdown.</p> <p><u>Continuous Feed Method.</u> The label should specify an initial dose, based on the volume of water in the cooling system, to establish an initial product concentration. For volatile products, continuous feed is based on total makeup water. For non-volatile products, continuous feed is expressed as amount of product to be applied per stated volume of water lost by blowdown. The claim to maintain a pesticide concentration in the system may be made for this method of application. The following is an example of acceptable directions for use:</p> <p><u>Initial Dose.</u> When the system is noticeably fouled, apply ___ (volume or unit weight) of ___ (product name or active ingredient) per (unit volume) of water in the system. Badly fouled systems must be cleaned before initial treatment.</p> <p><u>Subsequent Dose.</u> Maintain this treatment level by starting a continuous feed of ___ (volume or unit weight) of ___ (product name or active ingredient) per ___ (unit volume) of water lost by blowdown.</p> 	<p>Directly below/following the General Directions for Use statement or attached as supplemental labeling</p>

Description	Required Labeling	Placement on Label
Specific Directions for Use (required for products registered for Hard Surface Disinfectants)	<p>General or broad spectrum disinfectants may bear label claims as hard, food-contact surface disinfectants. Use directions must indicate that following the specified contact period, the product should be removed from the treated surfaces with a final sanitizing rinse which may be worded as follows:</p> <p>"CLEANING AND DISINFECTING FOOD PREPARATION AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution. Scrub to loosen all soils. Allow to soak for (contact time) in a 600 ppm available chlorine solution. Thoroughly rinse all wetted and cleaned surfaces with a final sanitizing rinse solution of 200 ppm available chlorine."</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Specific Directions for Use (required for products registered for Hard Non-Food Contact Surfaces Sanitizers)	<p>A product intended for use on non-food contact surfaces which does not eliminate but significantly reduces the numbers of target microorganisms should be represented and qualified in labeling as being effective at the sanitizing level only. Examples of acceptable label claims are: "Sanitizes", "Significantly reduces", or "Reduces the number of bacteria by 99.9%." Products recommended for use in critical hospital or medical environments that are not effective at the sterilizing or disinfecting level should bear a label disclaimer statement such as: "This product is not a disinfectant or sterilizer."</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Specific Directions for Use (required for products registered for Circulate-In-Place (CIP) Applications)	<p>Label claims for CIP applications as "germicidal" or "disinfecting" are not generally acceptable because these methods have not been shown to be an effective means of disinfecting surfaces in these systems. Representations for CIP applications to sanitize the surfaces of the systems are acceptable.</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Specific Directions for Use (required for products registered for Hard Food Contact Surface Sanitizers)	<p>(a) The major area(s) in which the product is recommended for use (e.g., restaurants, dairies, food processing plants).</p> <p>(b) The identification of the types of hard surfaces, or objects, intended for treatment.</p> <p>(c) The necessity for removal of gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak treatment. In addition, instructions must be provided for a thorough washing of the surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.</p> <p>(d) The recommended use solution and instructions for preparing it. The units of measure (e.g., volume or weight per unit volume of water) to be employed in diluting the product must be given, and must be understandable to the user. The concentration (in parts per million) of available chlorine provided by the recommended use solution should also be given.</p> <p>(e) The method of application (e.g., immersion, flooding, spraying) to wet all surfaces thoroughly. Additional instructions for in-place sanitizing may be required (e.g., filling piping with the sanitizing solution).</p> <p>(f) A contact time of a least 1 minute.</p>	Directly below/following the General Directions for Use statement or attached as supplemental labeling

Description	Required Labeling	Placement on Label
<p>Specific Directions for Use (required for products registered for Hard Food Contact Surface Sanitizers) (continued)</p>	<p>(g) The directions should also indicate if, and how, the product is to be removed from the surfaces after the recommended contact time. Instructions to drain the use solution from the surface and allow to air dry are appropriate for products cleared for use on food contact surfaces under the Federal Food, Drug and Cosmetic Act. However, the recommendation of a potable water rinse after food-contact surfaces have been treated with a sanitizing rinse is not acceptable for products intended for use as a terminal sanitizing rinse.</p> <p>(h) For mechanical operations, the limitation that the prepared use solution may not be re-used for sanitizing but may be re-used for other purposes (e.g., cleaning floors, etc.). For manual operations the label should include a recommendation that a fresh sanitizing solution should be prepared at least daily or more often if the solution becomes diluted or soiled.</p> <p>(i) Additional instructions may be necessary for certain use patterns and/or categories of products to ensure safe and effective use of a product. Such additional instructions may be recommended by the applicant, or required by the Agency, as determined on a case-by-case basis.</p>	<p>Directly below/following the General Directions for Use statement or attached as supplemental labeling</p>
<p>Specific Directions for Use (required for all products registered for Human Drinking Water Treatment)</p>	<p>(a) <u>Public Water Supplies</u>. Municipal drinking water must meet the requirements of the Safe Drinking Water Act (42 U.S.C. 300f). Label claims and directions, as well as testing and performance requirements, must be acceptable to the Office of Drinking Water of the EPA, and appropriate documentation of such acceptance must be submitted.</p> <p>(b) <u>Emergency Water Supplies</u>. This section applies to emergency purification of small quantities of drinking water of questionable potability by the general public in the absence of bacteriological monitoring facilities. The special directions for use of a product intended for field or emergency disinfection of small quantities of drinking water must include the following information:</p> <ul style="list-style-type: none"> ! The effective dosage. ! The water source to be treated (e.g., lake, pond, stream) and its characteristics (e.g., clear, muddy, brackish). ! The exposure time. 	<p>Directly below/following the General Directions for Use statement or attached as supplemental labeling</p>
<p>Specific Directions for Use (required for all products registered for disinfectants for treatment of sewage and wastewater effluent)</p>	<p>The amount of chlorine delivered to treat sewage and wastewater effluent will depend on the flow rate of the water being treated, the number and placement of feed tubes and the outlet weir size opening.</p> <p>Specific use directions must be provided on the label or in collateral literature to enable the user to determine the amount of chlorine to satisfy treatment demands and the appropriate residue levels required for disinfection.</p>	<p>Directly below/following the General Directions for Use statement or attached as supplemental labeling</p>

Description	Required Labeling	Placement on Label
Specific Directions for Use (required for products registered for Sanitizing Use for Fruit and Vegetable Wash Water Treatment must include the following information:	Specific use directions must be provided on the label or in collateral literature to enable the user to determine the amount of chlorine to satisfy treatment demands and the appropriate residual levels required for sanitization.	Directly below/following the General Directions for Use statement or attached as supplemental labeling
Storage & Disposal Heading and Statements (required for all End Use Products)	<p style="text-align: center;">“STORAGE & DISPOSAL</p> <p>STORAGE: Store cylinders and ton containers in a dry area away from sources of heat and protected from direct sunlight and precipitation. Do not store in excessive heat. Segregate chlorine containers from other compressed gases, and never store near hydrocarbons, finely divided metals such as filings or granules, turpentine, ether, anhydrous ammonia, or other flammable materials. All storage containers and cylinders must have a weather resistant label and must not be accessible to the general public. Do not drop container. If container is damaged or leaking, refer to procedures in the [state the name of the manual being used] and/or notify supplier immediately. Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law.”</p> <p>“LEAK PROCEDURES: Make daily inspections for leaks. Stop a leak at once, since it will become worse with time.</p> <p>In case of a leak, evacuate everyone from the immediate area. For entry into the affected area to correct problem, wear personal protective equipment (including prescribed respirators) specified in the Hazards to Humans section of this labeling. When possible, move leaking or damaged cylinders outdoors or to an isolated location. Observe strict safety precautions. Work upwind, if possible. Allow any liquid chlorine to evaporate. Only correctly trained and PPE-equipped handlers are permitted to perform such cleanup. Do not permit entry into the leak area by any other person until the chlorine has completely dispersed.</p> <p>DISPOSAL OF CONTAINER: Container is returnable and must be properly identified with return tag and returned as promptly as possible to supplier according to prescribed instructions and practices in the” [state the name of the manual being used] “. All valves must be closed tight and closures or caps secured. It is illegal to ship a leaking chlorine container.”</p>	Directly below/following DIRECTIONS FOR USE statements.

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

The Agency has determined that registrants may distribute and sell chlorine gas products bearing old labels/labeling until April 1, 2001, which is approximately 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for an additional year or until April 1, 2001, which is approximately 38 months from the date of issuance of this RED. After then, or April 1, 2001, products must bear new labels. These actions on these dates will coincide with implementation of State certification programs as discussed above. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restricted Entry Interval (*)	Geographic Allowed (*)	Geographic Disallowed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
FOOD/FEED								
EGG HANDLING EQUIPMENT Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FISH/SEAFOOD PROCESSING PLANT EQUIPMENT (FOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FISH/SEAFOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FOOD PROCESSING PLANT EQUIPMENT (FOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Porous, Not applicable for this use	PrG	NOL	NOL	15	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Porous, Not applicable for this use	PrG	NOL	NOL	15	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FOOD PROCESSING PLANT PREMISES (NONFOOD CONTACT) Use Group: INDOOR FOOD								
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	100	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FOOD PROCESSING WATER SYSTEMS Use Group: INDOOR FOOD								
Wash water treatment, Postharvest, Dump tank Not applicable, Not applicable for this use	PrG	NOL	100	150	NOL			Contact time: 45 to 90 seconds. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Dump tank Not applicable, Not applicable for this use	PrG	NOL	30	150	NOL			Contact time: 2 to 5 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
FOOD PROCESSING WATER SYSTEMS Use Group: INDOOR FOOD (Continued from previous page)								
Wash water treatment, Postharvest, Dump tank Not applicable, Not applicable for this use	PrG	NOL	100	200	NOL			Contact time: 1 to 5 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.

APPENDIX A) Case Number 4022, Chlorine Gas, (Chemical Number: 020501)

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restrict ed Entry Interval (*)	Geograph ic Allowed (*)	Geograph ic Disallow ed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
Wash water treatment, Postharvest, Dump tank Not applicable, Not applicable for this use	PrG	NOL	30	50	NOL			Contact time: 2 to 3 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Dump tank Not applicable, Not applicable for this use	PrG	NOL	200	300	NOL			Contact time: 2 to 3 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Flume Not applicable, Not applicable for this use	PrG	NOL	30	50	NOL			Contact time: 45 to 90 seconds. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Flume Not applicable, Not applicable for this use	PrG	NOL	100	200	NOL			Contact time: 1 to 5 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Flume Not applicable, Not applicable for this use	PrG	NOL	200	300	NOL			Contact time: 2 to 5 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Sprayer Not applicable, Not applicable for this use	PrG	NOL	10	400	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Sprayer Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Sprayer Not applicable, Not applicable for this use	PrG	NOL	1	3	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Sprayer Not applicable, Not applicable for this use	PrG	NOL	20	20	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Sprayer Not applicable, Not applicable for this use	PrG	NOL	NOL	5	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Sprayer Not applicable, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
FOOD PROCESSING WATER SYSTEMS Use Group: INDOOR FOOD (Continued from previous page)								
Wash water treatment, Not on label, Cooler Not applicable, Not applicable for this use	PrG	NOL	1	1	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Not on label, Cooler Not applicable, Not applicable for this use	PrG	NOL	5	20	NOL			Contact time: 1 hour. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.

APPENDIX A) Case Number 4022, Chlorine Gas, (Chemical Number: 020501)

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restrict ed Entry Interval (*)	Geograph ic Allowed (*)	Geograph ic Disallow ed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
Wash water treatment, Postharvest, Hydrocooler Not applicable, Not applicable for this use	PrG	NOL	30	150	NOL			Contact time: 20 to 30 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Tank Not applicable, Not applicable for this use	PrG	NOL	10	25	NOL			Contact time: 60 to 90 seconds. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Tank Not applicable, Not applicable for this use	PrG	NOL	50	100	NOL			Contact time: 1 to 3 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Tank Not applicable, Not applicable for this use	PrG	NOL	100	350	NOL			Contact time: 2 to 3 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Drencher Not applicable, Not applicable for this use	PrG	NOL	100	200	NOL			Contact time: 3 to 5 minutes. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Proper ventilation required.
Wash water treatment, Postharvest, Wash tanks Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Wash water treatment, Postharvest, Brush washer spray Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Wash water treatment, Postharvest, Flume Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Wash water treatment, Postharvest, Rinser Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Wash water treatment, Postharvest, Cooler Not applicable, Not applicable for this use	PrG	NOL	50	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
FOOD PROCESSING WATER SYSTEMS								
Use Group: INDOOR FOOD (Continued from previous page)								
Not on label, Postharvest, Drencher Not applicable, Not applicable for this use	PrG	NOL	20	30	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Postharvest, Hydrocooler Not applicable, Not applicable for this use	PrG	NOL	30	75	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.

APPENDIX A) Case Number 4022, Chlorine Gas, (Chemical Number: 020501)

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restricted Entry Interval (*)	Geographic Allowed (*)	Geographic Disallowed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
Not on label, Postharvest, Not on label Not applicable, Not applicable for this use	PrG	NOL	20	400	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Wash water treatment, Postharvest, Not on label Not applicable, Not applicable for this use	PrG	NOL	10	200	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Spray, Postharvest, Sprayer Not applicable, Not applicable for this use	PrG	NOL	200	200	NOL	FL		Two minute contact time. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Dip treatment, Postharvest, Dip Tank Not applicable, Not applicable for this use	PrG	NOL	200	200	NOL	FL		Two minute contact time. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
HUMAN DRINKING WATER SYSTEMS Use Group: INDOOR FOOD								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	NOL	NOL	NOL			This pesticide is toxic to fish, keep out of lakes, streams, ponds; Do not contaminate water by cleaning of equipment or disposal of wastes; Permits may be required for discharges containing this pesticide into lakes, streams, ponds or public waters. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Do not discharge effluent containing this product to sewage treatment plant authority. 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 Pollution Discharge Elimination System permit and the permitting authority has been notified in writing prior to discharge.
MEAT PROCESSING PLANT EQUIPMENT (FOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
MEAT PROCESSING PLANT PREMISES (NONFOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
MEAT PROCESSING PLANT PREMISES (NONFOOD CONTACT) Use Group: INDOOR FOOD (Continued from previous page)								
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
POULTRY PROCESSING PLANT EQUIPMENT (FOOD CONTACT) Use Group: INDOOR FOOD								

APPENDIX A) Case Number 4022, Chlorine Gas, (Chemical Number: 020501)

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restricted Entry Interval (*)	Geographic Allowed (*)	Geographic Disallowed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
POULTRY PROCESSING PLANT PREMISES (NONFOOD CONTACT) Use Group: INDOOR FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
Not on label, Not on label, Not on label Hard, Not applicable for this use	PrG	NOL	NOL	200	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
NON-FOOD/NON-FEED								
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	NOL	NOL	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Do not discharge effluent containing this product to sewage treatment plant authority. 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 Pollution Discharge Elimination System permit and the permitting authority has been notified in writing prior to discharge.
EGG PLANT/HATCHERIES/BROODER ROOMS/SHOE BATHS (HATCHING) Use Group: INDOOR NON-FOOD								
Spray, Not on label, Sprayer Hard, Not applicable for this use	PrG	NOL	50	50	NOL			Preclean claim. Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
LAKES/PONDS/RESERVOIRS (WITHOUT HUMAN AND WILDLIFE USE) Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	3	5	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
ORNAMENTAL PONDS/AQUARIA Use Group: AQUATIC NON-FOOD RESIDENTIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	3	5	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS Use Group: INDOOR NON-FOOD								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	10	15	NOL			Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.

APPENDIX A) Case Number 4022, Chlorine Gas, (Chemical Number: 020501)

Application Type, Application Timing, Application Equipment) Surface Type & Efficacy Influencing Factor	Form (*)	Min. Interval Between Apps. @ Max. Rate (*)	Minimum Appl. Rate (ppm) (*)	Maximum Appl. Rate (ppm) (*)	Restricted Entry Interval (*)	Geographic Allowed (*)	Geographic Disallowed (*)	Use Pattern Limitations (*)
USES EVALUATED FOR REREGISTRATION								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	10	15	NOL	CA		Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit.
PULP/PAPER MILL WATER SYSTEMS USE Group: AQUATIC NON-FOOD INDUSTRIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	NOL	NOL	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Do not discharge effluent containing this product to sewage treatment plant authority. 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 Pollution Discharge Elimination System permit and the permitting authority has been notified in writing prior to discharge.
SEWAGE SYSTEMS Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	NOL	NOL	NOL			Proper ventilation required. This pesticide is toxic to fish, keep out of lakes, streams, ponds; Do not contaminate water by cleaning of equipment or disposal of wastes; Permits may be required for discharges containing this pesticide into lakes, streams, ponds or public waters. 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 Pollution Discharge Elimination System permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewage treatment plant authority.
SWIMMING POOL WATER SYSTEMS Use Group: AQUATIC NON-FOOD RESIDENTIAL								
Not on label, Not on label, Not on label Not applicable, Not applicable for this use	PrG	NOL	NOL	NOL	NOL			Proper ventilation required. This pesticide is toxic to fish, keep out of lakes, streams, ponds; Do not contaminate water by cleaning of equipment or disposal of wastes; Permits may be required for discharges containing this pesticide into lakes, streams, ponds or public waters. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. Do not discharge effluent containing this product to sewage treatment plant authority. 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 Pollution Discharge Elimination System permit and the permitting authority has been notified in writing prior to discharge.
UNSPECIFIED SITE Use Group: UNSPECIFIED								
Not on label, Not on label, Not on label Not specified, Not specified	PrG	NOL	NOL	NOL	NOL			Proper ventilation required. Do not discharge into lakes, streams, ponds or public waters, unless in accordance with an NPDES permit. This pesticide is toxic to fish, keep out of lakes, streams, ponds; Do not contaminate water by cleaning of equipment or disposal of wastes; Permits may be required for discharges containing this pesticide into lakes, streams, ponds or public waters.

Abbreviations used:

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

Geographic: CA = California; FL = Florida

Form: PrG = Pressurized gas

Rate: ppm = parts per million

In general: NOL = not on the label

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 4022 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 4022 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 Chlorine Gas

REQUIREMENT	USE PATTERN	CITATION(S)
<u>PRODUCT CHEMISTRY</u>		
61-1	Chemical Identity	FGLM 41767301
61-2A	Start. Mat. & Mnfg. Process	FGLM 41767301
61-2B	Formation of Impurities	FGLM 41767301
62-1	Preliminary Analysis	FGLM 41767302
62-2	Certification of limits	FGLM 41767302
62-3	Analytical Method	FGLM 41767302
63-2	Color	FGLM 41767303
63-3	Physical State	FGLM 41767303
63-4	Odor	FGLM 41767303
63-7	Density	FGLM 41767303
63-8	Solubility	FGLM 41767303
63-9	Vapor Pressure	FGLM 41767303
63-10	Dissociation Constant	FGLM 41767303
63-11	Octanol/Water Partition	FGLM 41767303
63-12	pH	FGLM 41767303
63-13	Stability	FGLM 41767303
<u>ECOLOGICAL EFFECTS</u>		
71-1A	Acute Avian Oral - Quail/Duck	FGLM 94673
71-2A	Avian Dietary - Quail	FGLM 104674
71-2B	Avian Dietary - Duck	FGLM unknown
72-1A	Fish Toxicity Bluegill	FGLM unknown
72-1C	Fish Toxicity Rainbow Trout	FGLM 94672
72-2A	Invertebrate Toxicity	FGLM 94672
72-3A	Estuarine/Marine Toxicity - Fish	FGLM EPA 440/5-84-030
72-3B	Estuarine/Marine Toxicity - Mollusk	FGLM EPA 440/5-84-030
72-3C	Estuarine/Marine Toxicity - Shrimp	FGLM EPA 440/5-84-030
72-4A	Early Life Stage Fish	FGLM EPA 440/5-84-030

Data Supporting Guideline Requirements for the Reregistration of Chlorine Gas

REQUIREMENT	USE PATTERN	CITATION(S)
72-5 Life Cycle Fish	FGLM	EPA 440/5-84-030
<u>TOXICOLOGY</u>		
81-1 Acute Oral Toxicity - Rat	FGLM	WAIVED
81-2 Acute Dermal Toxicity - Rabbit/Rat	FGLM	WAIVED
81-3 Acute Inhalation Toxicity - Rat	FGLM	WAIVED
81-4 Primary Eye Irritation - Rabbit	FGLM	WAIVED
81-5 Primary Dermal Irritation - Rabbit	FGLM	WAIVED
81-6 Dermal Sensitization - Guinea Pig	FGLM	WAIVED
82-1A 90-Day Feeding - Rodent	FGLM	WAIVED
82-1B 90-Day Feeding - Non-rodent	FGLM	WAIVED
82-3 90-Day Dermal - Rodent	FGLM	WAIVED
82-4 90-Day Inhalation - Rat	FGLM	43170101
84-2A Gene Mutation (Ames Test)	FGLM	42002801
84-2B Structural Chromosomal Aberration	FGLM	42002802
84-4 Other Genotoxic Effects	FGLM	42002803
<u>ENVIRONMENTAL FATE</u>		
161-1 Hydrolysis	FGLM	WAIVED
161-2 Photodegradation - Water	FGLM	WAIVED
162-3 Anaerobic Aquatic Metabolism	FGLM	WAIVED
162-4 Aerobic Aquatic Metabolism	FGLM	WAIVED
163-1 Leaching/Adsorption/Desorption	FGLM	WAIVED
164-2 Aquatic Field Dissipation	FGLM	WAIVED
165-3 Accumulation - Irrigated Crop	FGLM	WAIVED
165-4 Bioaccumulation in Fish	FGLM	WAIVED
165-5 Bioaccumulation - Aquatic NonTarget	FGLM	WAIVED

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

-
- 00094671 Buccafusco, R.J. (1978) Acute Toxicity of Lithcoa Lithium Hypochlorite to Bluegill (*Lepomis macrochirus*): Report #BW-78-2-030. (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-A)
- 00094672 Buccafusco, R.J. (1978) Acute Toxicity of Lithcoa Lithium Hypochlorite to Rainbow Trout (*Salmo gairdneri*): Report #BW-78-2-031. (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 LD₅₀ Study in Mallard Ducks: Project No. 668-107. (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-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)
- 00094675 Piccirillo, V.J. (1977) Final Report: Subacute Dietary LC50 Study in Mallard Ducks: Project No. 668-108. (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-F)
- 00104674 Piccirillo, V.J. (1977) Final Report: Subacute Dietary LC50 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)
- 41767301 Damico, J.; Doyle, J. (1991) Chlorine: Product Identity and Composition. Unpublished study prepared by SRA International, Inc. 3 p.
- 41767302 Damico, J. (1991) Chlorine: Analysis and Certification of Product Ingredients. Unpublished study prepared by SRA International, Inc. 11 p.
- 41767303 Damico, J. (1991) Chlorine: Physical and Chemical Characteristics. Unpublished study prepared by SRA International, Inc. 8 p.

BIBLIOGRAPHY

MRID

CITATION

-
- 42002801 Xu, J. (1991) Evaluation of Chlorine Gas in the Salmonella typhimurium Plate Incorporation Mutagenesis Assay in the Presence and Absence of Aroclor-Induced Rat Liver S-9: Lab Project Number: 0166/2120. Unpublished study prepared by SITEK Research Labs. 45 p.
- 42002802 Gudi, R. (1991) Evaluation of Chlorine Gas in the in vivo Test for Chemical Induction of Micronucleated Polychromatic Erythrocyte in Mouse Bone Marrow Cells: Lab Project Number 0166\1521. Unpublished study prepared by SITEK Research Labs. 40 p.
- 42002803 Kirby, P. (1991) Evaluation of Chlorine Gas in the L5178Y TK +/- Mouse Lymphoma Mutagenesis Assay with Colony Size Evaluation in the Presence and Absence of Aroclor-Induced Rat Liver S-9: Lab Project Number: 0166-2400. Unpublished study prepared by SITEK Research Labs. 52 p.
- 43170101 Barrow, C., Popp, J. A., and Wong, K. L. (1993), A Chronic Inhalation Toxicity Study of Chlorine in Female and Male B6C3F1 mice and Fischer 344 Rats. Unpublished study by Chemical Industry Institute of Toxicology, RTP(NC).
- Abdel-Gawad, S.T. and Bewtra, J.K., "Decay of Chlorine in Diluted Municipal Effluents", Canadian Journal of Civil Engineering, 1988, vol.15, pp.948-954.
- Abdel-Rahman, M.S., D. Couri and R.J. Bull. 1982. Metabolism and pharmacokinetics of alternate drinking water disinfectants. Environ. Health Perspect. 46: 19-23.
- Abdel-Rahman, M.S., D.M. Waldron and R.J. Bull. 1983. A comparative kinetics study of monochloramine and hypochlorous acid in rats. J. Appl. Toxicol. 3: 175-179.
- Abdel-Rahman, M.S., D.H. Suh and R.J. Bull. 1984. Pharmacodynamics and toxicity of chlorine in drinking water in the rat. J. Appl. Toxicol. 4: 82-86.
- 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.
- Baker, R.W. 1947. Studies on the reaction between sodium hypochlorite and proteins: I. Physicochemical study of the course of the reaction. Biochemistry 41: 337-341.

BIBLIOGRAPHY

MRID

CITATION

-
- Blabaum, D.J. and M.S. Nichols. 1956. Effect of highly chlorinated water on white mice. J. Am. Water Works Assoc. 4: 1503-1506.
- California Department of Pesticide Regulation, "Case Reports Received by the California Pesticide Illness Surveillance Program in Which Health Effects were Attributed to Exposure to Chlorine 1992-1993".
- Chernoff, N., E. Rogers, B. Canover, B. Kavlock and E. Gray. 1979. The fetotoxic potential of municipal drinking water in the mouse. *Teratology* 19: 165-169.
- Chlorine: FIFRA - 88/PHASE-4 REVIEW (MEMO: Mauer to Brisco/Compton, 11/04/92).
- Cotton, F.A. and Wilkinson, G. Advanced Inorganic Chemistry, Fifth Edition, 1988, John Wiley and Sons, New York.
- Cumming, R. 1978. The potential for increased mutagenic risk to the human population due to the products of water chlorination. In: Water Chlorination: Environmental Impact and Health Effects, Vol. 1, R.L. Jolley, Ed. Ann Arbor Science Publishers, Inc., Ann Arbor, MI. p. 229-241.
- Daniel, F., L. Condie, M. Robinson et al. 1990. Comparative subchronic toxicity studies of three disinfectants. J. Am. Water Works Assoc. 82: 61-69.
- Daniel, B.F., H. Ringhand, M. Robinson, J. Stober, G. Olson and N. Page. 1991. Comparative subchronic toxicity of chlorine and monochloramine in B6C3F1 mice. J. Am. Water Works Assoc. 83: 68-75.
- Dennis, W.H., V.P. Olivieri and C.W. Kruse. 1978. Reaction of uracil with hypochlorous acid. *Biochem. Biophys. Res. Comm.* 83: 168-171.
- Done, A.K. 1961. Bulletin of Supplementary Material. *Clinical Toxicology of Commercial Products*. 5: 13-14.
- DRAFT-Addendum Report, ARB/SRRD, dated 09/10/92.
- Druckrey, H. 1968. Chlorinated drinking water toxicity tests involving seven generations of rats. *Food Cosmet. Toxicol.* 6: 147-154.

BIBLIOGRAPHY

MRID

CITATION

-
- Greenwood, N.N. and Earnshaw, A. The Chemistry of the Elements, 1984, Pergamon Press, Oxford, UK.
- Haas, C.N. Review of Chlorine Decay in Freshwater. Prepared for The Chlorine Institute, September 1990. Submitted as part of reregistration package for CHLORINE.
- Hasegawa, R., M. Takahashi, T. Kokubo et al. 1986. Carcinogenicity study of sodium hypochlorite in F344 rats. Food Chem. Toxicol. 24: 1295-1302.
- Hayatsu, R., H. Hoshimo and Y. Kawazoe. 1971. Potential co-carcinogenicity of sodium hypochlorite. Nature 23: 495.
- Heinimman, T.J., et al. "Summary of Studies of Modeling Persistence of Domestic Wastewater Chlorine in Colorado Front Range Rivers" in Water Chlorination: Environmental Impact and Health Effects, 1983, vol. 4, pp. 97-112.
- Hoyano, Y., V. Bacon, R.E. Summons, W.E. Pereira, B. Halpeen and A.M. Duffield. 1973. Chlorination studies. IV. The reaction of aqueous hypochlorous acid with pyrimidine and pyrine bases. Biochem. Biophys. Res. Comm. 53: 1195-1199.
- Jolley, R.L. "A Review of the Chemistry and Environmental Fate of Reactive Oxidant Species in Chlorinated Water" in Water Chlorination: Environmental Impact and Health Effects, 1983, vol. 4, pp. 3-47.
- Jones, P.E. and R.A. McCance. 1949. Enzyme activities in the blood of infants and adult. Biochem. J. 45: 464-467.
- Lubbers, J.R., J.R. Bianchine and R.J. Bull. 1983. Safety of oral chlorine dioxide, chlorite and chlorate ingestion in man. In: Water Chlorination: Environmental Impact and Health Effects, Vol. 4, Book 2, R.L. Jolley, W.A. Brungs, J.A. Cotruvo, R.B. Cumming, J.S. Mattice and V.A. Jacobs, Ed. Ann Arbor Science Publishers, Inc., Ann Arbor, MI. p. 1335-1341.
- Lubbers, J.R., S. Chauhan, J.K. Miller and J.R. Bianchine. 1984. The effects of chronic administration of chlorite to glucose-6-phosphate dehydrogenase deficient healthy adult male volunteers. J. Environ Pathol.
- Mack, R.B. 1983. Some non-caustic remarks about bleach. NC Med. J. 44: 221.

BIBLIOGRAPHY

MRID

CITATION

-
- Meier, J., R. Bull, J. Stober and M. Cimino. 1985. Evaluation of chemicals used for drinking water disinfection for production of chromosomal damage and spermhead abnormalities in mice. *Environ. Mutat.* 7: 201-211.
- Mickey, G. and H. Holden Jr. 1971. Chromosomal effects of chlorine on mammalian cells in vitro. *EMS Newslett.* 4: 39-41.
- Mink, F.L., W.E. Coleman, J.W. Munch, W.H. Kaylor and H.P. Ringhand. 1983. In vivo formation of halogenated reaction products following peroral sodium hypochlorite. *Bull Environ. Contam. Toxicol.* 30: 394-399.
- NRC (National Research Council). 1976. Chlorine and Hydrogen Chloride. Committee on Medical and Biologic Effects of Environmental Pollutants. Washington, D.C. p. 282.
- National Toxicology Program 1990. toxicology and carcinogenesis studies of chlorinated and chloraminated water in F344/N rats and B6C3F1 mice. NTP TR 392.
- National Toxicology Program 1992. Toxicology and Carcinogenesis studies of Chlorinated and Chloraminated water (CAS Nos. 7782-50-5, 7681-52-9 and 10599-90-3) in F344 Rats and B6C3F1 Mice (drinking water studies). NTP-TR 392.
- Osborne, L.L. "Response of Sheep River, Alberta, Macroinvertebrate Communities to Discharge of Chlorinated Municipal Sewage Effluent" in Water Chlorination: Environmental Impact and Health Effects, 1985, vol. 5, pp.481-492.
- Patton, W., V. Bacon, A.M. Duffield et. al. 1972. Chlorination studies. I. The reaction of aqueous hypochlorous acid with cytosine. *Biochem. Biophys. Res. Comm.* 48: 880-884.
- Pereira, W.E., Y. Hoyano, R., T. Summons, V.A. Bacon and A.M. Duffield. 1973. Chlorination studies. II. The reaction of aqueous hypochlorous acid with α -amino acids and dipeptides. *Biochem. Biophys. Acta* 313: 170-180.
- Pfeiffer, E. 1978. Health aspects of water chlorination with special consideration to the carcinogenicity of chlorine. II. Communication: On the co-carcinogenicity. *Zbl. Bakt. Hyg.* 166: 185-211.
- Revis, N.W., T.R. Osborne, G. Holdworth and P. McCauley. Effect of chlorinated drinking water on myocardial structure and functions in pigeons and rabbits. In: Water Chlorination: Chemistry, Environmental Impact, and Health Effects, vol. 5, R.L. Jolley et. al., Ed. p. 365-371.

BIBLIOGRAPHY

MRID

CITATION

-
- Robinson, M., R. Bull, M. Schammer and R. Long. 1986. Epidermal hyperplasia in mouse skin following treatment with alternative drinking water disinfectants. *Environ. Health Perspect.* 69: 293-300.
- Rosenkranz, H. 1973. Sodium hypochlorite and sodium perborate: Preferential inhibitors of DNA polymerase-deficient bacteria. *Mutat. Res.* 21: 171-174.
- Ross, J.D. 1963. Deficient activity of DPNH-dependent methemoglobin diaphoese in coral blood erythrocytes. *Blood.* 21: 51-62.
- Seegert, G.L. and R.B. Bogardus. 1980. Ecological and environmental factors to be considered in developing chlorine criteria. In: Water Chlorination: Environmental Impact and Health Effects, Vol. 3, R.L. Jolley, W.A. Brungs and R.B. Cumming, Ed. Ann Arbor Science Publishers, Inc., Ann Arbor, MI. p. 961-971.
- Sheldon, J.M. and R.G. Lovell. 1949. Asthma due to halogens. *Am. Pract.* 4: 43-44.
- Snoeyink, V.L. and Jenkins, D. Water Chemistry, 1980, John Wiley and Sons, New York.
- Staples, R.E., W.C. Worthy and T.A. Marks. 1979. Influence of drinking water-tap versus purified on embryo development in mice. *Teratology* 19: 237-244.
- Strange, D.C., J.C. Finneran, H.B. Schmacker, Jr. and D.E. Bowman. 1951. Corrosive injury of stomach. Report of a case caused by ingestion of Clorox and experimental study of injurious effects. *Arch. Surg.* 62: 350-357.
- Suh, D.H. and M.S. Abdel-Rahman. 1983. Kinetics study of chlorine in rat. *J. Toxicol. Environ. Health* 12: 467-473.
- Sweeny, A. and A. Chen. 1985. Production of mutagenic artifacts by the action of residual chlorine on XAD-4 resin. *J. Chromat.* 325: 95-102.
- Tchobanoglous, C. and Schroeder, E.D. Water Quality- Characteristics; Modeling; Modification, 1985, Addison-Wesley, Reading, MA
- U.S..EPA. 1981. Ambient Water Quality Criterion for the Protection of Human Health: Chlorine. Prepared by the Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Water Regulations and Standards, Washington, DC.

BIBLIOGRAPHY

MRID

CITATION

- U.S. EPA. 1984. Ambient Water Quality Criteria for Chlorine - 1984. U.S. EPA, Office of Water Regulations and Standards, Criteria and Standards Division, 401 M St. SW, Washington, DC. 20460. EPA 440/5-84-030. 57 pp.
- U.S. EPA. 1994. Drinking Water Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion (External Review Draft). Prepared by the Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Drinking Water, Washington, DC. (ECAO/OHEA-CIN-D004).
- U.S. EPA. 1987. Chlorine Poisoning Summary. Prepared by Exposure Assessment Branch, Office of Pesticide Programs, Washington, DC. 18 pp.
- Walton, M. and R. Cumming. 1976. 5-Halogenated uracil base analogue mutagenesis. *Mutat. Res.* 38: 371.
- WHO (World Health Organization). 1982. Environmental Health Criteria, Chlorine and Hydrogen Chloride. Geneva. p. 1-95.
- Wlodkowski, T. and H. Rosenkranz. 1975. Mutagenicity of sodium hypochlorite for *Salmonella typhimurium*. *Mutat. Res.* 31: 39-43.
- 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.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,
2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,
3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

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 and 2070-0057 (expiration date 3-31-99).

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

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

The Attachments to this Notice are:

- Attachment 1 - Data Call-In Chemical Status Sheet
- Attachment 2 - Data Call-In Response Form (Insert A)
- Attachment 3 - Requirements Status And Registrant's Response Form (Insert B)
- Attachment 4 - List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

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

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

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

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

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

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

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

- a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,
- b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

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

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

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) 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 (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

Option 1, Developing Data

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must

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

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

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

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

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. 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 (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study --

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

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

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

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been

prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

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

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

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

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

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the

Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

Option 6, Citing Existing Studies --

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

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

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

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

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

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

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

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

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

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

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

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

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).
6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:
 - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,
 - b. fulfill the commitment to develop and submit the data as required by this Notice; or,
 - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend.

The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have,

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

CHLORINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of chlorine. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this chlorine Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for chlorine are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on chlorine are needed. These data are needed to fully complete the reregistration of all eligible chlorine products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Patrick Dobak at (703) 308-8180.

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

Patrick Dobak, Chemical Review Manager
Reregistration Branch I
Special Review and Registration Division (H7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Chlorine, Case 4022

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

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

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

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

INSTRUCTIONS

- Item 1. This item identifies your company name, number and address.
- Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.
- Item 3. This item identifies the date and type of data call-in.
- Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
- Item 5. Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.
- Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed

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

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

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

- Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.
- Item 7a. Check this item if this call-in is a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.
- Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.
- Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.
- Item 9. Enter the date of signature.
- Item 10. Enter the name of the person EPA should contact with questions regarding your response.
- Item 11. Enter the phone number of your company contact.

United States Environmental Protection Agency
 Washington, D.C. 20460
DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
 2070-0057

Approval Expires 03/31/99

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

1. Company name and Address		2. Case # and Name 4022 Chlorine Chemical # and Name 020501 Chlorine		3. Date and Type of DCI GENERIC	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7. Product Specific Data 7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative _____			9. Date		
10. Name of Company Contact			11. Phone Number		

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

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

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

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

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

INSTRUCTIONS

- Item 1. This item identifies your company name, number, and address.
- Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.
- Item 3. This item identifies the date and type of data call-in.
- Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.
- Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

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

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

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

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

TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*See: guideline comment	

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

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

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.
2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.
3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.
4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice

and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.
7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.
8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

- Item 12. Enter the name of the person EPA should contact with questions regarding your response.
- Item 13. Enter the phone number of your company contact.



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

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

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 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six 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 (Insert A)
- 3 - Requirements Status and Registrant's Response Form (Insert B)
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). 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 Insert B, Requirements Status and Registrant's Response Form (Insert B), 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, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

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 (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). 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 (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) 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(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). 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 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). 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 (Insert B). 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 (Insert A) 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 (Insert A) 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(Insert A). 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 here in 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 (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty

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

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of

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

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

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

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

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

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

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

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

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

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

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

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

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

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

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

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 (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), 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(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

- 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 CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled 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 canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form (Insert A)
- 3 - Requirements Status and Registrant's Response Form (Insert B)
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice

CHLORINE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of chlorine, please contact Patrick Dobak at (703) 308-8074.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Wanda Mitchell at (703) 308-6345.

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

Wanda Mitchell,
Regulatory Management Branch
Antimicrobial Division 7510C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Chlorine; Case 4022

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

- Item 1-4. Already completed by EPA.
- Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.
- Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."
- Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.
- Items 8-11. Self-explanatory.

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

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

- Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5. The study title associated with the guideline reference number is identified.
- Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.
1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification with Respect to Citations of Data (in PR Notice 98-5)**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
 2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification with Respect to Citations of Data (in PR Notice 98-5)**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data**" (EPA Form 8570-32). I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

EPA'S DECISION ON BATCHING PRODUCTS CONTAINING CHLORINE 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 chlorine 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 in the preceding paragraph. 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 1 below lists a single batch of the currently registered products containing 99.5 - 100% chlorine as liquified gas.

Table 1: Chlorine Batch 1

148-707	2792-61	34910-2	46266-1	51551-1	59597-1	66760-1	70598-1
168-372	5382-38	35317-2	47075-1	52374-12	59732-1	67209-1	71207-1
266-35	6785-1	35934-1	48867-1	54135-1	61219-2	67544-1	71413-1
335-178	7870-2	37982-2	49256-1	56410-1	61602-1	67553-1	CA89005000
464-99	8176-9	37982-34	49405-1	56652-1	61616-1	67624-1	HI98000900
550-177	8996-6	41209-4	49720-1	57101-1	61667-1	67649-5	LA95000100
748-31	9488-1	41211-3	49721-1	57135-1	63015-1	67714-1	
813-10	9768-21	43407-1	49723-1	57476-1	63802-1	67770-1	
935-8	10464-2	43843-3	49756-1	57966-1	64454-1	67799-1	
1258-779	33458-1	45085-1	50221-1	58415-1	65560-1	67985-1	
1744-10	33593-1	45851-1	50397-1	58618-1	65782-1	69413-1	
1803-25	33981-2	45869-1	50400-1	58687-1	65862-1	70264-1	
2686-3	34277-1	45880-1	50956-6	59301-2	66534-1	70529-1	

Since all currently registered products are batched together in Table 1, there is no table of non-batched products.

Pesticide Registration Forms are available at the following EPA internet site:

<http://www.epa.gov/opprd001/forms/>.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hard copy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit

www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
 - a. Registration Division Personnel Contact List
Biopesticides and Pollution Prevention Division (BPPD) Contacts
Antimicrobials Division Organizational Structure/Contact List
 - c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 487-4650. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.